Uptake and choice of commercial weight loss products and services by adults in the UK

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Alisha Michelle Crayton

Abstract

Objectives: 1) To assess the use and reasons of choice of commercial weight loss products and services (CWLPS), 2) Critically assess the effectiveness of CWLPS.

Methods: A mixed method study design was used to assess the use and reasons of choice of CWLPS (survey and Q-method) and investigate the effectiveness of CWLPS (systematic review).

Results: Weight loss group based programmes such as Slimming World were the most popular type of CWLPS used. The Q-method study identified four different groups of participants who had similar needs for their preferred CWLPS, which mapped onto the different types of CWLPS available. The systematic review showed that CWLPS result in weight loss, although attrition rates are often quite high. Slimming groups such as Weight Watchers appeared the most effective.

Discussion and conclusion: It is clear that most CWLPS are used, preferred, and effective for some people, at least for a short period of time. However, different users have different needs for their preferred CWLPS. The cost of a CWLPS is not a critical factor in its use, popularity, or effectiveness.

UPTAKE AND CHOICE OF COMMERCIAL WEIGHT LOSS PRODUCTS AND SERVICES BY ADULTS IN THE UK

VOLUME 1 (of 2)

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the degree of Doctor of Philosophy

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Declaration

I confirm that the work in this thesis is my own and has not been submitted for any other degree at another university.

The review within this thesis was slightly amended from the Cochrane Systematic Review (protocol stage) which I am the lead author of (Commercial weight loss products and services for obese and overweight adults). All authors from the Cochrane systematic review (excluding Professor Summerbell) played no part in the review for this thesis.

Statement of Copyright

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Much loved family members who sadly passed before the completion of the PhD kept me upbeat, and spurred me on to complete my PhD. Therefore, I wish to dedicate my PhD to my grandparents, Mr and Mrs D Hammersley.

Dissemination of work

Submitted work

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Hillier FC, Batterham AM, Nixon CA, Crayton AM, Pedley CL, Summerbell CD. A community-based health promotion intervention using brief negotiation techniques and a pledge on dietary intake, physical activity levels and weight outcomes: lessons learnt from an exploratory trial. Public Health Nutrition.2012; 15(8):1446-1455.

Presentations

Uptake and choice of commercial weight loss products and services by adults in the UK: Is current practice fuelling health inequalities? School of Medicine and Health Postgraduate Research Annual Conference, 21st March 2012

Who can afford to lose weight?: A regional commercial weight loss survey Postgraduate Poster Event and Wolfson Fellows Lunch November 2011

Commercial Weight Loss Programmes for obese or overweight people: Cochrane Systematic Review; Metabolic and Endocrine Disorders Group Postgraduate Poster Competition November 2010

1st year overview School for Medicine and Health Postgraduate Research Annual Conference

Commercial Weight Loss; Is cost that important? Wolfson Research Institute for Health and Wellbeing Research Colloquium April 17th - April 18th 2013

Professional Development

Durham University Internal Course: Starting your Doctorate (Oct 09)
Durham University Internal Course: Media Training (Oct 09)
ASO Conference: Inequalities, Ethics and Obesity (Nov 09)
The Spirit Level: why more equal societies almost always do better presented by Professor Richard Wilkinson, Emeritus Professor of Social Epidemiology (March 2010)
Birmingham University module: Q-Methodology Short Course (Module Leader Dr Stephen Jeffares)
Durham University Postgraduate module: Public Policy, Health and Health Inequalities January to March 2010 (participant)
Introduction and methods for systematic reviewing: UK Cochrane Centre July 2010
Quantitative health research methods module 2010 Durham University (participant)
Qualitative health research methods 2010 Durham University (participant)
Qualitative Health Research Group – Post-Grad Student Challenge Durham University 2012 (participant)
Using q methodology in qualitative research Teesside University 2011 (participant)

Chapter One

Introduction

1.1 Overview

This introductory chapter outlines the rationale and components of my PhD thesis. It provides an overview of the background to my research, and why the research I did was undertaken. The aims and objectives are discussed prior to outlining the thesis structure.

1.2 Foundation of the research proposal

This research was undertaken during 2009 to 2012, and was funded by an Interdisciplinary Research Scholarship from Durham University. The topic area I chose to study was the effectiveness of commercial weight loss products and services (CWLPS), and the use of these in the North East of the United Kingdom.

My previous education and employment experiences led me to choose this field of interest. In 2006-2007 I completed an MSc in Weight Management at the University of Chester. Core and optional modules were varied. During the course we touched on CWLPS, and I remember being surprised at the lack of evidence and general information on this topic (except from companies producing CWLPS).

Between 2007 and 2009 I worked as a research assistant on the Community Challenge Project (CCP); a Food Standards Agency funded project aimed at engaging adults living in the Tees Valley area to make one small change to diet (increasing fruit and vegetable consumption or decreasing fat intake) and one small increase to physical activity, for 12 months. Community participants discussed the use of CWLPS. A significant amount of participants reported positive and negative views and behaviour changes. Participants who reported losing weight through CWLPS stated that once they had stopped using CWLPS, weight gain occurred. This process of weight cycling is well documented in the literature and can be defined as *"repeated loss and regain of weight although there is no standard definition for weight cycling"* (Elfhag & Rössner, page 75, 2005*)*. This information on weight cycling by CCP participants was disclosed verbally within the interviews and focus groups.

When I was working on the CCP project, I read the Foresight Report (2007a) which estimated the value of the weight loss industry in the UK at £2 billion/year at that time. However, I did not come across any literature on the popularity of CWLPS, or the stereotypical CWLPS consumer.

My interest in commercial weight loss was strengthened in April 2009, when the European Commission authorized the release of the first over-the-counter non-prescription weight loss aid (Alli; 60mg). Upon further research of the product, it was apparent that a large scale marketing campaign would complement the launch and anticipated success of this product. At the point of release, the manufacturers (Glaxo Smith Kline) had not published any

results of their randomised controlled trial for Alli. Marketing relied upon the published material for xenical (120mg), the sister drug of Alli that is only available on prescription to individuals with a Body Mass Index (BMI) of >30 or >28 with significant co-morbidities. At this point my interest heightened in the variety of 'self-help' methods available for individuals who wanted to lose weight, enticing individuals to purchase their product or service with catchy taglines *("it can reward your hard work with 50% more weight loss, Want to slim down for a special occasion, and don't have time to waste?"*).

As part of my preparations for my application for PhD funding, I collated a significant amount of literature. Using a simple scoping search, I found that there were very few randomised controlled trials which had been published in peer-reviewed journals (e.g. Ditschuneit et al, 1999; Foster et al, 2003; Heshka et al, 2003). My simple scoping search was carried out within three relevant databases (Medline, CINAHL, and Psych Info) using the search terms including 'commercial weight loss', and I found 44 hits. One qualitative research study which I found involved the investigation of individuals' experiences of commercial weight loss programmes (Herriot et al, 2008). Herriot et al (2008) conducted a study which I found very interesting, which involved participants being randomised to a commercial weight loss programme, but free of charge. When I read this paper, I did wonder whether the results of this study could be of any real use (i.e. be translated to the real world), because people who use CWLPS need to pay for them. For those less well off in society, the cost of CWLPS may be a barrier to whether or not they use CWLPS, or may be a barrier to which CWLPS they choose. On reading this paper, my research plans for my PhD started to develop further,

and I decided I wanted to try and explore if and how views and use of CWLPS vary dependent on the financial status of the individual.

In discussion with my PhD supervisors, we developed a PhD research plan, which was a mixed method study design, to investigate the effectiveness of CWLPS (by systematic review of trials), and also the use and determinants of choice of CWLPS by users (survey and Q-method). In all components of my research, I planned to try and explore whether socioeconomic status of participants had an impact on the effect and/or use of CWLPS.

Background

1.3 Epidemiology

The 12 areas of the North East, apart from Newcastle (Gateshead, Darlington, Sunderland, Redcar and Cleveland, South Tyneside, Northumbria, North Tyneside, Newcastle, Middlesbrough, Hartlepool, and County Durham) observe higher obesity statistics than the current UK average; 24.2% (Gateshead: 30.7%, Darlington: 27.6%,: 27.7%,Sunderland: 28.6%,Redcar and Cleveland: 29.6%,South Tyneside: 27.4%,Northumbria: 27.3%,Tyneside: 26.6%,Newcastle: 23.9%,Middlesbrough: 27.9%,Hartlepool: 27.5%, and County Durham: 28.6%).

Gateshead's obesity prevalence of 30.7% (Public Health England, 2013) is worse than the highest UK average of 30.2%. Kumanyika et al (2008)

estimated that the number of overweight and obese individuals could increase to 1.5 billion by 2015, and using this model and in line with trends seen in 2013, the North East region could, in theory, observe obesity levels beyond 23.9%-30.7% by 2015. Data at the time of my PhD commencement for the North East, illustrates that obesity prevalence has increased. In 2009, 25.2% (APHO and Department of Health, 2010) of the North East population were classified as obese, this figure now ranges from 23.9% (Newcastle) to 30.7% (Gateshead).

1.3.1 Policy

In response to the escalating prevalence of obesity and overweight in adults and children (although the rise in these rates have slowed down in recent years), and building on the two key documents described below, the UK government commissioned the Foresight Report (Foresight, 2007a), which included recommendations of how best to tailor campaigns and initiatives to suit national objectives.

In 2004, the Cabinet Office published a discussion paper outlining the requirement for cost effective behavioural interventions over traditional service delivery to tackle obesity, and concluded that a patient-centred approach is required to support individuals in their communities to change their behaviour. Behavioural interventions are based on key motivational interviewing techniques; direct advice is only successful in 5-10% of healthcare consultations (Emmons & Rollnick, 2001). This discussion paper

did not discuss commercial weight loss programmes for some reason, which do have a behavioural component.

Also in 2004, the Department of Health published a White Paper 'Choosing Health: Making healthy choices easier' (Department of Health, 2004) which identified obesity as one of six key priorities for the government's Public Health strategy. They suggested that informed choice is essential, combined with co-operation and partnership from all sectors of the government, for successful delivery at a local level. The White Paper emphasised the need for individual responsibility through suitable resources, specifically in socially deprived areas.

In 2006, The National Institute for Clinical Excellence produced a comprehensive review of the evidence and guidance on obesity management (National Institute for Health and Clinical Excellence, 2006). This guidance did contain a section in relation to 'self-help' for weight loss and commercial weight loss products and services, but the evidence base at that time was limited.

The findings of the Foresight Report 'Tackling Obesities: Future Choices' (Foresight, 2007a) was purposively provocative and attracted a lot of attention. The report estimated that 50% of the UK population could be obese by 2050, potentially doubling current statistics at the time of print.

In 2008, the Department of Health & Department for Children, Schools and Families produced 'Healthy Weight, Healthy lives: A Cross-Government strategy for England Strategies' which centred upon health, transport and planning services to work in synergy with one another to tackle obesity. The

proposed strategy incorporated five key themes; the healthy growth and development of children, promoting healthier food choices, building physical activity into our lives, creating incentives for better health, and personalised advice and support. The strategy aimed to engage individuals to make informed choices through local support networks. The strategy recommended that treatment options should be accessible for those who have an increased BMI, combined with assistance from specific weight related services. At the time of publication, the strategy acknowledged other treatment options outside of the NHS; however, the focus of was on bariatric surgery and pharmacotherapy.

In 2009 the Department of Health supported a multimillion pound government and commercial sector funded social marketing programme designed to help tackle obesity 'Eat Well, Move More, Live Longer'; Change4Life. Change4Life incorporated simple exercise and diet tips and tools that could be included in everyday life. Seven official sub-brands; Breakfast4Life, Swim4Life, Walk4Life, Bike4Life, Play4Life, Cook4Life and Dance4Life provided toolkits for individuals and families. Nondescript characters used to promote Change4Life target individuals and families through an extensive marketing mix of posters, TV adverts, billboards, information leaflets and a specifically designed website.

At about the same time, and working in synergy with Change4Life, the Department of Health funded the 'Healthy Town' project, where nine towns were selected and designated as a 'Healthy Towns'. Each 'Healthy Town' developed interesting and novel projects to encourage healthy lifestyles by

providing/increasing opportunities for their population to be more active and make healthier food choices. The Middlesbrough Healthy Town project, for example, developed and ran 32 projects in total. Across the Healthy Towns, some projects included opportunities for learning about CWLPS, but sadly the evaluations which are available from the Healthy Towns project are limited in their ability to help us know more about CWLPS.

The National Child Measurement Programme (NCMP) was also set up seven years ago in line with the Governments strategy to reduce obesity prevalence, and also has six years of reliable data for 4-5 year olds and 10-11 year olds. The NCMP provides height and weight data, and used to calculate a BMI centile. The data collected can inform initiatives at national and local level. Prior to March 2013, Primary Care Trusts (PCT's) were responsible to collect, hold, and process the NCMP data. However, Local Authorities are now responsible for NCMP data collection, and a new system for the submission of NCMP data will be replaced for 2013/2014 school year (Health & Social Care Information Centre, 2013) . Since 2006/2007 and 2011/2012 there has been a significant increase in BMI since 2010/2011, the trend between 2007/2008 and 2011/2012 also shows a significant increase. However, a decrease was observed in 4-5 year old boys since 2010/2011, though no significant trend was observed since the start of the NCMP. An increase was observed in 4-5 year old girls since 2010/2011, though no significant trend was observed since the start of the NCMP. For both age groups health inequalities are widening. Children in Year 6 (10-11 years) observe increases in obesity prevalence that are statistically significant for boys and girls living in the most deprived 50% of areas. Children in reception

class (4-5 years) observe decreases in observe prevalence that are statistically significant for boys living in the least deprived 50% of areas, and girls in the least deprived 10% (National Obesity Observatory, 2013). It is unclear at present whether the change from PCT's to Local Authorities' collecting and submitting NCMP data will result in any changes. For example, whether parents become more resistant, and wish to withdraw their child from the NCMP, resulting in a smaller amount of data being collected. Also dependant on the training given by the health professionals collecting the data could affect the results. For example professionals might not be trained to The International Society for the Advancement of Kinanthropometry (ISAK) standard, whereby inter and intra reliability is assessed. Therefore, there could be professionals whose inter reliability (between colleagues) is above -/+2% technical error of measurement, or a professionals intra reliability (against themselves) is above -/+1.5% technical error of measurement

I am aware that the National Institute for Clinical Excellence is planning to produce an update on its guidance on obesity, which I expect will include advice for commissioners of services on CWLPS, in 2013. Once my thesis is in the public domain, I intend to disseminate to various people and organisations who might find some of my research interesting and useful.

1.3.2 Service

When I started my PhD, we had PCT's and these were responsible for commissioning. On 1st April 2013, the organisation of public health and

healthcare changed, and Public Health England is now in place. For the foreseeable future, Local Authorities will now commission public health services in England.

As Local Authorities move towards a commissioning role, it is they who now need to decide whether they want to commission commercial weight loss programmes as part of their obesity strategies . At the time of planning my research, two-thirds of England's PCT's offered a 10-12 week referral scheme to a commercial weight loss programme (Slimming World/Weight Watchers). At the time, only those commercial weight loss interventions which fulfilled the following criteria (National Institute for Health and Clinical Excellence, 2006) were allowed to be recommended and used by PCT's:

- Be based on a balanced healthy diet
- Encourage regular physical activity
- Expect people to lose no more than 0.5–1 kg (1–2 lb) a week

Beyond a primary care setting, commercial weight loss products and services were one of the most popular weight loss methods available for individuals who wanted to lose weight.

Also, in conjunction with the changes to the NHS, bariatric surgery will be the responsibility of NHS England, rather than the Local Authority. Therefore, it could be possible that there is an increase or decrease in bariatric surgery provision, as more or less people could meet the criteria for bariatric surgery consideration (specifically for individuals who have not been severely/morbidly obese for at least five years).

1.3.3 Issues

Effective research and evaluation is required for healthcare providers to make informed decisions about products and services they wish to commission and deliver. The National Institute for Clinical Excellence will continue to endeavour to provide this information, and I hope that my research helps in some small way.

Individuals, on the other hand, who do not seek professional assistance from their GP to lose weight, may be enticed by the efficient marketing strategies of CWLPS companies that have little or a weak evidence base to support their efficacy claims. Diet programmes regularly make weight loss claims without any supporting proper research or evidence from independent randomised controlled trials (Hamilton & Greenway, 2004).

Individuals of lower socioeconomic status could be more susceptible to these marketing strategies, because I have found out during my PhD; CWLPS companies focus their marketing at certain groups within society. I did want to explore this particular issue as part of my PhD, but it would require a substantial amount of work. I am hopeful that I will be able to have the opportunity to conduct some research in this area after my PhD.

1.4 Aim and objectives

Aim

The aim of my research was to provide additional evidence to inform public health policy and practice for the provision of CWLPS, and also individual users (i.e. the public).

Objectives:

1. To assess the use of CWLPS in the one of the most deprived regions in England, and explore where usage is associated with socioeconomic status.
2. To assess the reasons for choice of CWLPS in the one of the most deprived regions in England, and explore whether this varies by socioeconomic status.
3. Critically assess the effectiveness of CWLPS.

1.5 Research questions

1. What is the uptake and reasons for choice of commercial weight loss products and services by adults in the UK, and is current practice fuelling health inequalities?
2. What is the effectiveness of commercial weight loss products and services?

1.6 Overview of the thesis

Succeeding this chapter is a review of the relevant literature, which includes an overview of the issues associated with obesity and overweight and a particular focus on CWLPS and health inequalities (Chapter 2). Chapters 3 and 4 outline the methods and methodology employed for research which I conducted for my PhD. Chapter 5 describes the results of my research, and finally I have presented a discussion of my findings and conclusions in Chapter 6.

Chapter Two

Review of the literature

2.1 Introduction

This chapter provides an overview of the methods of assessment of obesity, definitions of obesity, prevalence of obesity on a global, national and regional level, and the consequences and costs of obesity. Finally, this chapter reviews the treatment options available for overweight and obese adults within and outside of the primary care setting in England, UK.

2.2 Methods of assessment

2.2.1 BMI

The BMI or Quetelet Index is the preferred measurement of predicting adiposity amongst adults in a primary care setting, as it is the most practical, reliable, valid, and a cost-effective method of choice. BMI is a measure of weight relative to height, calculated by dividing weight (kg) by height in metres squared (m^2) (Foresight, 2007b). For BMI to be measured effectively it is advised that electronic digital weighing scales and a freestanding stadiometer to measure height is used. The equipment should be placed on a flat surface; individuals should be measured after removal of their shoes and heavy items removed

from their pockets. ISAK is just one organisation which provides guidance and training resources on the measurement of height and weight *(and I have attended an ISAK course)*.

The World Health Organization (1997) have established different cut-off points for the classification of overweight and obesity status amongst Caucasian adults, which are based on mortality data from insurance companies. Asian populations, for the same BMI, have an increased risk of cardiovascular disease (CVD) compared with Caucasians (Bell et al, 2002). As such, the World Health Organization have established slightly different (lower) cut-offs for Asians.

Table 1: World Health Organization (1997) guidelines

Classification	**BMI**
Underweight	< 18.5
Ideal weight	18.5–24.9
Overweight	25.0–29.9
Class I obesity	30.0–34.9
Class II obesity	35.0–39.9
Class III obesity	≥ 40.0

In public health, these BMI cut-offs are widely used amongst healthcare professionals as a means of categorising people for treatment options. Individuals who have a high muscle mass, and low fat mass, such as athletes, could be misclassified as obese when in actual fact they are not. This is one of the limitations of using BMI.

In 1996 the BMI index became widely used in the UK and across the world, 122 years after Quetlet proposed the use of it. Some argue that it is not the best index of obesity (Bray, 1998). The use of BMI as an index of body fatness relies on the premise that, at any particular body weight, a set proportion of that weight it made up of muscle and a set proportion is made up of fat. Most athletes (apart from say marathon runners) would typically be classified as obese due to their higher than normal muscle mass. So, for these athletes, additional methods of assessment are needed to assess BMI.

The general public faces confusion and controversy around the risks of obesity to health. Some reports suggest that that overweight is not damaging to health, and should not be held up as a major public health concern (Campos et al, 2006). However, other research is quite clear that obesity is a significant risk factor for health and the current high levels of obesity in some countries requires effective public health interventions (Kim & Popkin, 2006).

Cohort studies have demonstrated a J-shaped or U-shaped association between BMI and mortality. Within these studies, the mortality rate increases in individuals with a higher and lower BMI compared to those with normal weight (Allison et al, 1997). However, research (Lewis et al, 2009) has suggested that thin and obese people are most likely to die than overweight persons. Controversy surrounds overweight status, some report that introducing interventions for overweight populations to reduce their weight could have detrimental effects (Campos et al, 2006). Though others argue that individuals in the overweight range could be harbouring substantial health risk (Kim and

Popkin, 2006), and could lead to obesity classification, therefore public health interventions of overweight populations are of paramount importance. Overall, with a raised BMI, cardiovascular risk factors increases (type 2 diabetes mellitus and systemic hypertension), and could benefit from weight targeted interventions as part of their treatment regime.

Katzmarzyk and colleagues (2012) recent study of 10,522 adults, 18-74 years of age who participated in the Canadian Heart Health Surveys (1986-1995) were divided into five BMI categories (< 18.5, 18.5-24.9, 25-29.9, 30-34.9, and > or = 35 kg/m^2). Between BMI and mortality at baseline a J-shaped curve was observed for cardiovascular and total mortality, lowest risk of mortality was observed in normal weight participants (18.5-24.9).after age and multivariate-adjusted hazard ratios were undertaken significant associations between cardiovascular disease and cancer mortality were observed in men. However, cancer mortality was not apparent until a man's BMI reached 35. In women cancer, mortality from all cause, and cardiovascular consequences observed a significant liner trend across the five BMI categories. However, excess mortality risk was only significant when females reached a BMI of 30-34.9, overweight women did not have an observed elevated risk. BMI at which the increase begins varies with different populations. For example, research is still trying to identity why Asian populations have higher weight-related risk factors at a lower BMI. One possible explanation is in relation to body fat. In comparison to white Europeans of the same BMI, Asian populations have 3-5% more body fat (Deurenberg et al, 2002), and are more susceptible to abdominal obesity,

whereby the risk of developing cardiovascular disease and type 2 diabetes significantly increases.

In my personal opinion I believe that a person's BMI can be the contributing cause of cardiovascular disease, cancer and mortality; specifically when an individual's BMI is beyond 30. However, when BMI is assessed, all contributing factors should be taken into account (age, gender, ethnicity, smoking, alcohol consumption, physical activity, and environment). Alike health inequalities, BMI is a complex subject, and requires additional research, specifically in Asian populations.

2.2.3 Waist circumference

Waist circumference is widely accepted as a useful additional method of assessment of body fatness in research settings, and is used in a few clinical practices. A variety of different protocols can be used to measure waist circumference; immediately above the iliac crest (National Institute of Health recommendation), umbilicus, and minimal waist (International Society for the Advancement of Kinanthropometry-ISAK). The World Health Organization (2008b) recommends that the midpoint point between the lowest rib and immediately above the iliac crest should be used, with hip measurement, to calculate the waist: hip ratio to assess metabolic syndrome. Metabolic Syndrome is the collection of conditions which cluster together (Table 2; Campbell & Haslam, 2005).

Table 2: Criteria levels by condition used to define the Metabolic Syndrome

Condition	Criteria
BMI	>30
Waist: hip ratio	>0.9
Fasting glucose	between 5.6-6mmol/L
Triglycerides	>1.7mmol/L
High density lipoprotein	<1.04 mmol/L
High blood pressure (hypertension)	>130/85mmHg

Waist circumference is highly correlated with cardiovascular risk factors (high blood pressure, raised lipids, insulin resistance) and visceral adipose tissue. BMI is also commonly associated with an increased risk of developing type 2 diabetes, certain cancers, and a reduction in overall life expectancy.

Table 3: The relationship between waist circumference and odds ratios for risk amongst male and female adults (adapted from Han et al, 1995)

	Action level 1 (increased risk)		Action level 2 (high risk)	
	Men	Women	Men	Women
Waist (cms)	94 cm	80 cm	102 cm	88 cm
Odds ratio for risk	2.2	1.6	4.6	2.6

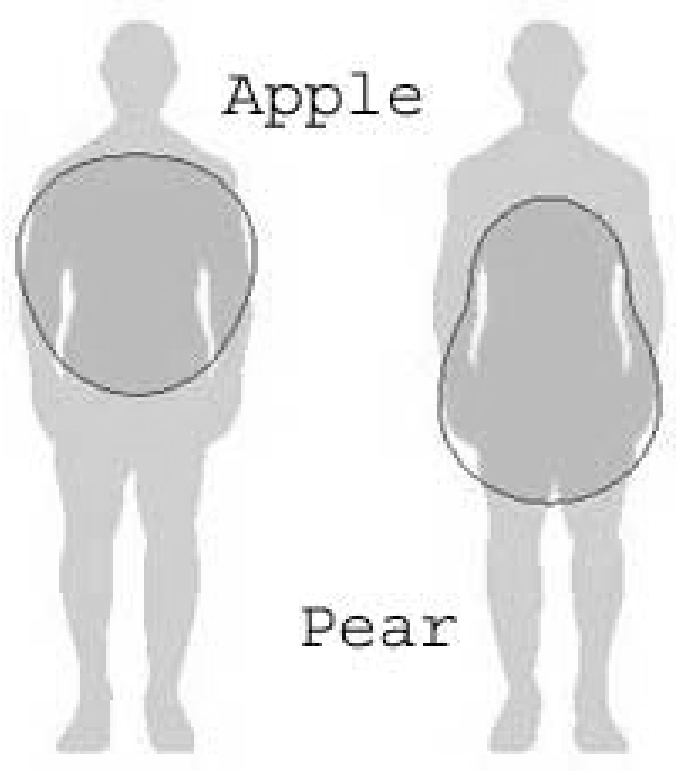


Figure 1: Apple (Gynecoid) vs. Pear (android) illustration

As illustrated in Figure 1, there are two body shapes; apple and pear. Apple shapes are typically observed in males; visceral and subcutaneous fat is mainly concentrated in the abdominal area. Pear shapes are traditionally observed in women; subcutaneous fat is primarily accumulated on the thighs, hips and legs. Greater health risks are associated with people with apple shapes, because of the increasing cardiovascular disease consequences and metabolic abnormalities that are almost exclusively related to visceral fat. As illustrated in Table 2, waist circumference is a simple proxy estimate for various risk factors; predominately cardiovascular.

Independently used, waist circumference is also a reasonable predictor of total adipose tissue, subcutaneous adipose tissue, and increased blood pressure.

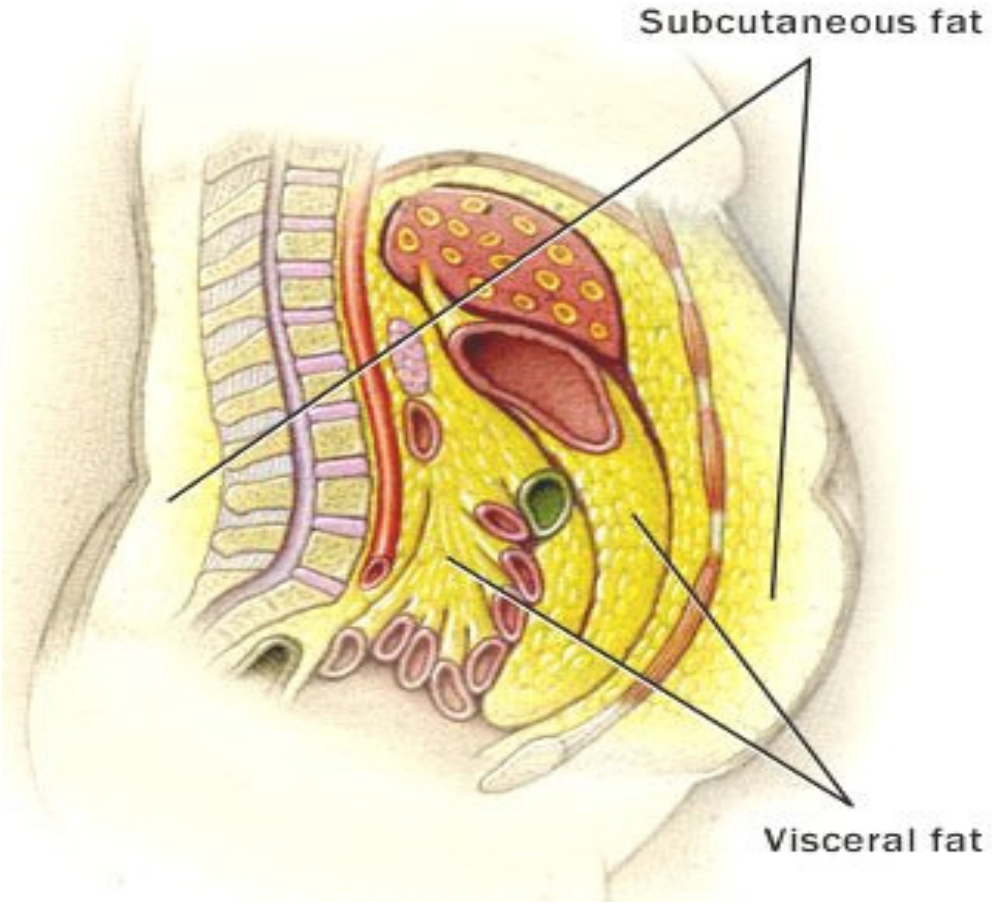


Figure 2: Illustration of visceral and subcutaneous fat

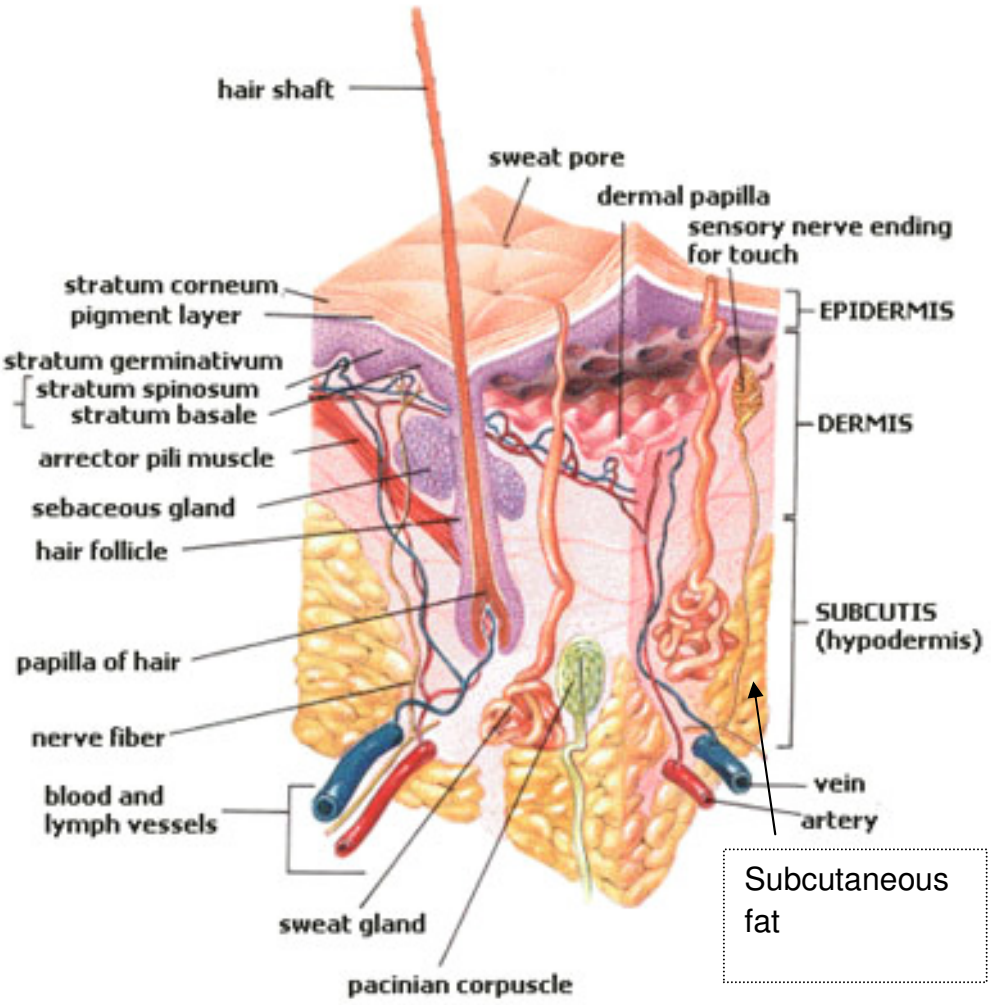


Figure 3: Subcutaneous fat illustration

Subcutaneous fat is located just beneath the skin in the hypodermis, and is easier to reduce through weight loss attempts than intra-abdominal fat, situated around and within the abdominal and thoracic cavities (heart, lungs, liver, and kidneys).

2.2.4 Waist: Hip ratio

Formiguera and Canton (2004) support the requirement for waist to hip ratio to be conducted in individuals whose BMI is >35, stating that this measure is better than just waist circumference for the evaluation of fat distribution pattern. Waist hip ratios are used to assign health risks; above 0.82 and 0.94 for men and women, respectively.

2.2.5 Skinfolds

ISAK notes that the measurement of skinfold thickness has the poorest accuracy and precision compared with other anthropometric measurements, and that people who take such measurements should be trained sufficiently and follow a series of checks in a protocol:

a) the calliper indicator must be on zero
b) the calliper is held at 90 degrees at all times
c) the skinfold is picked up at the marked site
d) the calliper is placed 1cm below the marked site
e) measurement is taken after two seconds, after the full pressure of the calliper has been applied
f) skinfold measurements should be taken in succession to avoid experimenter bias
g) inter and intra tester error should be quantified, and should be 10% at inter-tester level and 7.5% at intra-tester level.

Predictive equations which were derived from skinfold thickness experiments have been used in clinical and epidemiological settings for decades (Durnin & Womersley, 1974), and they provide good correlations with body fat approximations from Dual energy X-ray absorptiometry (DXA), neutron activation analyses (doubly-labelled water), and underwater weighing. Various skinfold thickness prediction equations have been developed, including all or selected skin fold sites to estimate body fat. Garcia and colleagues (2005) have reported that Durnin and Womersley's (1974) internationally recognised prediction equations using four skinfold sites (bicep, tricep, subscapular and supra-iliac) underestimate the amount of body fat in the obese. They suggest that prediction equations using additional skinfold sites should be used in sex-specific equations, combining skinfold thickness measured at various sites (chin, biceps, triceps, subscapular, chest, abdominal, hip, thigh, knee and calf), various circumferences (waist, hip and thigh), and bone breadth measurements (chest, elbow, knee, wrist, and ankle). Garcia and colleagues (2005) have shown that using these multiple measures within their equations improves the validity of estimates of body fatness in obese people. Hume and Marfell-Jones (2008) have highlighted the importance of measuring, identifying and marking the skinfolds, concluding that practitioners should be trained to the standards recommended by ISAK.

In summary, the validity of estimation of body fat is variable between the different methods listed above, and the reliability of estimates for each method is also variable. Correct training for those carrying out these measurements can

increase the reliability of the measurements, and the ISAK accreditation course is considered a gold standard training course.

2.2.6 Bioelectrical impedance

Bioelectrical impedance is a simple and useful method for predicting body fat. The method involves passing a mild current through electrodes that are worn at various points on a person's body, or via standing upon the electrodes with bare feet. The principle of this method relies on the fact that lean body mass and bones are good conductors, whereas body fat is a poor conductor of electricity. Various outlets offer weighing scales that incorporate bioelectrical impedance, which can be used by the public for a small nominal fee. This method of assessment relies upon a presumed and normal hydration status of the individual, and the derived equations do not take ethnicity into account.

2.2.7 Doubly labelled water

"The doubly labelled water (DLW) method is a technique used to measure the average daily energy expenditure of free living humans" (Trabulsi et al, page 1370, 2003). Schoeller et al (1995) have reported that there is a high degree of accuracy from doubly labelled water measurements. The method involves the participant consuming water that is labelled with the stable isotopes deuterium and ^{18}O; deuterium is eliminated through the body as water and ^{18}O is eliminated through the body as water and carbon dioxide. The principle of this method relies measuring (in urine) and estimating the amounts of two isotopes,

and subtracting one from the other (Schoeller, 1999). This method is easy to administrate, but is very expensive.

2.2.8 Air-displacement plethysomograhpy and hydrodensitometry

Air-displacement plethysomograhpy (BOD POD) and hydrodensitometry are considered the 'gold standards' when assessing body composition. Hydrodensitometry requires the subject to be submerged in a tank of water, preferably in a tight fitting swimsuit to minimise air trapped in fibres of clothing. It is advised that the participant be of normal hydration (three hours after a meal, showered and recently urinated and defecated). The participant climbs into the tank, immersing him or herself and removing excess air from the skin and swimsuit. To measure body weight in water, the participant uses the weighing equipment available within the tank. The head and shoulders are lowered into the water whilst exhaling for five seconds; weight is taken and repeated, taking the mean of the heaviest reading. The density of the body is calculated using the standard formula (Siri, 1961):

$$\frac{\text{Body weight (air)}}{\text{Body weight (air) - Body weight (water)}}$$

Body fat percentage is calculated from body density using the Siri (1961) equation:

$$\text{Body fat} = (4.95/\text{body density} - 4.50) \times 100$$

The BOD POD uses a similar principle of displaced volume as is used in hydrostatic weighing, except it uses displaced air (rather than water). The inverse relationship between pressure and volume is used to obtain an estimate of the body volume of a participant. Procedures are similar to hydrostatic weighing; a participant is weighed in air, has their height taken, and is advised to wear a tight fitting swimsuit. Body volume is derived initially by measuring the interior volume of the empty chamber, and subtracting that from the volume whilst the subject is within the BOD POD. This method of assessment is otherwise known as Boyle's Law:

$$P_1V_1 = P_2V_2$$

P= Pressure

V= Volume

The density of the body can be calculated using the standard formula:

Body Density= Mass/Volume

Mass= Body weight (kg)

Volume= Litres (l)

Air-displacement plethysomograhpy uses the same Siri (1961) equation in order to calculate body fat percentage of a subject. Fields et al (2000) validated the BOD POD against hydrostatic weighing, reporting the limitations associated with the type of clothing worn within the BOD POD. Agreement between both methods was demonstrated for body density, and body fat predictions were similar. However, the authors reported that caution should be taken when participants wear clothing that is not a tight fitting swimsuit.

2.2.9 Magnetic resonance imaging (MRI)

Magnetic resonance imaging scans are able to diagnose conditions related to tissue, organs and bones. Powerful magnets within the scanner produce strong magnetic fields and radio waves, producing a detailed image of the inside of the body. Basic T1 and T2 weighted MRI scans offer clinician's accurate assessments of adiposity, but these type of scans can only be done in a number of specialist centres within the United Kingdom. Adiposity can be estimated from routine MRI scans, but these are less accurate (Campbell & Haslam, 2005).

2.2.10 Computed tomography (CT)

Rössner and colleagues (1990) have suggested that computed tomography (CT) scans are the most reproducible and accurate form of body fat assessment, specifically in relation to abdominal adipose tissue. Images produced of cross-sections of the body provide the practitioner with a two-dimensional picture of specific parts of the body. Typically, CT scans are used in obese patients to examine endocrine organs associated with obesity related co-morbidities, or a more generalised examination of the abdomen. These types of scans are time consuming, and carry the risk of developing cancer from exposure to radiation, and as such have made clinicians apprehensive in prescribing CT scans as a method of body fat assessment.

2.2.11 Dual energy X-ray absorptiometry (DXA)

DXA or DEXA scans are traditionally used to determine the bone mineral density of an individual, and are most commonly used to assess the risk of a person developing osteoporosis. In obese patients, DEXA scans are used to estimate the amount of fat mass.

Personally, I feel that the majority of the population would assess their level of obesity according to their clothing size. Currently, the average clothing size for a woman in the UK is a size 16 (Nicholas, 2013). Therefore, I feel that women would only feel that they need to lose weight when they are larger than a size 16 unless someone (family member, colleague, friend etc.) has commented that they should lose weight. This would also apply for men too. Men that are bigger than a large sizing in UK clothes (KGB answers, 2012), I feel would only lose weight beyond this sizing, or unless someone has commented that they should lose weight.

2.3 Definition and health risks of obesity in adults

Obesity can be described as an excess of fat in the subcutaneous connective tissue that is a threat to health and well-being. This excess of fat is associated with reductions in life expectancy (National Audit Office, 2001) and susceptibility to a number of chronic diseases, including cardiovascular, pulmonary,

gastroenterological and endocrine disease. Excess fat in men and women is associated with musculosketal problems, and also psychosocial problems.

For any level of obesity, overweight middle-aged men (in general) have greater health risks compared with women because they tend to carry more of their excess fat around their abdomen (apple shaped), which is more detrimental to health than being pear shaped (described above).

Excess fat in men is associated with a higher risk of prostate cancer, kidney stones and gout. Excess fat in women is associated with an increased risk of polycystic ovarian syndrome (PCOS) and post-menopausal breast cancer.

2.4 Prevalence of obesity in adults

The Foresight report (2007b) found one in four adults in the UK were classified as obese and predicted, if the then current trends continued, the prevalence could double by 2050.

2.4.1 North East prevalence

As previously mentioned in 1.3, the 12 areas of the North East, apart from Newcastle (Gateshead: 30.7%, Darlington: 27.6%,: 27.7%,Sunderland: 28.6%,Redcar and Cleveland: 29.6%,South Tyneside: 27.4%,Northumbria: 27.3%,Tyneside: 26.6%,Newcastle: 23.9%,Middlesbrough: 27.9%,Hartlepool:

27.5%, and County Durham: 28.6%) observe higher obesity statistics than the current UK average; 24.2% (Public Health England, 2013).

Gateshead's obesity prevalence of 30.7% is worse than the highest UK average of 30.2%. Kumanyika et al (2008) estimated that the number of overweight and obese individuals could increase to 1.5 billion by 2015, and using this model and in line with trends seen in 2013, the North East region could, in theory, observe obesity levels beyond 23.9%-30.7% by 2015.

2.4.2 Global prevalence

Globally the number of overweight and obese individuals could increase to 1.5 billion by 2015 (Kumanyika et al, 2008). Below illustrates the difference in the prevalence of obesity between countries for men (Figure 4) and women (Figure 5) in 2005, and Figure 6 shows the trends in the prevalence of obesity in difference countries since 1978.

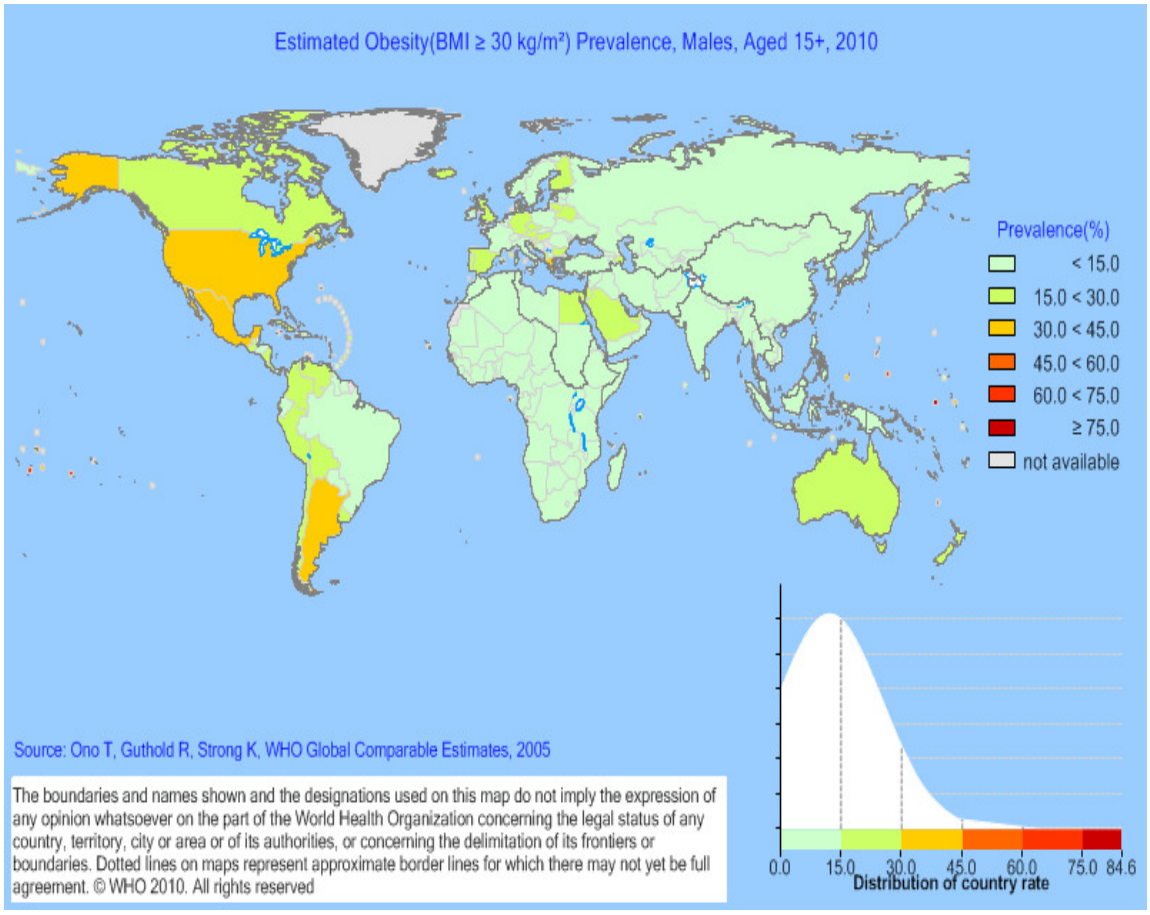


Figure 4: The prevalence of obesity in males above 15 years of age in 2005

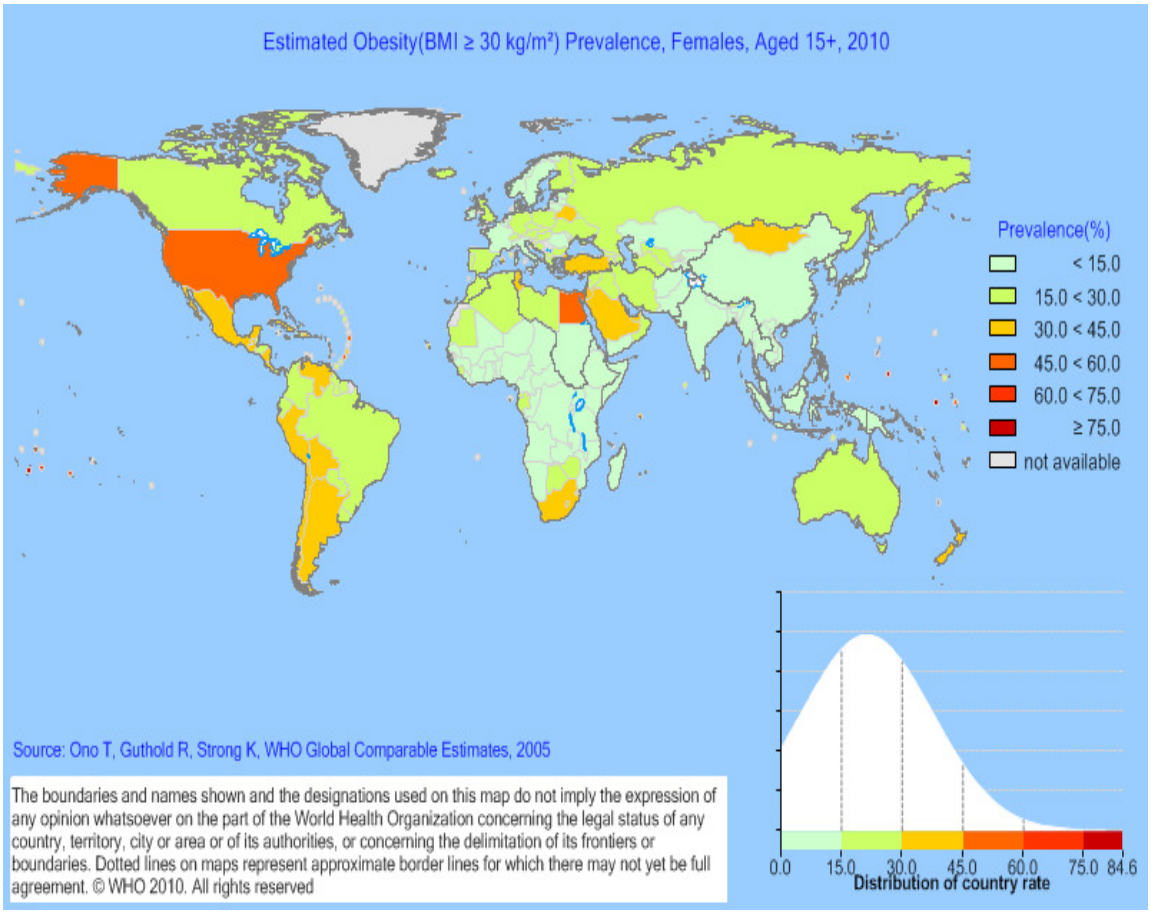


Figure 5: The prevalence of obesity in females above 15 years of age in 2005

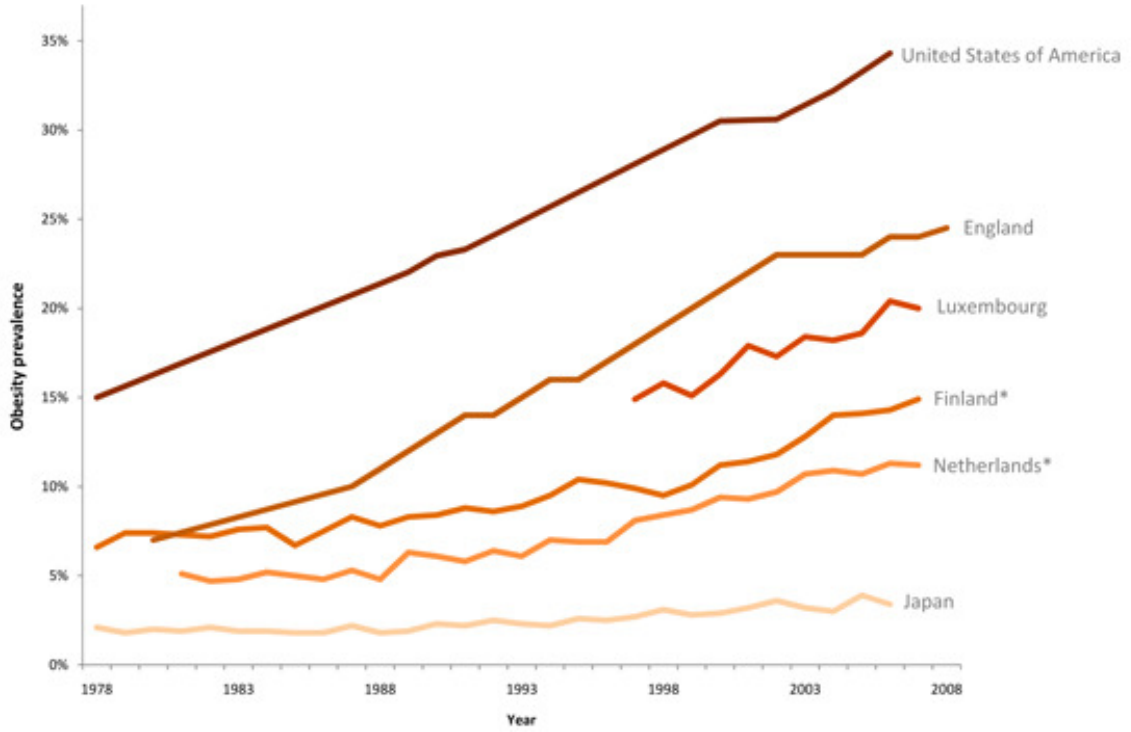


Figure 6: A line graph to illustrate trends in the prevalence of obesity global obesity trends from 1978

2.6 Summary

As demonstrated in Figures 4, 5 and 6, the prevalence of obesity in adults rose rapidly in the UK, as in many other countries, up to 2000, but since then the prevalence rates have slowed down although they still remain high.

2.7 Costs to society

Financial implications of obesity include costs to the state, and to the individual. Direct costs to the NHS for the prevention, diagnosis and treatment of obesity have been estimated at £10 billion per year (Campbell & Haslam, 2005).

However, additional (indirect) costs through increased number of sick days, earlier retirement; decreased performance, earnings, productivity and capability could equate to £49.9 billion per year for England (Campbell & Haslam, 2005).

Table 4 illustrates the predicted of direct and indirect costs associated with obesity for 2050 (data taken from Foresight; Tackling Obesities: Future Choices—Modelling Future Trends in Obesity & Their Impact on Health, 2007b).

Table 4: Predictive costs associated with obesity in England in 2050

Cost type	**2050 projected cost £billion/year**
Total NHS cost of diabetes	3.5
Total NHS costs of coronary heart disease	6.1
Total NHS costs of stroke	5.5
Total costs of other related diseases	7.8
Total cost (all related diseases)	22.9
NHS cost increase above current, due to elevated BMI (overweight and obesity)	5.5
NHS cost attributed to elevated BMI (overweight and obesity)	9.7
NHS costs attributable to obesity alone	7.1
Projected percentage of NHS budgets at £70 billion	13.9%

2.8 Risks and consequences

2.8.1 Cardiovascular consequences

Obesity is associated with a range of cardiovascular problems, including congestive heart failure. Poirier et al (2006) suggest that obesity could lead to congestive heart failure by promoting diabetes, hypertension and coronary heart disease, and Levy et al (2002) has shown that this risk increases with increasing level of obesity. Gradual weight loss of 5-10% in an obese individual can significantly improve obesity related risk factors for coronary heart disease (Klein et al, 2004).

The term 'Syndrome X', otherwise referred to as Metabolic Syndrome (mentioned above), is often present in obese adults. The diagnosis of this syndrome is by the presence of at least three of the criteria listed in Table 2.

2.8.2 Psychological and social consequences

Obesity is associated with a number of psychological and social problems, including low self-esteem, and there is some debate about whether obesity is the cause, or the consequence, of these problems. These problems can affect individuals in many ways, including their employability, and thus their potential to get a good job. An obese individual could also suffer lower rates of pay. Baum and Ford (2004) report that an obese person could suffer a wage penalty in the range of 0.7%-6.3%. Therefore, in relation to CWLPS, obese individuals could be in a 'chicken and egg situation'. An obese person might want to lose

weight through a CWLPS, though cannot afford to do so as their weight has been reflected in their pay grade. Register and Williams' (1990) analysis of the National Longitudinal Survey Youth Cohort of 8000 18-25 year old men and women indicated that obese women earned 12% less than their non-obese colleagues, and are more likely to have lower paid jobs than 'thinner' women. Typically, CWLPS is purchased by a female population, therefore obese women could continue to increase their weight as they cannot afford to purchase CWLPS based upon their lower wage than non-obese women. Employment law should protect individuals from discrimination in the workplace, but there is evidence to suggest that this is hard to uphold. Polinko and Popovich (2001) researched discrimination in the workplace, common thoughts of obese are that they are 'lazy, unproductive, and unattractive'. Therefore, these misconceptions are still evident in society. More specifically in the context of my PhD, obese individuals could choose a CWLPS that is more acceptable in their workplace than a CWLPS that is more effective. For example Slimming World could be chosen as other colleagues are also following this commercial weight loss programme, and it is acceptable amongst peers. However, a produce like Alli might not be acceptable in the workplace, due to the inconvenience of the individual requiring additional toilet breaks, or Slim Fast could cause embarrassment to the individual due to the large marketing logo wrapped around the bottle. In my personal opinion, I believe that women would be more concerned about their choice of CWLPS in the workplace than a man.

Some research (Miller and Downey, 1999) suggests that there is a relationship between self-esteem and weight, a moderate relationship was found for women.

Though self-esteem is moderated by body esteem. Friedman and colleagues (page 33, 2002) found that "*for both men and women, body-image satisfaction partially mediated the relationship between degree of overweight and depression/self-esteem".* Weight stigma has been researched for some time, and is dominant in employment bias. Obese individuals also could delay seeing a health care professional due to bias in medial settings (Obesity Society, 2010), and due to negative past experiences might not seek advice from a GP, and decide to use CWLPS instead.

2.8.3 Pulmonary consequences

Obesity is associated with sleep-associated breathing disorders, including sleep apnoea and Pickwicken syndrome. These disorders are associated with coronary heart disease (Leung & Bradley, 2001), and obese patients with congestive heart failure or/and sleep disorders are at increased risk of fatal arrhythmias, resulting in sudden death. Riley et al (1976) suggest that pulmonary embolism could occur if obesity-linked hypoventilation syndrome is apparent, resulting in death or a poor quality of life.

There is some interesting data in the literature about asthma and obesity, particularly for those individuals who suffer from severe asthma who require regular steroid medication (Rodriguez et al, 2002); regular use of steroids increases visceral adiposity.

2.8.4 Endocrine consequences

The most common medical condition that is associated with obesity is type 2 diabetes. Campbell and Haslam (2005) estimate that 85% of type 2 diabetics are either overweight or obese. As one might expect, the primary treatment for type 2 diabetes in those individuals who are obese (i.e. the majority) is weight loss. However, where patients are unable to comply with weight loss programmes, they are prescribed medication. Self-management of the prescription drug Metformin is the current treatment option for type 2 diabetes in England. Treatment of type 2 diabetes for one year ranges from £23.07p-£69.22p per individual (Department of Health, 2013a).

2.8.5 Gastrointestinal consequences

The most common gastroenterological complication of obesity is non-alcoholic fatty liver disease. Non-alcoholic fatty liver disease is a broad-spectrum disease ranging from fatty infiltration of the liver alone, or combined with inflammation. Early detection of the disease can be managed with diet and medication, but a late diagnosis might require a liver transplant.

2.9 Determinants of obesity

2.9.1 Socio-economic status and obesity

Like in many other countries in Europe, obesity is positively associated with economic and social deprivation in England (House of Commons; Health

Committee, 2004; Law et al, 2007). Howard et al (2000) have explored the relationship between socioeconomic status and obesity, concluding that the relationship the positive association continues to strengthen as the level of obesity increases.

As mentioned earlier (1.3), the North East region has high levels of obesity prevalence. The most highly disadvantaged Super Output Areas (SOAs) are classified as deprived on several of the seven Domain Indices that make up the Index of Multiple Deprivation (IMD) (Noble et al, 2006). Ten percent of the most deprived SOAs on the IMD are located in the North East. Specific geographical locations in England, including the North East, Humber and Yorkshire, and West and East Midlands, show significant health inequalities (White et al, 2007). Postcodes within the Tees Valley area (TS1-TS18) were chosen specifically as the initial method to recruit participants was via the Evening Gazette, which covered these postcodes, and these postcodes were consistently within one of the most deprived regions in the North East.

My research was specifically aimed at investigating the use of commercial weight loss products and services in the North East, which I hope will be part of the preliminary work for a randomised trial in the future. Currently, I would like to develop a trial which aims to increase awareness and access to the best CWLPS options for obese individuals who live in deprived areas of the North East. I understand that such a trial would be challenging for a variety of reasons, including the likelihood of a low recruitment rate. Health promotion interventions targeted at individuals who live in low socioeconomic areas consistently attract poor participation rates (Michie et al, 2009).

2.9.2 Gender and obesity

Sobal and Stunkard (1989) conducted a review of 144 epidemiological studies, and found that the relationship between SES and obesity was inconsistent for men in high income countries, but that there was a strong and consistent inverse relationship between SES and obesity in women in high income countries.

The relationship between SES and gender in England has been looked at in more detail by the National Institute for Health and Clinical Excellence; no apparent relationship has been observed between IMD and the prevalence of obesity in men (National Institute for Health and Clinical Excellence, 2006). In contrast, the prevalence of obesity in women living in the most deprived areas (IMD) of England was relatively high, and the prevalence of obesity in women living in the least deprived areas (IMD) of England was relatively low.

This gender differences could be due to a plethora of factors including cultural differences, work status and patterns, income, and pay inequality. Certainly, groups of women in the UK with a lower household income, who work in an unskilled profession, and have fewer qualifications, have higher rates of obesity (Wardle et al, 2002).

It is clear from the literature that women are more likely to take part on health promotion research compared with men, particularly in area of deprivation. I was very aware that I needed to design a recruitment plan for my study which involved a variety of engagement opportunities that appealed to both men and women.

Reeder et al's (2002) study of 26,293 men and women aged 18 to 74 years report that BMI (27+) increased with age more so in men than in women; 35% and 27% respectively. As age increased in men and women (55-64 years old), so did their BMI. However, in men after 64 years of age their BMI decreased, though remained unchanged in women. Men of a healthy (BMI 20-24) weight decreased by 24% between the youngest and oldest age groups, in comparison to 20% in women. Class II obesity was found to be more prominent in women aged 55-74. Within both males and females, as age increases, so did the high blood pressure, centripetal fat distribution, plasma cholesterol, triglycerides, and low density lipoprotein (LDL). Gender has an important role in relation to the storage of adipose tissue, metabolism (Power and Schulkin, 2008), and get fat in different ways. Women have greater adipose tissues stores, after correcting for BMI, have larger stores of subcutaneous fat, and adipose tissue is more likely to be stored on the thighs and buttocks. Men are more likely to have visceral of fat, and be more susceptible to abdominal obesity. Research has also shown that the effects of visceral fat on health vary between genders as well (Jensen et al, 2006). The metabolism of fat also is different between males and females, women are more likely to store fat than men, however, *"women also appear to utilise fat as an energy substrate during periods of sustained exertion more so than do men"* (Power and Schulkin, page 934, 2008. Therefore, gender plays a significant role in obesity and overweight prevalence.

2.9.3 Ethnicity and obesity

As mentioned earlier, lower BMI cut-off points for overweight and obesity are recommended for Asian populations (World Health Organization, 1997). A higher level of body fat and central fat distribution, for the same BMI as Caucasians, is observed, increasing the risk of cardiovascular disease outcomes at a lower BMI (Bell et al, 2002). Lear (2005) found higher values of total cholesterol, low-density lipoprotein, triglycerides, and C - reactive protein, and lower values of high-density lipoprotein, in Asian men compared with matched Caucasian men. Similar findings were observed for women.

2.9.4 Age and obesity

It is well documented that a person's age is associated with the prevalence of obesity. In 16-24 year olds, the prevalence of obesity in England is at its lowest, and it increases steadily over the decades until the age of about 75 (Figure 7).Research suggests that different cut-off measures should be included for a person's age; specifically for waist circumference (Després et al, 2001) . Waist circumference and visceral fat is affected by age and menopausal status. As males and females age, their regressions slopes increase, and are more apparent in men than women at any age. When a female starts the menopause, the slope then starts to become similar to that of the male slope. In men and women over 50, abdominal obesity has been found to be a strong predictor of insulin resistance (Racette et al, 2006), and the cardiovascular risk profile also deteriorates with age. Baum and Raum (2009) report that obesity and BMI

prevalence grow rapidly with a person's age. Also deprived individuals have a higher BMI, and the gradient steepens with a person's age. Therefore, age is in important factor in obesity and overweight prevalence, and should not be assessed independently. Other factors including gender (see 2.9.2), physical activity, and SES should be reported. It is unclear as to why the prevalence of obesity in England varies by age, but a general decline of physical activity with age is likely to play a key role. In my personal opinion Figure 7 should not be taken at face value, due to the rise in general living costs, older individuals might not be obese as they cannot afford to eat sufficiently, their state pension might only be enough to pay for household bills, and an elderly person might wish to spend the rest spend of their pension on their children/grandchildren than on food. As a hypothetical scenario, if all age groups were given the same wage/pension, obesity levels would still show a marked gradient based upon where an individual lives, gender, whether they smoke, how much alcohol they drink, and so forth. Therefore, alike health inequalities, age is also a contributing factor to obesity and overweight prevalence.

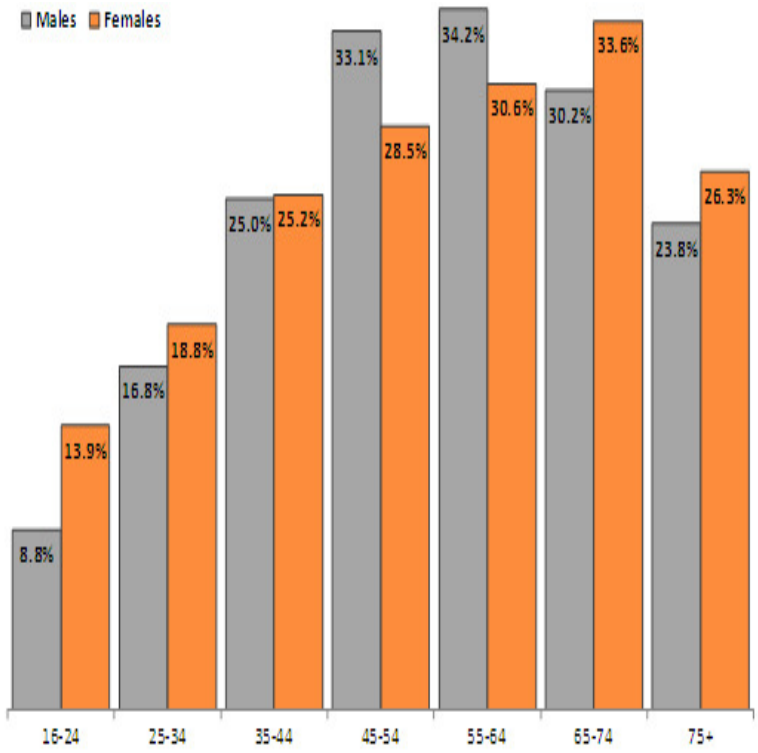


Figure 7: Prevalence of obesity in England by age (Public Health England, 2013

2.9.5 Sleep and obesity

Recent studies (Knutson, 2012) have found a relationship between the prevalence of obesity and sleep duration in adults. Experimental and observational studies have suggested that reduced sleep (<6 hours/day) could potentially increase the risk of obesity, but this assumes a causal mechanism, and this is hotly debated. Additional research on the relationship between sleep and obesity, especially in low socioeconomic groups where more individuals work shifts, would be useful.

2.9.6 Education and obesity

As demonstrated in Figure 8 as the level of education increases the level of obesity decreases. A variety of factors could be the reason for this association. Education and obesity is a complex subject, whereby education is at the focal point of secondary variables as such as income, occupation status or characteristics of the area of residence. Conclusions of the Low Income Diet and Nutrition Survey (Food Standards Agency, 2007) showed that the higher the level of education, the better the persons overall diet was, specifically fruit and vegetable consumption was better. An individual with poor literacy or numeracy skills might not be able to read nutritional labelling or understand how the different nutritional properties affect their health (fat, calories, sodium). Key policy messages might not be accessed by those with a lower education level, especially when messages do not demonstrate how they would be applied to a person's life (how can fruit and vegetable consumption be increased when it is cheaper to buy unhealthy foods. Most research focuses on the health of the individual and socio-economic factors, or mortality, only limited evidence exists concerning the relationship between obesity and education. Cutler and Lleras-Muney's (2006) research has suggested that additional years of schooling reduces the likelihood of smoking, excessive drinking, illegal drugs, obesity and overweight. In relation to policy implications, Cutler and Lleras-Muneys (2006) suggest that obesity rates could decrease by 9% in the UK if education was increased by 1 year. At present the casual link between obesity and education is not conclusive. However, within the region which this study was situated (North East), it is my personal opinion that the secondary variable of income

could be the cause of obesity prevalence. A person's qualifications would determine what type of job is available, typically, a person with no qualifications would be in an unskilled or manual job, whereby the monthly income would be lower than someone who has a degree and would be in a managerial or skilled role. Therefore, education would be the primary cause of a person having a wage that reflects their qualifications, and monthly income. Dependent upon monthly income would determine what foods are purchased by the individual. Low monthly incomes could lead to the consumption of unhealthy items, as they are cheaper to buy than healthy items.

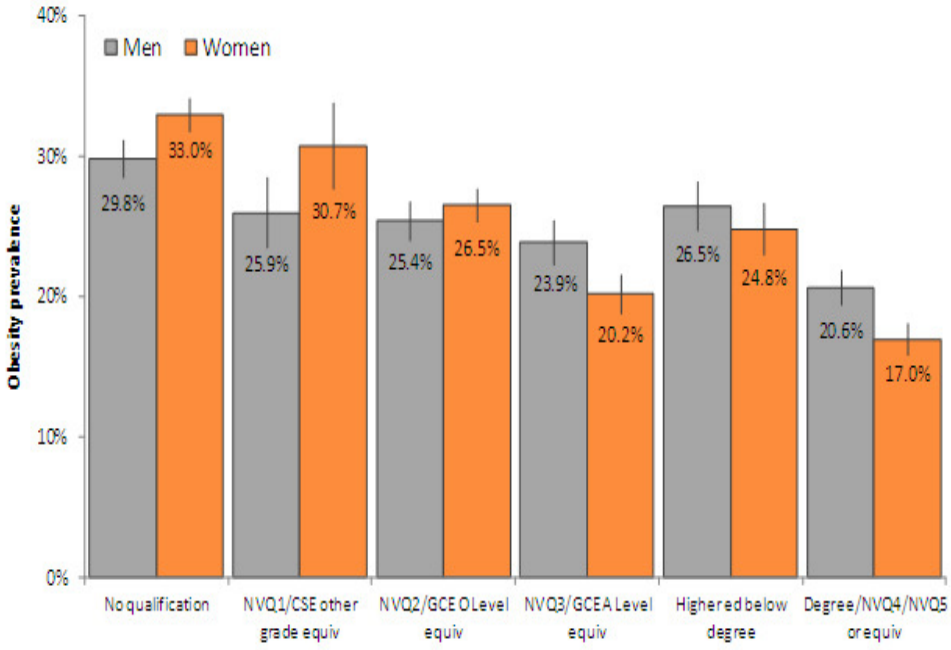


Figure 8: Prevalence of obesity in England by educational level (Public Health England, 2013).

2.9.7 Other determinants of obesity

For individuals who have certain rare genetic disorders, e.g. Prader-Willi syndrome, it is almost inevitable that those who are obese in adolescence will also remain obese as an adult.

2.9.8 Summary of determinants of obesity

The obesity system map (Foresight (2007b) has acknowledged that there are over 100 direct and indirect variables of obesity, divided into seven distinctive themes.

- Biology: An individual's genetic makeup will influence overall health and ill-health.
- Activity environment: The influence of the environment on an individual's activity behaviour. For example an individual might not wish to cycle due to their workplace due to road safety fears, inadequate shower facilities.
- Physical Activity: Duration, intensity and type of physical activity carried out by individuals on a daily basis.
- Societal influences: A variety of factors can impact on the individual including culture, peer pressure, education and the media
- Individual psychology: An individual has different psychological triggers/drives, for example a woman might eat high calorie/high fat food at certain times of a menstrual cycle, consumption and physical activity patterns could depend upon a person's working hours, and physical

activity preferences could be due to an individual's previous experience, or what type of exercise they enjoy participating in.

- Food environment: The individual's food environment can impact on food choices, for example the purchase of unhealthy food could be due to the location of a takeaway, and the price of their food.
- Food consumption: Portion sizes, quality of the food, and frequency of eating/snacking.

The seven themes can also be drawn upon in relation to health inequalities:

- Biology; individuals of low SES have poorer health have less access to health care facilities.
- Physical activity; individuals of low SES are less physically active.
- Activity environment; there might be (perceived and real) barriers to individuals of low SES to be physically active, e.g. safety of area in which they live may be poor and therefore they do not want to go out alone, particularly at night. This could be because they are scared of gangs of youths, or because the environment is not pleasant, e.g. dog poo on the pavements and poor lighting on streets.
- Societal influences; there is some evidence that social norms are very important in determining an individual's health behaviours. So, for individuals of low SES who are living in a community where nobody walks or is physically active unless they absolutely have to be, then it is hard for one person in that community to engage in regular exercise to

simply improve their health. They might get laughed at by others, for example.

- Individual psychology; as previously mentioned individuals of low SES are more likely to have low esteem, which in turn may be a barrier to them believing that they can maintain a weight loss programme and reduce their weight.
- Food environment; depending on whether an individual with a low SES has a car or not will influence where they do their food shopping. For those individuals who tend to do most of their shopping in 'corner' shops in deprived areas, and because everything that they buy must be perceived as 'value for money' then they are less likely to buy fruits and vegetables, and more likely to buy ready-made foods.
- Food consumption; individuals of low SES are more likely to purchase foods which they know their family will eat and enjoy, and avoid the risk of buying or making meals which may go to waste.

2.10 Treatment and management of obesity

2.10.1 Pharmacotherapy

In the last decade in the UK, three drugs were licensed for the treatment of obesity; orlistat (xenical), sibutramine (reductil) and rimonabant (accomplia). The European Medicines Agency (EMEA), a European Union (EU) body, concluded in June 2008 that rimonobant should be withdrawn based upon

research that the benefits did not outweigh the risks associated with taking the drug. Upon that recommendation, the National Institute for Health and Clinical Excellence withdrew its recommendation on the use of rimonabant. The National Institute for Health and Clinical Excellence also suspended their recommendation for the prescription of sibutramine in January 2010, based upon the findings of a review conducted by the European Medicines Agency which found that the cardiovascular risks of sibutramine outweigh its benefits.

These drugs could be reinstated in the future, if additional evidence is produced to support their efficacy, and long-term benefits.

2.10.1.1 Performance of orlistat, sibutramine and rimonabant

2.10.1.1.1 Orlistat

Orlistat is a non-centrally acting anti-obesity agent, which acts locally in the gastrointestinal tract; lipase binds to triglycerides producing monoglycerides and free fatty acids. Brownell and Fairburn (2002) report that the recommended dosage of 120mg, which is required three times per day, alongside a hypo caloric diet, results in inhibitory effects of dietary absorption by 30%.

2.10.1.1.2 Sibutramine

Sibutramine is a dual physiological anti-obesity drug whereby it acts upon the neurotransmitters; serotonin and norepinephrine as a reuptake inhibitor to enhance satiety.

2.10.1.1.3 Rimonabant

Rimonabant blocks the CB1 receptors in the endocannabinoid system that are located in abdominal fat, the liver, the gastrointestinal tract, muscle, and the brain.

2.10.1.2 Supporting studies

2.10.1.2.1 Orlistat

In Sweden a 4 year, double blind, prospective study was conducted with 3304 randomised normal or impaired glucose tolerance patients to assess the effectiveness of orlistat (120mg) or placebo. Participants were obese patients at risk of developing type 2 diabetes. Alongside the drug, patients were advised to reduce their calorie intake by 800 kcal per day, engage in moderate daily physical activity, and attend counselling sessions.

The XENDOS (Xenical in the Prevention of Diabetes in Obese Subjects) study included patients with a mean BMI of 37 and a mean age of 43 (Torgerson et al, 2004). Results from the 4 year study demonstrated that the incidence rate of diabetes was considerably lower in the orlistat group compared with the placebo group; a risk reduction of 37.3%, p=0.0032. Improvements were observed (placebo vs. intervention group results) in relation to body weight; 4.1kg vs. 6.9kg; proportion achieving a ≥5% weight loss, 37% vs. 53% and ≥10% weight loss; 16% vs. 26%; LDL cholesterol, -5% vs. -12.8%; systolic blood pressure, -3.4 vs. -4.9; diastolic blood pressure, -1.9 vs. -2.6.

Wirth (2005) also highlight that weight loss with orlistat leads to reductions in medications for the treatment of co-morbidities. 26% percent of hypertensive patients reduced or stopped their medication during the trial. 34% of patients with type 2 diabetes reduced or stopped their medication during the trial, and 40% of dyslipidaemic patients reduced or stopped medication during the trial. The National Institute for Health and Clinical Excellence guidance (2006) guidance states that only patients with a BMI of >30, or >28 with co-morbidities, should be prescribed orlistat.

2.10.1.2.1.1 Side effects

The primary side effect of orlistat is steatorrhea (oily, loose stools) because orlistat blocks 30% of the dietary fat from being absorbed by the gut, and this fat is excreted unchanged in the faeces, causing faecal incontinence, frequent or urgent bowel movements, and flatulence (Torgerson et al, 2004).

2.10.1.2.2 Sibutramine

Many studies have been conducted to illustrate the efficacy of sibutramine in obese patients. The well-documented STORM (Sibutramine Trail of Obesity Reduction and Maintenance) study was a two-year double blind, placebo controlled trial of 605 patients. James et al (2000) found that the STORM trial achieved a 12kg weight loss, which was well maintained for 2 years when sibutramine administration was combined with lifestyle changes. Decreases in waist circumference, visceral fat, triglycerides and HbA1c were found.

Improvements in high-density lipoprotein (HDL) cholesterol were also reported. However, side effects of the drug include tachycardia, palpitations, hypertension and vasodilatation of the cardio vascular system. Thus, frequent and regular monitoring of blood pressure and pulse rate is an essential part of the protocol for this drug. The National Institute for Health and Clinical Excellence guidance (2006) states that only patients with a BMI of >30, or >27 with co-morbidities, should be prescribed sibutramine.

2.10.1.2.2.1 Side effects

In addition to tachycardia, palpitations, hypertension and vasodilatation of the cardio vascular system, as mentioned above, frequent side effects from sibutramine include, dry mouth, increased appetite, nausea, upset stomach, constipation, disturbed sleep, dizziness, drowsiness, headache, flushing, joint and muscle pain (National Institute for Health and Clinical Excellence, 2006).

2.10.1.2.3 Rimonabant

The Rimonabant in Obesity (RIO) study followed patients for 1 year whilst taking 20mg of the drug, compared with a placebo group. Patients in the placebo group reduced their weight by an average of 2.3kg, compared with 8.6kg in the group taking rimonabant. 75% of patients taking rimonabant also lost at least 5% of their body weight in comparison to only 25% in the placebo group (Van Gaal et al, 2008).

2.10.1.2.3.1 Side effects

Reports of severe depression (including suicidal tendencies) associated with taking this drug are frequent. This is thought to result from the drug being active in the central nervous system, an area of human physiology so complex that the effects of a drug are extremely difficult to predict or anticipate, varying from one individual to another.

2.10.1.3 Costs of obesity drugs

The cost of the drug per patient per year were estimated in 2005 as orlistat £533, sibutramine £455, and rimonabant £528 (Campbell & Haslem, 2005).

2.10.2 Physical activity as a treatment for obesity

It has been well documented that increased physical activity reduces the risk of coronary heart disease and stroke, diabetes, hypertension, colon cancer, breast cancer and depression (Hu et al, 2004). Moderate and vigorous physical activity also has other health benefits, and is associated with a reduced the risk of type 2 diabetes, certain cancers, cardiovascular disease, and joint and bone problems.

To achieve a clinically meaningful weight loss through increased physical activity alone, the American College of Sports Medicine (ACSM) recommends 60 minutes of daily physical activity (Jakicic & Otto, 2005).

2.10.3 Fat and fitness

Research by Ortega et al (2013) has suggested that it is possible to be obese and metabolically healthy, as long as that person is physically active. This research has received a lot of press coverage, and a small group of researchers are advocating for a focus on physical activity interventions and fitness, rather than weight loss.

2.10.4 Bariatric surgery

Weight loss surgery, also known as bariatric surgery, is used as the last resort for people who are morbidly obese. There are two types of weight loss surgery, gastric banding, and gastric bypass. Gastric banding is when a band is fitted around the top of the stomach, resulting in small amounts of food being consumed and the feeling of fullness. Gastric bypass is when your digestive system is re-routed past most of your stomach, resulting in the digestion of less food and the patient feels full with a reduced amount of food. Not everyone will be able to qualify for bariatric surgery on the NHS, unless certain criteria are met. A person with a BMI of 40 or above, or a person with a BMI of 35 or above with another co-morbidity (type 2 diabetes or high blood pressure) would be eligible for weight loss surgery on the NHS. NHS waiting lists for weight loss surgery are increasing in England, and the numerous TV programmes which profile good news stories about individuals who have probably contributed to the length of these waiting lists. Gastric banding, on average will cost £6,500, and a gastric bypass will cost on average £12,250. Bariatric surgery is also

available privately in some countries, and is popular amongst those who are rich and want to be thinner, including some TV presenters and pop stars.

Surgery of this nature will cause rapid weight loss, and could require cosmetic procedures to remove unwanted lose folds of skin (including an 'apronectomy').

Following weight loss surgery, patients are supposed to adhere to a lifelong commitment of regular exercise and healthy diet. The follow up care associated with private surgery is of variable quality.

2.10.5 Alternative methods

Alternative methods to lose weight vary in price and duration, and have a limited (in number) and poor (in quality) evidence base. Examples include acupuncture, hypnotherapy, and reflexology, to name but a few. These alternative methods are normally not available on the NHS, and will not be discussed here in my thesis.

2.10.6 Commercial weight loss products and services

2.10.6.1 Primary Care setting

Individuals in England who want to lose weight and seek advice from their GP may be offered, depending on their circumstances, bariatric surgery or drugs. However, the vast majority will only be offered a diet and/or physical activity product or service, which often includes a behavioural motivation component.

What they are offered will depend on where they live. Some of these diet/physical activity treatment options are delivered by the Primary Care staff (e.g. a weight loss clinic run by dieticians), and others are on prescription (e.g. Weight Watchers, Alli). The general advice is that people in the UK who are seeking treatment for their obesity should go to their GP first, as patients who are advised by their GP to lose weight are more likely to do so than those who are not advised (Levy & Williamson, 1988).

However, Lowe et al (2001) have found an increasing number of individuals wishing to lose weight are avoiding the NHS, and instead seeking assistance from commercial weight loss products and services (CWLPS) which are available without a referral or prescription from their GP. Womble et al (2004) have suggested that this may be due to the fact that Primary Care offers a limited range of treatment options for an individual.

2.10.6.2 Commercial weight loss products and services (CWLPS) and health inequalities

One of the questions of my research was whether a person's socioeconomic status determined if they chose (rather than it being prescribed by their GP) to use CWLPS, and if they did then what sort of CWLPS did they choose and why. At the start of my PhD, I spent a considerable amount of time looking for information about CWLPS and SES/health inequalities; however I was unable to find any useful information. I had observed that adverts for certain CWLPS were more commonly to be found in certain magazines and newspapers, and during commercial breaks of certain TV programmes but not others. Although I

observed that there may be an association between the SES of the typical reader of the magazine or newspaper, or viewer of the TV programme, and the CWLPS being advertised, I did not conduct a rigorous study.

In relation to health inequalities and the research question, I personally believe that the reasons of choice of CWLPS and uptake of CWLPS can vary significantly. As described in 2.9.6, education can influence the choice of CWLPS, a person with a lower educational achievement, might chose a CWLPS based upon how easy it is to follow, in comparison to an individual educated at degree level (or beyond), whom might chose a CWLPS that could be difficult to follow, though they might know that the CWLPS is more effective than a similar CWLPS. Education could also impact on the type of job a person holds, typically as the level of education increases, the annual household income also rises. Therefore, a person who has a high level of educational achievement, could possibly have a higher annual income, and therefore might choose a CWLPS that is higher in cost, and could be more effective in the long-term. As documented earlier (2.9.4), a person's age could impact on the uptake and choice of CWLPS. As a person ages, their level of obesity increases, therefore, it could be assumed that the older the person gets the more CWLPS have been tried and tested in comparison to a younger person. Younger individuals might not be as health conscious compared to someone in their 50's (see Figure 7). Therefore, the uptake of CWLPS could increase with age, as does their BMI. One factor that I firmly believe is the most contributor to the uptake and choice of CWLPS is a person's gender (see 2.9.2). Male and female biology are very different, how fat is stored and where varies significantly.

However, the choice and uptake of CWLPS is dominated by females. This does not necessarily mean that men do not use CWLPS, though the choice for men is limited. Currently, Lighterlife, Slimming World and Weight Watchers (online), only cater and advertise to the male market, products like Slim Fast, Alli, Special K only feature females and use taglines that are more appealing to women. Therefore, if marketing was unisex, and commercial weight loss groups had the male and female only classes, might attract a larger male population. Men and women would possibly use a CWLPS for different reasons; a woman might use a CWLPS as they have put on a few lbs. and want to slim down for a holiday. Whereas a man might want to use a CWLPS as they have recently been told that they have type2 diabetes due to their weight, and losing weight will impact on their long-term health.

Current practice in the provision of 12 week referral schemes could possibly fuel health inequalities. A low SES individual might not to in close proximity to a GP surgery, and would not be able to enquire about weight loss through a 12 week referral scheme, or the individual might be able to visit a GPs surgery via public transport, though this would cost money that the individual might not have. Whereas a high SES individual might live in closer proximity to a GP surgery (or have access to a car), and might possibly enquire about weight loss through a 12 week referral scheme. Regardless of SES, access is an important factor in relation to weight loss. Overall it might be cheaper for a low SES individual to walk to their local Boots/supermarket/pharmacy, and purchase a CWLPS, than it is to pay for public transport/fuel. Therefore, low SES individuals could be benefiting from the provision of commercial weight loss 12 week referral

schemes via a GP due to the level of access. Research has not been conducted to demonstrate this possibility. However, based upon the changes in primary care and the provision of public health services in England, pharmacists will play a larger role in relation to accessing weight loss information. GP's will be able to refer patients to pharmacists that will be closer to an individual (better access). This method could have better outcomes than an individual using a CWLPS. As previously mentioned patients who are advised by their GP to lose weight are more likely to do so than those who are not advised (Levy & Williamson, 1988). just as much weight might be lost by a pharmacist giving weight loss advice, as a GP.

Within the CWLPS industry, I firmly believe that a commercial weight loss company targets certain audiences which they feel best fit those who they know normally use their products and services.

2.10.6.3 Changes in primary care and the provision of public health services in England

Since the commencement of the PhD in 2009, the way in which Primary Care operates and the provision of public health services has changed significantly, and on 1st April 2013 Public Health England was launched. The modernisation of the NHS as a commissioning system is now in place, ensuring that the patients' needs are at the heart of the clinical process, and underpinned by the NHS constitution. Nationally, the NHS Commissioning Board will ensure the new system provides a clear national standard, is accountable, and is fit for

purpose. The five domains (Table 5) of The NHS Outcomes Framework (Department of Health, 2013b) is led by the Board, and took on its full statutory responsibilities in April 2013. Until March 31st March 2013, the NHS planning and delivery responsibilities were with the Department of Health, Strategic Health Authorities, and PCT's.

Table 5: The five domains of the NHS Outcomes Framework

Domain 1	Preventing people from dying prematurely;
Domain 2	Enhancing quality of life for people with long-term conditions;
Domain 3	Helping people to recover from episodes of ill health or following injury;
Domain 4	Ensuring that people have a positive experience of care; and
Domain 5	Treating and caring for people in a safe environment; and protecting them from avoidable harm.

After 1st April 2013, GP's may be able to refer an increasing number of their patients to commercial weight loss groups, or prescribe a wider range of commercial weight loss products. GP's will be encouraged to put the patients' needs first, using their extensive knowledge on what they believe is best for the patient. There could, in theory, be an increased referral rate of patients to commercial weight loss groups (e.g. Slimming World, Weight Watchers), as the GP will be able to assess their patients on what they believe will work best for them, rather than referring a patient a routine clinic (e.g. dietician led weight loss clinic).

2.10.6.4 The difference between self-help and CWLPS

For the purpose of my thesis, and using the approach described by Gould and Clum (1993), I have separated possible sources of advice and support about weight loss which the public could seek (without the help of their GP) into two categories; self-help and CWLPS. Self-help could, for example, include advice from a friend, or within a general (not specifically a dieting) magazine article. I have defined CWLPS as those which an individual would have to specifically pay for. Because CWLPS can be purchased by an individual, and prescribed by GPs, I decided that there was more value in researching CWLPS for my PhD than self-help methods. A number of CWLPS incorporate a screening criterion before a participant can proceed, particularly if the product or service is prescribed by a GP. Screening criteria may include BMI and age. Lowe et al (2001) emphasised the requirement to evaluate CWLPS, and the National Institute for Health and Clinical Excellence, 2006 noted the dearth in good quality evidence in this area.

2.10.6.5 Definition of commercial weight loss products and services (CWLPS)

For the purpose of my PhD, I have defined CWLPS as those which involve a single or continuous payment (paid by the individual, or their GP). CWLPS include; meal replacement programmes (e.g. Slim Fast, Special K), energy controlled or very low calorie diets coupled with physical activity guidance in a group or online environment (e.g. Slimming World, LighterLife, Weight

Watchers, Cambridge Diet), educational materials (e.g. DVD's/CD's/Websites) or over the pharmacological aids to reduce weight (e.g. Alli).

Participants involved in the survey and the Q-methodology studies of my PhD were clearly informed that the definition of CWLPS for the purpose of these studies involved a one-off or continuous payment.

To the layperson, this definition might appear too broad, but I was confident that to people who have used a CWLPS they would know which products and services this included. To help potential participants who may have been unclear about the definition, I provided examples within the participant information sheets:

- Weight loss programmes or clubs (e.g. Slimming World, Weight Watchers, LighterLife, Rosemary Connelly, Diet Chef, Tony Ferguson, etc.)
- Products (Alli, Slim Fast, Special K, Lipobind, Adios, etc.)
- Other (Weight loss books, DVDs, magazines, websites, CDs, etc.)

This broad context was specifically used to capture the CWLPS that have featured extensively in research to date, and CWLPS that have not had any qualitative or quantitative research conducted. The CWLPS that had not been included in database searches, though were marketed heavily were included to assess whether participants chose these CWLPS without effective research being conducted.

Within the commercial weight loss domain, companies cannot make false claims about the efficacy of their products or services, but they are often very clever in their marketing which can infer that individuals will lose significant amounts of weight if they use their products and services. For example, Adios featured a catchy strap line whereby women using their product were saying goodbye to the weight they did not want. Consumers can be drawn toward the catchy slogans and attractive packing of the products and services.

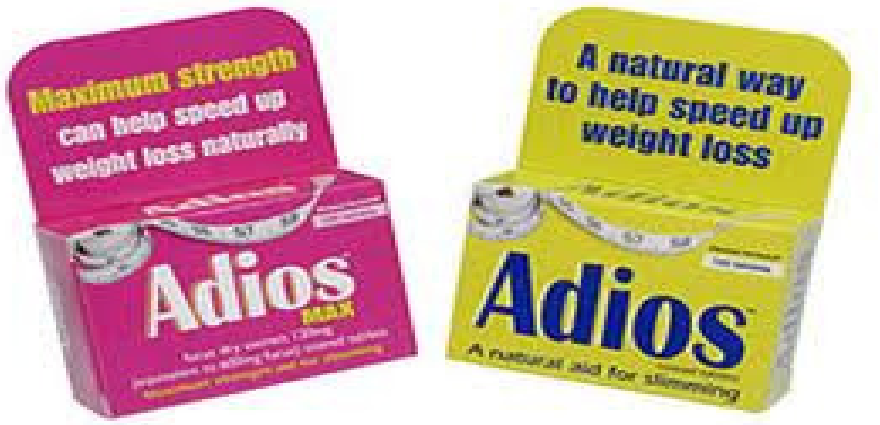


Figure 9: Adios packaging

Randomised controlled trails to assess the efficacy of some CWLPS have been conducted, and these have usually funded and conducted by the company who produces the CWLPS (e.g. Bye et al, 2005; Ditschuneit et al, 1999; Foster et al, 2003; Heshka et al, 2000; Heshka et al, 2003; Lowe et al, 2008; Pallister et al, 2009) and are systematically reviewed as part of my PhD thesis. Some independent (of the CWLPS company) evaluations of the efficacy of CWLPS have been conducted, but these are rare. Although there are benefits of funding and conducting a RCT of a CWLPS for the company who produces it, there are

also potential disadvantages. Hamilton and Greenway (2004) point out that some companies may not prioritise the funding of a trial if they believe that the results may not square with the weight loss targets of their potential clientele.

Conflicting research surrounds weight maintenance after discontinuing with CWLPS. Wadden and Foster (2000) note that programmes with a combination of dietary and lifestyle intervention modification result in weight regain after five years. However, Gosselin and Cote (2001) highlight that 38.2% of participants' maintained weight lost after 5-6 years of the commercial weight loss programme ending.

There is very little research in the existing literature on the general usage of CWLPS in the UK population, and reasons why individuals choose certain CWLPS. I have attempted to answer these questions as part of my PhD. Greater understanding of personal experiences of using commercial weight loss products and services would help to inform public health policy and practice.

When PCT's were still in existence, many offered 12-week referral schemes to commercial weight loss programmes, such as Slimming World and Weight Watchers. These companies provided feedback to the PCT primary care on the attendance and weight loss of the client. One high quality study has supported this provision compared with other forms of treatment, including dietetic-led clinics (Jolly et al, 2011).

Slimming World and Weight Watchers were selected by PCT's as organisations which they would refer patients to for weight loss because of recommendations

in the National Institute for Health and Clinical Excellence guidance (2006). The National Institute for Health and Clinical Excellence guidance stated that such programmes should be:

- Based on a balanced healthy diet
- Encourage regular physical activity
- Expect people to lose no more than 0.5–1 kg (1–2 lb.) a week.

When I was starting my PhD, I spent a considerable amount of time talking with commercial weight loss companies to determine the extent of qualitative and quantitative research produced internally and externally, and their sales to date. Although I was surprised at the time, I now realise that I was naive about the sensitivity of commercial data. The majority of CWLPS companies were not keen to share any information with me. I now understand that most of these companies have conducted extensive market research on their products and services. Marketing of CWLPS appears to me to be more of an art than a science where; packaging is appealing to the eye, testimonials from a handful of clients are featured on websites and print material; TV advertising shows the simplicity of the product and service alongside predicted weight loss.

2.10.6.6 Marketing of CWLPS

Throughout the nineteen nineties, the commercial marketplace for the treatment of overweight and obesity had been a high-profile topic among policy makers, the media, academia, the scientific community, and government regulators. The House Subcommittee on Small Business heard in 1990 that marketing of

commercial diet clinics, and very-low-calorie weight loss programs, failed in assisting consumers to lose weight and/or keep it off. The need for increased government inspection of the weight loss marketplace, to regulate misleading advertising claims, was highlighted.

Specific codes of practice have been set out by The Committees of Advertising Practice (2013) and the Broadcast Committee of Advertising Practice, which are independently administered by the Advertising Standards Authority, for the marketing communications for slimming and weight control products. The principle components are that the claims are legal, decent, honest and trustful.

Even with regulations, it is apparent that the marketing of some CWLPS includes claims of effectiveness which are not backed up by research. In 2005, the Advertising Standards Authority conducted a compliance report, whereby 50% of the slimming advertisements examined (n=48) in women's magazines and newspapers breached the code. The Advertising Standards Authority noted most breaches were for slimming pills and ingestibles, and an alarming proportion of the breaches occurred in regional press.

2.10.6.7 Online advertising of CWLPS

From my own observations, there has been a steady rise in the amount of CWLPS advertisement on the internet, and I do wonder whether the internet is now the most popular avenue for advertising CWLPS.

Reviews of new CWLPS in national newspapers can be a useful marketing strategy. However, they can also backfire, and this case study of the OMG diet

describes how marketing can go horribly wrong. The OMG diet was conceived by British sports scientist and personal trainer Paul Khanna, who goes by the pen name Venice A Fulton. The diet offers controversial tips for losing weight, such as skipping breakfast, taking cold baths, and drinking black coffee before exercising. This diet was recently tried by Independent Newspaper reporter Emily Jupp (12 June 2012) who did not approve of the diet, particularly:

- taking a cold shower
- eating less fruit
- swapping broccoli for coke
- skipping breakfast

She did not lose any weight on the diet. The unconventional theories of the diet were not approved of by a number of TV celebrity dieticians and doctors, including dietician and sports nutritionist Linia Patel, Dr Christian Jessen the presenter of the 'Embarrassing Bodies series', and the celebrity fitness trainer Jay Darrell Ingleton. However, will readers take notice of this advice from trained professionals, or will they be persuaded by the powerful marketing of the diet?. One of the key straplines in the marketing of the OMG diet was 'you can become skinnier than your friends', which I found interesting psychology. However, one should note that only a sample size of 1 was utilised for this particular piece of research, and Jupp's conclusions should not be taken seriously based upon this sample size. For this research to be acknowledged a statistician would be required to estimate the required sample size, and a comparison group (control and/or other CWLPS) would need to be utilised. It is

unknown whether readers of Jupp's findings did not chose to use this CWLPS based upon her write up of the diet (not losing any weight).

2.11 Health inequalities and behaviour change

Widely acknowledged in public health, lifestyle behaviours play in important role in a person's health. Many public health preventative strategies targeting lifestyle behaviours such as diet and physical activity are employed in the UK. Two UK publications were produced in 2004; a discussion paper published by the Cabinet Office (2004), and a White Paper "Choosing Health: Making Healthy Choices Easier" (Department of Health, 2004). On the back of these publications, the government has employed initiatives, programmes and campaigns to attempt to tackle adult and childhood obesity. Intervention strategies focus on empowering the individual to make informed choices for the long-term maintenance of desired behaviours. Two large scale UK initiatives have focused upon regional and national campaigns; Healthy Towns and Change4Life. Within all of these government strategies and interventions, the overall aim is not only to decrease the prevalence of obesity in England, but to reduce the inequalities in the prevalence in obesity between the richest and poorest in our society.

2.11.1 Change4Life

Change4Life was a multimillion pound social marketing programme designed to help us 'Eat Well, Move More, Live Longer' (Department of Health, 2009). Consumers, commercial organisations, and academic researchers provided

insights on exercise, diet, and obesity and for the scoping process. Families were recommended to include simple tips and tools into their everyday life. These toolkits were also tied into seven official sub-brands: Breakfast4Life, Swim4Life, Walk4Life, Bike4Life, Play4Life, Cook4Life and Dance4Life. Advertising of the campaign used extensive marketing. I understand that an evaluation of the Change4Life was planned, but I have not been able to find it in the peer review literature to date. Key to the programme was a focus on health inequalities, but it is hard to judge whether the programme met its objectives given that there is very little useful data available on outcomes.

2.11.2 Healthy Towns

To work in synergy with Change4Life, nine Healthy Towns were funded by the Department of Health; Tewkesbury, Halifax, Thetford, Tower Hamlets, Manchester, Middlesbrough, Dudley, Sheffield and Portsmouth. Each Healthy Town commissioned an independent local evaluation, and a marketing strategy and logos etc. National evaluation was also funded. Key to the programme was a focus on health inequalities, but it is hard to judge whether the programme met its objectives given that there is very little useful data available on outcomes in the peer review literature. However, I was lucky enough to be part of the research team who evaluated the Middlesbrough Healthy Towns project, and did get some insight into how difficult it is to engage with and change lifestyle behaviours in communities living in deprived areas.

Regardless of the lack of useful information I could find about obesity and health inequalities from the Change4Life programme and the Healthy Towns

programme, there is useful information published from other similar programmes in other countries, particularly the USA and Australia.

Many conventional health promotion interventions in the UK target poor diet and physical inactivity, and continue to be based upon traditional advice-giving approaches (i.e. provision of unsolicited advice and direct persuasion), which are appropriate for the management of many medical conditions, but can run into serious difficulties when the issue of behaviour change is raised in clinical encounters (Rollnick et al, 2008). This is demonstrated by the frustratingly small percentage of people who respond positively to advice on behaviour change, and the tendency for clinicians to label patients as 'resistant to change' with associated negative consequences for both parties (Emmons & Rollnick, 2001).

Evidence illustrates that behaviour is not merely influenced by age, sex and constitutional factors, but is deeply embedded in the cultural context, and influenced by material and social factors. Attempts to change the behaviour of individuals have been largely unsuccessful, or particularly successful, due to interventions failing to recognise the need for the importance of *"theories and principles of successful planning, delivery and evaluation"* (National Institute for Health and Clinical Excellence, page 6, 2007).

Typically, behavioural change interventions which aim to help obese people lose weight, combine treatments that aim to change dietary and physical activity habits. Behavioural change interventions benefit from a theoretical underpinning to maximise effectiveness and maintenance of weight loss after discontinuation of the intervention. In order for a person to take responsibility for the changes to

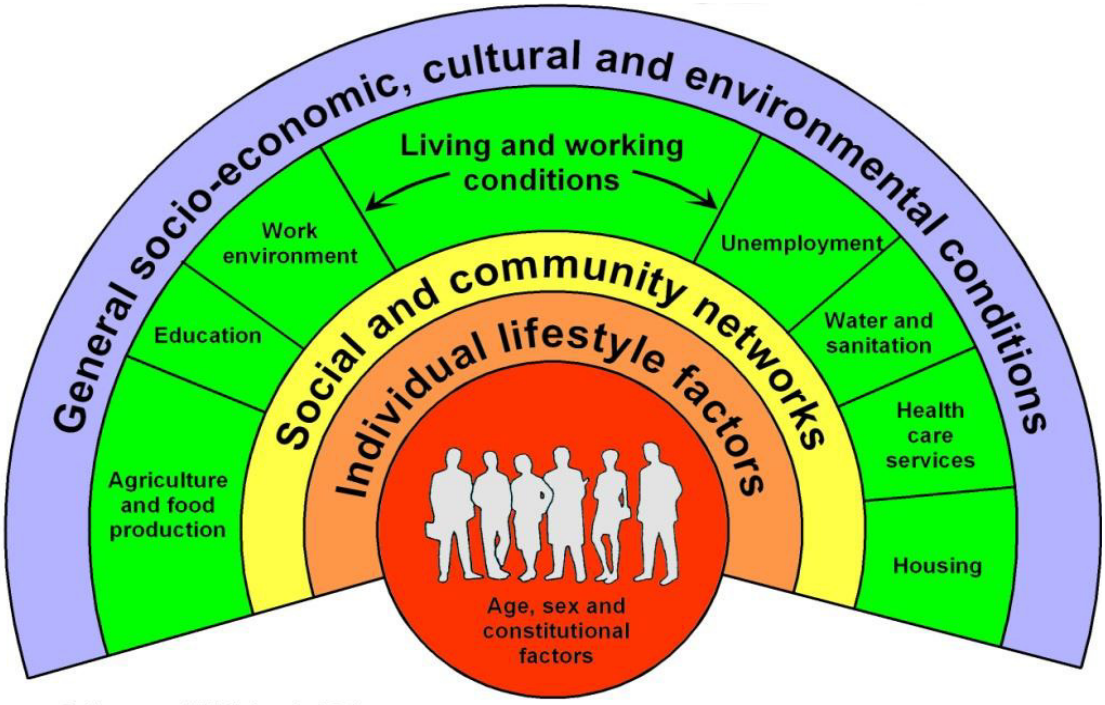
be made to their lifestyle, 'goal directed' modifications are increasing being proposed in the literature (Hillier et al, 2012), which involves participants taking responsibility for the changes in their lifestyle. Hillier et al (2012) conduct a study involved two arms; one of which was underpinned by two psychological models of health behaviour change (the Theory of Planned Behaviour (TPB) and Social Cognitive Theory (SCT), and the second arm utilised standard advice giving techniques that were not underpinned by TPB and SCT. Changes in BMI, waist circumference and weight did not show a significant difference between the control and intervention groups in this pilot study (which was not powered to assess efficacy). However, there was a definite trend that the participants in the intervention group lost more weight compared with the control groups.

Behavioural lifestyle interventions to support obese people in their attempt to lose weight which are delivered via the internet have increased in number during the last five year. This method is, in theory, low cost, for both the provider and the user. In previous years individuals might not have been able to afford computers and internet access, and thus could have increased health inequalities as these individuals would not have had access to internet based commercial weight loss interventions. In the past having access to the internet could have been a barrier, however, as internet providers are constantly competing for new customers, a variety of providers now offer deals that are reasonable for individuals of a lower SES. Therefore, the availability and access to the internet is narrowing the health inequality gap, and policy/service providers can now distribute their information cost effectively. Low SES

individuals could choose internet based CWLPS as a cheaper alternative, which could be less effective than reading a weight loss manual (Womble et al, 2004).

2.11.3 Health inequalities and obesity

The way in which society is organised creates inequalities in lifestyle behaviours and levels of obesity, and these in turn cause are major contributors to overall inequalities in health, morbidity and mortality. As demonstrated in Figure 10, unequal distributions of social, economic and environmental factors are the drivers of inequalities.



Source: Dahlgren and Whitehead, 1991

Figure 10: Health determinants model (Dahlgren &Whitehead, 1991)

These factors impact upon the risk of a person getting ill, treatment facilities, prevention of sickness, and other opportunities for better health. Certainly, the lower SES group within the English population has a reduced life expectancy

and a longer duration of poor health compared with other SES groups in the same population.

2.11.4 Key documents

The Black Report (Department of Health and Social Security, 1980) was one of the first key documents to detail the extent of the unequal distribution in death and ill health, by SES, and suggested that these inequalities had widened since the establishment of the National Health Service in 1948. Black did not suggest that the NHS was the cause of the widening in inequalities.

Freeman (2006) outlines that The Acheson Report (1998) mirrored the findings of the Black Report (1980), and highlighted the fact that the primary cause of health inequalities was poverty. Acheson reiterated that the health gap between the richest and poorest in society needed to be dramatically reduced. More recently, the World Health Organization Commissioned report on the Social Determinants of Health (2008a) further supported this view. The Marmot Review, 'Fair Society Healthy Lives' details the most effective evidence-based strategies for reducing health inequalities in England from 2010, and concludes that reducing health inequalities would require action on six policy objectives.

The National Institute for Health and Clinical Excellence guidance (2007) on behaviour change at population, community and individual levels usefully highlights the requirement to change behaviours according to specific factors, and the interactions that put those of lower SES at a disadvantage.

In order to assess how the most deprived in our society can change their lifestyle behaviours, it is vital to understand what is important to them, and what can be done to assist them. This is what I try and do in my thesis. I acknowledge that weight loss is important to people, and that there are a plethora of weight management options available to help people lose weight in the UK. However, as mentioned, health inequalities can be mapped onto seven themes, and societal influences (which are one of those themes) could be a key theme in relation to how a person wishes to lose weight. For example, the media, and peer pressure, could be key reasons for the method of choice of weight loss for some people. Because of the cost of CWLPS their use could, in theory (assuming they are effective), be widening health inequalities in the UK.

Dr George Cuthbert Mura M'Gonigle (1889-1939) also produced two key documents for the region in which this study was based.

M'Gonigle was a public health pioneer who became the medical officer for Stockton-on-Tees in 1924, remaining until his death of pneumonia in 1939. At this period in time, Stockton suffered one of the worse unemployment rates in Britain, peaking at around 50%.

Known as the Housewives Champion, M'Gonigle's first Stockton study examined the impact of housing and health. Mortality rates increased when an unhealthy area in Stockton was divided in two. The housewife lane area was demolished, and people were re-housed in a self-contained housing estate (Mount Pleasant Estate), the other half (Riverside Area) was kept and remained as a comparison group. Average death rates in the new estate (Mount Pleasant) were higher than those who remained at Riverside, though rent was

double and families could not afford as much food (especially protein rich food), families suffered long term or sub-malnutrition. The findings of this study were documented in Poverty, Nutrition and the Public Health (Proceedings of the Royal Society of Medicine, 1933), demonstrating the strong correlation between death rates and income.

His book with John Kirby also demonstrated the wider application of the Stockton studies in a broader context, whereby social reformers and politicians took notice of their work. Kirby and M'Gonigle used publicly available data together with empirical studies to demonstrate *"poverty, not ignorance, was the cause of morbidity and mortality amongst the poor and this poverty was not the fault of the individual families but of a society that provided inadequate wages and welfare benefits" (Bambara, 2011).*

In the contest of this thesis, unemployment, specifically in relation to health inequalities is still in existence. The region in which this study is based has the highest rate of unemployment in the UK, at 10.2% (Parliament UK, 2013) compared to the UK average of 7.6%. In my personal opinion the North East could see obesity prevalence increasing in the future in parallel with unemployment rates. Similar to M'Gonigle's Stockton study, families might not be able to afford to buy as much food, and could potentially suffer from malnutrition if cheaper unhealthy foods with little nutritional value are bought.

Also with the restructuring of benefits (universal credit), there could be negative consequences. The new system of benefits is given as one lump sum to the individual, instead of organisations paying on their behalf people. Individuals

could sacrifice food as they have spent all of their money on unnecessary items (TV, IPad etc). However, there is no evidence at present to support this.

Chapter Three

Methodology

3.1 Introduction

Mixed method research was employed for my research. This chapter will detail the philosophical paradigms involved in research studies, specifically positivism, interpretivism, and pragmatism. Strengths and weaknesses, debate, and progression of mixed method research are presented herein. Justifications for this approach, in relation to the aims of my study are discussed in the latter part of this chapter.

3.2 Methodology

Sandelowski and Barroso (2003, p305), refers to methodology as *'an overall approach to inquiry regularly linked to particular theoretical frameworks'* and the research method as a *'synonym for the techniques for sampling, data collection, and data analysis with which the methodologies are implemented'*. Therefore, methodology refers to the theoretical frameworks under investigation, using methods to investigate these said frameworks. Philosophical paradigms are one of two constructs that scaffold a research study, the second underpinned by theoretical investigation.

3.3 Research paradigms

Paradigms are identified as a cluster of beliefs, and dictates which, for scientists in a particular discipline, influence that should be studied, how the research should be carried out, and how the results should be interpreted (Bryman, 2001). Paradigms are polarised worldviews or belief systems that are a reflection of and guide the decisions that researchers make (Tashakkori & Teddlie, 1998). These paradigms in the social and behavioural sciences have traditionally fallen into two schools of thought, with writers proposing various terminologies to distinguish these stances. Tashakkori and Teddlie (1998) use the terms “positivist” and “constructivist”, whereas Guba and Lincoln (1988) use different terminology for these paradigms; “scientific” and “naturalistic”. Since the conception of research, fierce rivalry has occurred between the two types of research inquiry: quantitative and qualitative. These two paradigms differ in their methodological assumptions, and effect on the research process. Ontology, a branch of metaphysics concerned with the nature and relations of being, Epistemology, the study or a theory of the nature and grounds of knowledge especially with reference to its limits and validity, and Axiology, the study of the nature, types, and criteria of values and of value judgments.

3.4 Positivism in quantitative research

Auguste Comte developed positivism at the start of the 19th Century, noting key components of this type of research; deductive logic or reasoning, researcher independence, and that reality is stable and can be observed and described from an objective viewpoint (Johnson & Onwuegbuzie, 2004).

Positivists collect data systematically, and present the findings in numerical form to discover trends and relationships between specific variables. Methods of data collection using quantitative research involve large amounts of data being collected through surveys, questionnaires, randomised controlled trials, and laboratory experiments.

Soon after the Second World War, this unchallenged approach was met with fierce criticism over the investigation of inquiry. Human science examination required a separate approach to understand social phenomena; Interpretivism.

3.4.1 Postpositivism

Personally, as a researcher I am a postpositivist. Unlike positivists, I do not believe that the world should merely be observed, measured, and that we should only describe what is seen. All measurement is fallible, as different types of measures can have errors no matter how conscious of intra-rater reliability the researcher is. For example a researcher could take multiple weight measurements in a variety of settings, and measurement error could creep in due to one surface being on a slight angle, or unconsciously a researcher could be testing an intervention vs. a control group whereby waist circumference is the primary measure, the researcher could pull the tape measure tighter in the intervention group without knowing. Therefore, I firmly believe in using multiple measures and observations to get a clear idea on the ‘bigger picture’, and would class myself as a postpositivist. Different observations and measurement techniques might have different types of error, and the use of triangulation helps to understand what is really going on in reality. Post-positivists commonly adopt

a philosophy called critical realism. Post-positivist critical realist's recognise that a variety of methodological tools should be utilised that fit and answer the research question (Angus, 2011); and lends its hand to the use of mixed method data collection. I firmly believe that the use of a survey, Cochrane based systematic review and Q-methodology study will be the most beneficial methodologies to answer my objectives, and to reveal the complex nature of CWLPS.

3.5 Interpretivism in qualitative research

Interprevitists argue the opposite of positivists. They believe that as humans think and reflect, scientific methods of data collection are inappropriate for the study of the natural world. To understand social action, it is imperative to study the reasons and meanings, which that action has for people. Interpretivism and its philosophical underpinnings form the theoretical basis for qualitative research. To understand peoples' actions it is essential to understand them in the way that the participants do, through flexible approaches of data collection, ethnography, phenomenology, and case studies. Interprevitists acknowledge that the social world consists of and is constructed through meanings; society is experienced subjectively as each person interprets the world differently in the way we behave. Unlike quantitative research, qualitative researchers (Interprevitists) use small sample sizes to generate data, abundant in subjectivity for the generation of understanding. Theory is built from observations, using an inductive approach (Thomas, 2006).

Researchers from these different paradigms have been at odds with one another since the conception of these different approaches. Positivists and Interprevitists agreed that it was more favourable to decide upon which paradigm successfully addressed the research question, rather than bickering over the strengths and weaknesses of the two approaches.

Since the 20th century, researchers have accepted the qualities of both qualitative and quantitative techniques, combining the strengths to form another approach, mixed method.

Mixed method has been underpinned by the philosophical paradigm, pragmatism. Feilzer (2010) argued that it was more important to ascertain which paradigm was most helpful in answering the research question, rather than be stuck in pedantic debates on the superiority of any one philosophical orientation over another. Realists acknowledge that both methods are not failsafe, arguing that sociologists can be pragmatic and use whatever methods are appropriate for particular circumstances, drawing on one or a mixture of both positivist and interpretivist methods.

3.6 Pragmatism in mixed method research

The “Paradigm Wars” commenced during the 1960s, challenging singular methods, which resulted in the emergence of mixed methods, and acknowledged the mixed model in the 1990’s as a valuable research technique (Tashakkori & Teddlie, 1998). During this debate methodology and paradigm relationships were questioned, particularly by the “incompatibility theorists”, and the “the compatibility theorists” (Cherryholmes, 1992). The debate of mixed

model, and mixed methods, led to the emergence of a third set of constructs, the pragmatic paradigm. Research using mixed methods has been firmly embedded in many disciplines; various reviews and studies have acknowledged the importance of the pragmatic paradigm (Morse, 1991). However, it is apparent that the terminology is not consistent amongst the various disciplines. Blended research, integrative research, multi-method research, multiple methods research, triangulated research, and mixed research, are all mixed method research terminologies.

The current dialogue about how mixed methods research is defined and perceived by researchers will change as this methodology evolves and becomes a wider used instrument for data collection. The present definition has been identified by Johnson et al (2007)

'Mixed methods research is the type of research in which a researcher or team of researchers combine(s) elements of qualitative and quantitative research approaches (e.g. use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration'.

3.7 Research implementation of mixed methods

It is widely acknowledged that there are three specific areas where a mixed methods approach is far superior to a single method (qualitative or quantitative). Primarily, mixed methods enable the researcher to answer several research

questions congruently, through the mixing of data collection. Secondly, this method is able to provide a rich and deep understanding of the data being collected to answer the social phenomena under investigation. Lastly, the researcher is able to interpret the data in the most appropriate way they believe expresses their findings.

In mixed methods research the collection and analysis of qualitative and quantitative data occur in parallel; qualitative and quantitative or quantitative and qualitative, or sequentially; qualitative/ quantitative or quantitative/ qualitative. Unlike singular forms of data collection (qualitative or quantitative), mixed methods studies may mix the data throughout or at certain time points (Tashakkori & Teddlie, 1998). Mixed methods research is an evolving methodology that has few weaknesses (Table 6).

Table 6: Strengths and weaknesses of mixed method research (adapted from Johnson et al, 2007)

Strengths	Weaknesses
Can be used to increase the generalizability of the results.	It is more expensive.
Qualitative and quantitative research used together produces more complete knowledge, informing theory and practice.	It is more time consuming.
Can answer a broader and more complete range of research questions.	It can be difficult for a single researcher to carry out both qualitative and quantitative research, especially if two or more approaches are expected to be done concurrently
A researcher can use the strengths of an additional method to overcome the weaknesses in another method by using both in a research study	The researcher has to learn about multiple methods and approaches and understand how to appropriately mix them.
Can provide stronger evidence for a conclusion through convergence and corroboration of findings	Methodological purists contend that one should always work within either a qualitative or a quantitative paradigm.
Words, pictures, and narrative can be used to add meaning to numbers.	Some of the details of mixed research remain to be fully worked out by research methodologists.
Numbers can be used to add precision to words, pictures, and narrative.	

To guide the research, it is essential to understand the type of research design that would be most appropriate for the study; implementation of data collection, priority given to quantitative or qualitative research, the stage in the research process at which integration of quantitative and qualitative research occurs, and theoretical perspectives. For my PhD study, the research design used was the sequential explanatory study design (Table 7). For my PhD study, I chose to use a mixed method methodology to enable me to provide a rich and deep understanding of the data being collected to answer the first of my two research questions 'What is the uptake and reasons for choice of CWLPS by adults in the UK'. I chose to use a sequential explanatory study design (Table 7).

First, a survey was used to collect quantitative data from a relatively large number of participants to assess the range and popularity CWLPS used by the general public. I also felt that a survey would provide data that would suit my first objective (see 1.4).

Second, Q-methodology was used to collect qualitative data from a number of participants in the survey who provided different choices, and different reasons for their choices, of CWLPS. This methodology, was conducted in several stages, and allowed me to better understand quantitative data through in-depth quantitative exploration. I used Q-methodology study as this methodology allowed participants own beliefs to emerge, rather than imposing my beliefs on the participants. This method was employed to limit the probability of researcher bias of qualitative interpretation of subjective opinion and feelings, and to limit obsequiousness bias. The utilisation of a Likert scale would increase researcher bias; the questions would be imposed by the researcher, purely agreeing or

disagreeing. As a researcher studying a rather complex subject, I did not want to provide data on my personal opinions as to why individuals choose CWLPS. Using Q-methodology allows participants to subjectively rank order why they chose their favoured CWLPS, providing rich data that could inform NHS policy and practice (see 4.5.3), and develop interventions that relate to the complex relationships between behaviour (choice of CWLPS) and beliefs, which may in the future inform the further development of weight loss interventions. This methodology also suited by second objective (see 1.4).

I chose to use a single method methodology, i.e. a systematic review of controlled trials, to enable me to provide a least biased estimate of the effectiveness of CWLPS to answer the second of my two research questions 'What is the effectiveness of CWLPS'. The review using Cochrane formatting was completed throughout the thesis, gathering quantitative data of a variety of different study designs. This method was used to answer my third objective (see 1.4). The review in a Cochrane format provided a great depth of understanding in relation to the effectiveness of CWLPS, and whether there were CWLPS that were effective (and cost effective) that were not provided by the NHS on a referral scheme. All three methods were given an equal amount of priority.

Table 7: Mixed methods designs by four criteria (Adapted from Tashakkori & Teddlie, 1998)

No.	Design type	Implementation	Priority	Stage of integration	Theoretical perspective
1	Sequential explanatory	Quantitative followed by qualitative	Usually quantitative; can be qualitative or equal	Interpretation phase	May be present
2	Sequential exploratory	Qualitative followed by quantitative	Usually qualitative; can be quantitative or equal	Interpretation phase	May be present
3	Sequential transformative	Either quantitative followed by qualitative or qualitative followed by quantitative	Quantitative, qualitative or equal	Interpretation phase	Definitely present (conceptual framework, advocacy, empowerment)
4	Concurrent triangulation	Concurrent collection of quantitative and qualitative data	Preferably equal; can be quantitative or qualitative	Interpretation phase or analysis phase	May be present
5	Concurrent nested	Concurrent collection of quantitative and qualitative data	Quantitative or qualitative	Analysis phase	May be present
6	Concurrent transformative	Concurrent collection of quantitative and qualitative data	Quantitative, qualitative, or equal	Usually analysis phase; can be during interpretation phase	Definitely present (conceptual framework, advocacy, empowerment)

3.8 Qualitative research designs

Phenomenology and ethnography are two qualitative methodologies (Cresswell et al, 2007) that could have been used instead of Q-methodology, to form the qualitative component of my mixed methods research.

3.8.1 Phenomenology

A phenomenological research study could have been employed to answer the question *'What is it like to experience CWLPS?'* by collecting rich data from the experiences of participants. However, this method of enquiry would have led to any bias which I have about CWLPS being introduced into the research. I did not wish to impose my personal opinions on the reasons why participants in my study chose CWLPS, especially when a study exploring the reasons why participants chose CWLPS had not been conducted at the time. Presenting, establishing reliability and validity, and interpreting the data can also be difficult. Participants who have experienced negative consequences as a result of using CWLPS might not wish to express these opinions in a face to face interview, in fear of judgement or embarrassment.

Because of the issues mentioned above, I did not choose this method of research enquiry for my PhD study.

3.8.2 Ethnography

To successfully adopt an ethnographic approach it is essential to study participants over a prolonged period of time in their natural setting. With

reference to my PhD study, this could have only been achieved by observing participants whilst they were using CWLPS. Also, it would have been essential to cluster those using the same CWLPS, and conduct separate ethnographic studies in each cluster, in relation to the type of CWLPS. This approach could have only been utilised if I was investigating one method of CWLPS (at least at a time).

Due to the fact that my research question was, in part, exploring comparisons between individuals using different CWLPS, I chose not to use this method.

3.9 Summary

After understanding the paradigms and designs in research, I concluded that a mixed method (pragmatism) using a sequential explanatory study design offered the best method to allow me to answer my research questions. A survey and a Cochrane systematic review were included in my research to address the quantitative elements of my research (usage and efficacy), and a Q-methodology study was included to address the qualitative elements (preferences etc) of my research.

In the next chapter (Chapter 4) I have described in detail the tools and techniques used for my PhD study.

Chapter Four

Methods

4.1 Introduction

This chapter will describe the overall design and methods of my PhD study, which has three distinct components. Two of these components are qualitative (a survey and a Cochrane systematic review), and one component is quantitative (a Q-method study), and these are described in detail in this chapter. The results of the survey informed the Q-method study.

4.2 Study design

My study employed a mixed-methods (pragmatic) sequential explanatory design, incorporating both qualitative and quantitative methods (Figure 11), and involving three components. The first component included a regional survey and a series of focus groups and interviews, and the results of this component informed the design of second component which was a Q-method study which included interviews. The third component of my PhD study was a systematic review using Cochrane methods which was completed in parallel with the survey and Q-method study. Findings about the efficacy of CWLPS that were collected from the systematic review (quantitative) and the Q-method study (qualitative) were considered together, and are described in the discussion (Chapter 6).

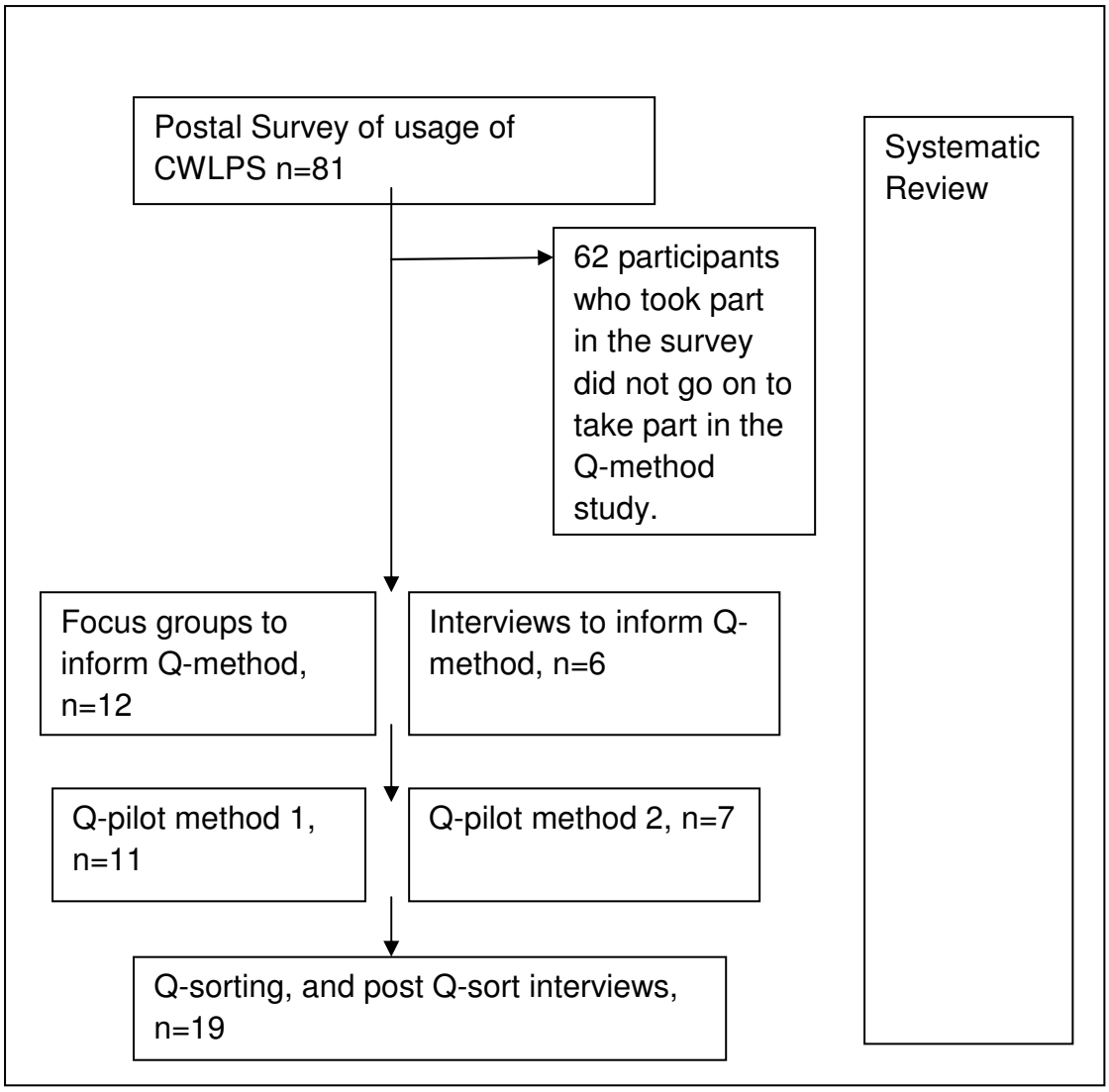


Figure 11: Research design flowchart

Figure 12: Study location in the North East

Given that I was particularly interested in assessing usage and views of CWLPS in individuals from various, and particularly low, socioeconomic backgrounds, the North East of England (Figure 12) was an ideal choice of location for the survey and Q-method study. The North East has some of the most deprived communities in the United Kingdom; around 10% of the most deprived Super Output Areas (SOA's) on the index of multiple deprivation (Noble et al, 2006) are located in the North East. When assessing deprivation the rank and/or score of an area should be considered. In general the higher the score within a domain the more deprived the SOA. The North East also has relatively high levels of obesity. The 12 areas of the North East, apart from Newcastle (Gateshead, Darlington, Sunderland, Redcar and Cleveland, South Tyneside, Northumbria, North Tyneside, Newcastle, Middlesbrough, Hartlepool, and County Durham) observe higher obesity statistics than the current UK average; 24.2% (Public Health England, 2013). There is a strong positive correlation

between the level of deprivation and the prevalence of obesity within geographical areas of the UK (House of Commons; Health Committee, 2004).

Table 8: Health indicator profiles in the North East compared with England (Adapted from APHO and Department of Health, 2010)

Indicator	England	North East
Adults who smoke (%)	22.2	27.9
Adults who binge drink (%)	20.1	30.1
Adults who have a healthy diet (%)	28.7	21.5
Adults who are physically active (%)	11.2	11.3
Prevalence of obesity in adults (%)	24.2	27.8
Early deaths: heart disease & stroke (%)	74.8	87.2
People diagnosed with diabetes (%)	4.30	4.35

Poor lifestyle behaviours tend to cluster, and the data in Table 8 shows that the adult population living in the North East tend to have a higher prevalence of obesity, smoking, and binge drinking, and fewer of them have a healthy diet. This is played out in the increased incidence of early deaths from heart disease and stroke in the North East.

In relation to my study design and health inequalities, I was particularly interested in collecting data from individuals that were deprived, though I was aware that I also needed to collect data from other populations as well (less deprived). As a junior researcher involved in a previous community and population health initiative I was aware that there could be recruitment issues, and I would therefore need a study design that enabled me to collect sufficient data. Recent research conducted by Demarest and colleagues (2013) demonstrates that survey participation was low in lower SES individuals, and that socio-economic inequalities can produce a bias in survey findings. Therefore, my study design needed to capture individuals of high and low SES. Previous knowledge had led me to believe that I would be able to recruit my required sample size from the Evening Gazette, that has a readership of approximately 125,000, and covers postcodes in the Tees Valley locality that vary in deprivation. As I was conscious of low SES not being able to afford to buy the Evening Gazette, or might have poor access to a Newsagent, all articles were also published online too. As described in 4.4.9 and Figure 13, initial recruitment was disappointing and led to additional methods of recruitment and the widening of postcodes from TS1 to TS18 to include all TS postcodes. Additionally, County Durham, Northumberland, and Tyne and Wear

postcodes were included. Within the new localities, I specifically used methods whereby I believed high and low SES would view posters/leaflets, and would register their interest in my survey. All venues to display posters and leaflets were carefully targeted. The IMD score for each venue was found, and I was satisfied that a low, medium and highly deprived individuals would be able to see the advertising for my survey. I was also confident that the re-launch of the survey in the New Year of 2010 would recruit a significant of individuals who had embarked on a CWLPS, through the additional Newspapers that advertised my study online and in print (Northern Echo, Stockton and Darlington times and Evening Gazette). After being on BBC Newcastle during a peak time (8am) when individuals would be listening to the radio whilst exercising, driving to work, listening to the radio whilst preparing breakfast, I was positive that I would be able to recruit a variety of low and high SES individuals for my survey. With the additional recruitment strategies (email recruitment and a commercial weight loss company), I felt that I had encompassed a variety of methods that would enable me to recruit high and low SES individuals.

4.2.1 Commercial weight loss companies

Prior to conducting my survey, and when I was originally planning the design of my PhD research, I contacted two of the largest commercial weight loss companies (Slimming World and Weight Watchers). I sought to obtain their data to assess what the average cost of a person using their service for a year would be, and whether they had data on demographics (SES, age, gender, and ethnicity). Weight Watchers did not wish to share any information with me.

Slimming World did not wish to share any information with me either, but did appear interested and supportive of my research. I was perhaps naive in thinking that they might have wanted to share their data with me, and now that I am at the end of my PhD studies I understand a little more about the politics and sensitivities regarding data held by commercial companies.

4.2.2 Study site and sampling

Originally, the study location was restricted to certain postcodes within the Tees Valley region (TS1 to TS18), which is covered by a local newspaper called the Evening Gazette. This range of postcodes includes the full range of socio-economic spectrum. To address my research question as to how the uptake and reasons for choice of CWLPS vary by SES, it was essential to plan the sampling of participants to include the full socio-economic spectrum. Only by analysing data, which includes the full spectrum from all socio-economic spectrum backgrounds, one can understand, differentiate, and better understand the relationship between health inequalities and obesity. From previous knowledge I was aware that the Evening Gazette covered a range of postcodes that would cover the full socio-economic spectrum, and not just that of low SES individuals. After speaking with the Evening Gazette, they were also confident that I would be able to recruit individuals from the full socio-economic spectrum.

I had initially hoped that I could recruit enough participants for my survey from this region by advertising in the local gazette. However, to my surprise, the response to the newspaper adverts disappointing, and I then extended the area

of recruitment to County Durham, Northumberland, and Tyne and Wear. I placed adverts in the relevant local papers, and even went on the radio (Radio Tees) at one point to try and boost recruitment.

When I started my PhD, I honestly did not appreciate how difficult it would be to recruit participants to this study. In a previous research job, we had similar problems with recruitment to the CCP study. I have learnt a lot about recruitment during the course of my PhD, and understand that it is a common problem across many public health studies.

4.2.3 Study population

The inclusion criterion for the survey was (i) all persons who had used a CWLPS in the last twelve months, (ii) live in the study area, and (iii) were over 16 years of age. It is well understood, and known, that by definition a person is classed as an adult at 18 years of age. However, for the purposes of this study 16 years and over was specifically chosen as the cut off because commercial weight loss programmes are offered to people in the UK from the age of 16.

4.3 Definition of CWLPS

Within the survey information sheets CWLPS were defined as:

'Commercial weight loss products and/or services which involve a one-off or continuous payment/subscription to lose weight'.

At the time of submission of my survey to the ethics committee, I extensively investigated commercial weight loss options that were featured in print, online

and advertised on the television, to define CWLPS for this study. The issue and problems in defining CWLPS was mirrored within the Cochrane systematic review process, due to the complex nature and perception of CWLPS.

From April to May 2010, I observed that there was an increase in the level of advertising of CWLPS on the TV and in magazines. I assumed that this increase was primarily due to the summer approaching, and the population wishing to 'slim down' for a holiday. Television advertising specifically featured meal replacements, group weight loss programmes, and anti-obesity medication. Online regional and national newspapers primarily featured anti-obesity medication, and group weight loss programmes. In print format, group weight loss programmes featured heavily in newspapers, which at that time were advertising reduced joining fees.

4.3.1 Final selection of CWLPS

The final selection of CWLPS to be included in the survey were; Slimming World, Weight Watchers, LighterLife, Rosemary Connelly, Diet Chef, Tony Ferguson, Alli, Slim Fast, Special K, Lipobind, Adios, Weight Loss book(s), DVD(s), Magazine(s), Website(s), and CD(s). The reason for choosing these specific products and services was based upon observation, personal experience, and products and services that had been evaluated in the academic literature. Within the survey, participants also had the option to list other CWLPS that they had used in the last twelve months (examples which were reported by the study participants included the use of exercise vibration plates, that were used as a one off or continuous payment, not via a gym, and appetite

suppressants that an individual had paid for privately). I chose to include participants who had used CWLPS within the last 12 months, and not further back in history, because I felt that participant recall would poor after this length of time.

The survey sought to assess the duration, and the cost, of the CWLPS used by the participants, and whether any products or services which they had used had been provided via their GP. Duration data was collected to assess whether participants adhered to specific products or services more than other CWLPS. This data was used to compare with the attrition rates of CWLPS reported in the systematic review, later. Cost effectiveness is of primary concern to all commissioners of services. In addition, this data is of importance in assessing whether individuals of low SES opt to pay for a CWLPS, and if they do then does the price influence their decision on which one they purchase. Or do they instead of seek advice from their GP.

4.3.1.2 Exclusion criteria

People were excluded from taking part in the study if they had provided no information about using a CWLPS as defined above.

I did receive interest from a number of people who wanted to take part in the study that had used cosmetic surgery (liposuction) or had been prescribed pharmacotherapy from their GPs.

4.4 The survey study

4.4.1 Aims and objectives

The aim of the survey was to assess the use and reasons for choice of CWLPS in the NE, and explore where usage is associated with socioeconomic status. The main objectives of the survey were to:

- Describe the characteristics of participants who choose to use CWLPS
- Describe the types, number, combinations, and cost of CWLPS used by participants
- Examine the relationship between socio-economic status, and other determinants, and choice of CWLPS.

4.4.2 Survey justification

A survey of this type has not been conducted previously, to my knowledge. Knowing whether people who wish to lose weight chose to pay for CWLPS, instead of consulting their GP, and whether this decision is based on the SES of the individual, is useful information for those who commission weight loss services and are responsible for public health..

4.4.3 Study variables

The survey involved the collection of discrete and continuous data. The variables included age, postcode, highest level of educational achievement, ethnicity, marital status, religion, average weekly household net income (after

housing costs), gender, occupation, where a participant buys their bulk food shopping, IMD status, duration of time they used the CWLPS, and the cost of each CWLPS.

4.4.4 Super output area

In terms of deprivation, postcodes were utilised to collect Index of Multiple Deprivation (IMD) data, at Super Output Area (SOA). A SOA is a specific and small geographical area on which to various statistics (e.g. health data) are collected and published. Data at a SOA level allows you to be reasonably confident that everybody in that area is comparable. Two layers account for the different levels of data provided; Middle Layer Super Output Area (MSOA) and Lower Layer Super Output Area (LSOA). To collate IMD data, Lower Layer Super Output Areas (LSOA's) were utilised. LSOA's are intended to be as consistent with the population size as possible. Minimum and mean population data is 1000 and 1500; respectively. Therefore, this dataset was utilised to report lower level statistics; scatter plots were performed in SPSS version 19.0 to demonstrate the relationship between the amount an individual spent on CWLPS and their level of deprivation.

Upon liaising with Dr Adeteyo Kasim (Research Statistician, Wolfson Research Institute for Health and Well-Being at Durham University), it was apparent that the IMD data which I was using do not show a relationship between level of deprivation and the amount an individual spent on CWLPS. Dr Kasim advised me to collate like-for-like data, specifically household income.

In conjunction with the LSOA Indices of Deprivation 2010 dataset (for IMD deprivation score) I also collated the required household income data from the MSOA April 2007-March 2008 dataset (Income: Model-Based Estimates). In discussion with Dr Kasim, it was decided that the MSOA using participant's postcodes, was the best indicator of deprivation to use in my analysis.

4.4.5 Ethical approval

On the 23rd of September 2010, permission to undertake this research was granted by the School of Medicine and Health's ethics committee at Durham University (Appendix 1). All participants were required to provide written consent (Appendix 2) before they could take part in the survey, and before they could take part in subsequent stages of the Q-methodology study. Within the information sheets, it was stressed that each participant would be given a specific ID number, so that data could remain anonymous. The information sheets stated that data collected would be stored in accordance with the Data Protection Act (Information Commissioners Office, 1998), and only the researcher (me) and named PhD supervisors would be able to access this information.

4.4.6 Data management

All information provided was kept strictly confidential, and was kept in locked filing cabinets and password-protected files on computers at Durham University in accordance with the Data Protection Act (Information Commissioners Office,

1998). Information was not shared or viewed by anyone who was not part of the research team.

4.4.7 Pilot survey

As will all research studies, it was important to pilot the survey (n=5) to assess its acceptability and appropriateness in terms of both process and questions. Piloting a survey is an essential part of a good study design. The pilot survey was not a small-scale version of the larger study, which in an ideal world it should have been. Instead, participants were made up of staff members (administrative staff) from Durham University, in response to an email request to all admin staff at Queen's campus.

A key reason for conducting a pilot survey is to alert the researcher about where the weaknesses of the survey design, and particularly whether the design was too complicated and a burden for participants, and potential practical problems. In the words of De Vaus (1993, 54) *"Do not take the risk. Pilot test first"*. However, pilot studies have limitations too, due to the small numbers involved, and of other issues might arise when the full survey/project is conducted. The pilot survey participant resources were assessed for low reading ability, using the readability statistics (Flesch-Kincaid) in Word 2007. The survey documents (participant information sheet, survey, additional information, useful contact details, letter, and registration of interest slip) were pitched at the reading age of an average 15 to 16 year old.

A convenience sample of five participants was chosen, as sample size calculations are usually not required for pilot studies. I felt that the five

participants would be enough for me to be able to assess acceptability. I was confident that five participants would provide useful information about the aspects that were being assessed for feasibility. Potential participants were asked to contact me via post, telephone/voicemail, or email.

Following analysis of pilot study findings, minor changes were made to the design of the survey, including the additional requirement for the participant to state the approximate cost of the CWLPS chosen. After minor adjustments were made to the survey, and after I had informed the ethics committee of these minor changes, I was ready to start the survey.

4.4.8 Survey methods

4.4.8.1 Survey design

The survey was cross sectional in design, and collected historical data. The validity of the data reported by the participants was potentially prone to recall bias (i.e. the participants might have forgot certain things). The subsequent Q-methodology study was conducted to collect data on why the (sub group of) participants chose to use certain CWLPS over others.

The survey utilised closed tick box binary questions, inviting yes/no answers to state the amount of time a participant had used the CWLPS, and how much it cost them. Participants were invited to list any other CWLPS that they had used in the previous 12 months that met the definition of CWLPS (Appendix 6), because I was aware that the survey list was not exhaustive. I used the survey

design in this way, as I wanted it to be as user friendly as possible, and to ensure that participants completed the survey without feeling that a researcher was judging them. From my experiences, I believe that some people do not wish to take part in obesity research studies because they think that what they say or do will be frowned upon by the researcher. In addition, the survey was designed in this way to aid the analysis of data collected.

4.4.8.2 Determinants of sample size

I met with one of the medical statisticians based in the School of Medicine and Health at Durham University (Dr Douglas Wilson), and took advice from him regarding the sample size for the survey. I explained that aim of the survey, the statistician advised that cluster analysis would be the statistical method of choice, using SPSS version 19. Dr Wilson estimated that 1250 would be the estimated number of participants required.

There was no exact hypothesis behind the choice of sample size. There was an attempt, however, to rationally find a ballpark figure. Any statistical analysis of proportions would involve at a minimum of testing two binomials, e.g. a deprivation difference of 40%, from 0.20 to 0.28 in two groups, at alpha=5%, 2-tailed, and power of 90% would require a sample size of 495 samples per arm, calculated using StatXact software, which is c1000 in total. Assuming there may be 20% non-responders that would approximate to 1250 which, given information from a previous study appeared achievable. Of course, there are many proportions that could be used but for pragmatic and some statistical conjecture, 1250 samples were chosen. Also from my involved with a previous

study which recruited 1073 participants via the Evening Gazette, I was confident that I would be able to recruit a similar number of participants for my research.

The recruitment method for the survey was adverts in The Evening Gazette, the local newspaper covering TS1-TS18 postcodes. Based upon the average readership of the Evening Gazette (n=125,000/week), 10% of the readership would be required to take part in the survey to reach the sample size required. This was, in theory, possible since we know that more than 10% of the population uses some form of CWLPS at any one time (and about 50% are trying to lose weight at any one time).

4.4.8.3 Survey recruitment

A dedicated project contact name and address, email, and phone line was set up for the purpose of this survey, and this information was detailed in the advert (Appendix 3). A variety of methods of communication were utilised in order to encourage participation from a broad range of participants to meet the overall aims of the study. The literature suggests that different populations prefer a variety of study advertising and contact methods. It was hypothesised that individuals, who viewed the newspaper article online, would have access to a computer, and would contact me via email, while others may prefer postal or telephone communication. It was important to include participants with poor literacy; Weiss et al (1992) highlight the association between low socioeconomic status and poor literacy skills. Thus, attention was given to voicemail and postal contact and, as noted above, the survey was designed to be accessible to participants with low literacy levels.

Participants who were interested in taking part in the survey were able to ask for further details about the project in a number of ways, through postal, email or telephone communication. However, regardless of their chosen method of communication with me they were only required to supply their name and address, because further information was only sent to them by post. Documents were posted to those who stated that they were interested in taking part in the survey; a consent form (Appendix 2), useful contact details (Appendix 4), demographic information (Appendix 5), survey (Appendix 6), and information sheet (Appendix 7), including a return pre-paid envelope. All those who received information in the post were allocated a unique study ID.

4.4.8.4 Contact methods

4.4.8.4.1 Postal

In the original ethics application I had intended to have a 'cut-out' registration of interest slip within the Evening Gazette, where those interested in taking part in the survey could write their name, address, contact telephone number, and postcode, and post it to the dedicated survey postal address.

However, the Evening Gazette decided (after our initial discussions with them about the 'cut-out' form) that they would prefer to publish a full article about the survey and project, which was featured in their online and print formats (Appendix 3). This article detailed my involvement in a previous study in partnership with the Evening Gazette; the Get a Better Life Campaign, and it

described why I was undertaking the new research project, and how to contact me if readers were interested in participating in the survey.

At this stage, participants were given the opportunity to participate in the survey and subsequent Q-method study (described later in this Chapter), or to only participate in the survey. Readers who were interested in participating in the survey (and for some of them the Q-method study too) could register their interest in a number of ways.

First, readers could register their interest by sending a note in the post, containing their name, address and contact telephone number. A survey ID number was written on the paper/slip from a master list of numbers, at which point I deleted this number from the master list. The ID number was written on the documents to be sent to the potential participant; the survey, useful contact details, consent form, participant information sheet, additional contact details, and associated covering letter. These documents were sent to the potential participant with a pre-paid envelope. The participants who wanted to take part in the survey completed and returned the documents in the pre-paid envelope to the dedicated project address. All data was entered into a spreadsheet for analysis. In the survey, there was a question that asked whether they would be willing to be contacted at later stage to take part in another, related, study (Q-methodology).

4.4.8.4.2 Internet

Participants who wanted to register their interest in taking part in the survey via email were able to do so by emailing the dedicated survey email address;

cwl.orbresearchgroup@durham.ac.uk. They were required to email their name, address and postcode.

Once the email had been received, I printed it off, deleted it, and then deleted the deleted folder to maximise participant confidentiality. At this point, a unique ID number was hand written on the printed email from the master list of ID numbers available. As with the postal contacts, I deleted the ID number from the master list, and wrote this ID number on all documents (covering letter etc.).

4.4.8.4.3 Telephone

Participants who wanted to register their interest in taking part in the survey were able to call the dedicated project phone number where I would answer any questions and ask potential participants for their name, address and postcode. If I was not able to answer the phone, the answerphone message asked for their name, address and postcode.

I kept a pile of blank registration interest slips by the dedicated phone line to transcribe the required information. I reviewed all answerphone messages within 24 hours. After answerphone messages had been listened to, and all the required details written down, the message was deleted from the answer phone. Data were handled as described above for email requests.

Participants, who wanted to take part in the survey, returned the consent form, completed survey and additional information in the pre-paid envelope to the dedicated project address within their pre-paid envelope.

4.4.9 Recruitment challenges and solutions

Unfortunately, on the day on which the article was published online and in the newspaper (November 19th 2010), Durham University's phone lines were not operational; internal and external calls could not be received, and the specific email account was not functioning correctly whereby the auto response that was set up was looping back and forth to the Durham University's server. After I spoke with the IT department, this issue was soon resolved. I was very disappointed at this set back, since I had spent many months planning this particular day.

This situation may have resulted in a number of potential participants calling/emailing for more information about the study, only to receive a constant engaged tone on the phone, or an error message by email. It is reasonable to assume that potential participants might have tried to phone a number of times that day to contact me but, having failed a few times, then gave up. The IT problems at Durham University were resolved after 2 days, while the telephone exchange problem was resolved after 5 days. Only 12 people registered their interest through email and telephone communication following the advert in the Evening Gazette on 19th November 2010.

After a discussion with my PhD supervisors, it was agreed to launch the survey again in the New Year, and the Evening Gazette agreed to republish the advertisement on 4th January 2011.

Following the re-launch, recruitment was slow but steady within the first month. The vast majority of participants were from a small geographical area in relatively affluent post-codes. Thus, sampling was extended to specifically

target people from more deprived areas of the North East to achieve the objectives of the survey. In pragmatic terms, the sampling was widened from postcodes TS1 to TS18 to include all TS postcodes. Additionally, County Durham, Northumberland, and Tyne and Wear postcodes were included. The communication department at Durham University was approached and offered assistance in advertising the study, attempting to reach a wider audience. A press release (Appendix 9) was compiled for print and radio press release. This press release was later featured in other newspapers in print and online format, thus reaching a much wider audience than previous attempts. After the press release was sent to regional radio stations, I featured on a radio broadcast (BBC Newcastle), in which I detailed why the research was required, described inclusion criteria, and asked people to contact me to express their interest in taking part in the survey. Disappointingly, this extra effort only attracted ten people to register their interest, seven of whom took part in the survey.

Therefore, once again other methods of recruitment were developed and conducted. I emailed all students, and all staff, at Durham University. An online advert describing the study was displayed on plasma screens around the University for six consecutive weeks. Additionally, the local PCT was contacted about the study and a senior health improvement specialist sent a copy of my recruitment email in poster format (Appendix 10) to all PCT employees. A neighbouring University (Teesside) also agreed to advertise the study; the same email was forwarded to all staff and students.

I then gained permission to advertise the study in a large range of local libraries, schools, businesses, retail shops, community centres, gyms, and swimming

pools across the North East, which were each provided with two A4 Posters and 25 leaflets. All venues (n=207) were followed up with a telephone call to ensure that the posters and leaflets had arrived, and to ask that the posters be appropriately displayed and leaflets made available.

Sadly (and to my surprise), these strategies did not result in many more additional people being recruited to the study. Again, I sat down with my supervisors to develop another plan.

The next strategy which I employed to increase participant numbers was to approach three senior members of commercial weight loss programmes (Slimming World, Weight Watchers and LighterLife) for permission to advertise the study. It was anticipated that these individuals would have more authority and influence in assisting with recruitment for my PhD than junior staff.

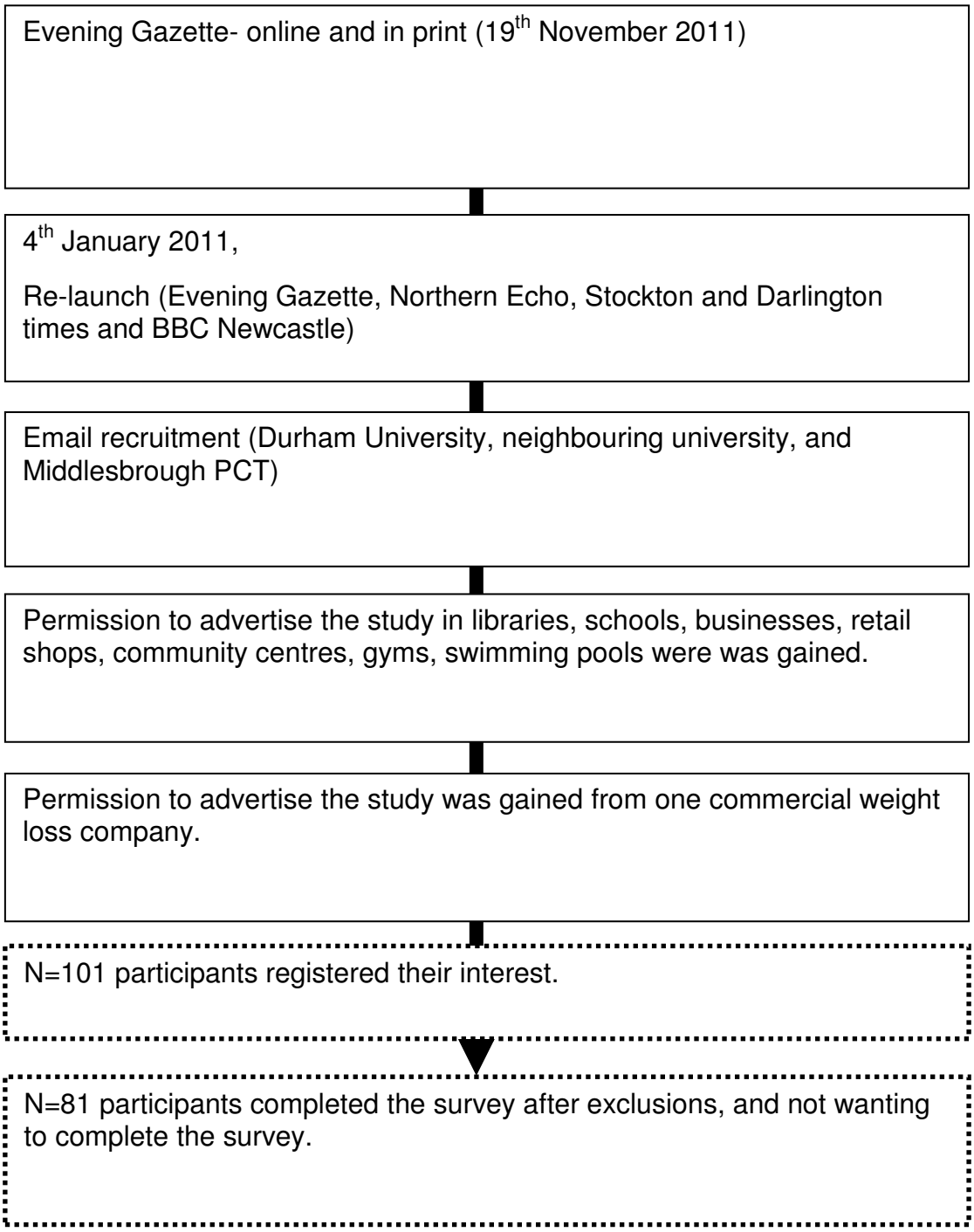


Figure 13: Research recruitment flowchart

Weight Watchers declined involvement, due to concerns that participation might negatively influence their members and impede their weight loss. Slimming World staff were keen to be involved but asked for permission to be sought from their Head Office; despite multiple attempts to speak to a senior staff member at Head Office, this did not come to fruition. LighterLife were the only CWLPS company which agreed to help; a senior staff member emailed all LighterLife counsellors within the NE region, asking for them to display a poster at group meetings, and for the counsellors to informally mention the research at group sessions.

The main negative risk of using CWLPS group members was, obviously, the risk of bias. A small number of participants (n=9) were recruited via LighterLife, which could have biased the survey results.

I did consider a further recruitment strategy, to advertise the study in NHS Primary and Secondary care premises. Although this may have increased recruitment rates, this would have required NHS ethical approval and the decision was taken not to extend the study, as these permissions would have taken several months, potentially delaying the study timetable.

At this point, I stopped recruiting participants even though I had not reached the sample size suggested by the statistician. I was very disappointed, but I was reassured by my supervisors that I should continue to the next stage of my PhD study.

4.4.10 Survey data analysis plan

The survey data was cleaned and analysed using SPSS software version 19. Unfortunately, the estimated sample for multilevel analysis (n=1250) was not reached, therefore appropriate statistics according to the data available are reported in Chapter Five. Descriptive statistics are also summarised in Chapter five.

4.4.11 Response and attrition rates

101 participants registered their interest in taking part in the study (Figure 13), of which three were excluded because they had never used a CWLPS. 17 participants expressed their interest in taking part in the survey, but were excluded because they did not wish to be involved further or withdrew later on. I telephoned participants if the data, which they supplied, was unclear.

As noted previously, 1250 participants were required to demonstrate a statistical significant association between costs and socio-economic status. Despite repeated and varied attempts to engage with a range of organisations, and significant investment in increasing the recruitment rate, only 81 participants were willing and able to take part in the survey. Therefore, lower level statistical tests were conducted on this data to explore (rather than test) the possible association between the level of deprivation of the individual and the cost of the CWLPS, weekly Household Net Income Estimate (equalised after housing costs), and IMD data. Scatter plots, using the line of best fit to

show any trends, are presented and described for hypothesis generation purposes (only) in Chapter five.

The survey and the Q-methodology study had two separate sample size requirements. The survey required 1250 participants for multilevel analysis to be conducted, and to illustrate the relationship between cost of CWLPS and IMD status. However, after a disappointing recruitment rate for the survey, lower level statistical test were performed on the participants involved (n=81). As explained in detail below a sample size of 20 was sufficient for the Q-methodology study. Webler, Danielson, Tuler (2009) suggest that a Q-methodology study should involve 8-30 participants for the definition of factors.

4.5 Q-methodology study

4.5.1 Aims/objectives

- Explore the reasons why participants chose commercial weight loss products and services, through operant categories.

4.5.2 Introduction

The literature suggests that Q-methodology incorporates 'qualiquantilogical' research that enables the researcher to understand the level of qualitative data through qualitative exploration. Bi-factor analysis provides specific categories that have emerged though participant responses, providing greater thematic understanding in relation to the complexity of choices in relation to CWLPS.

Q-methodology is most commonly applied in the fields of communication, political science, and the behavioural and health sciences (Brown, 1980).

Q-methodology was developed by William Stephenson (1902-1989) whose educational background, and employment, influenced his work. Stephenson studied undergraduate physics at Durham University, and then did a PhD at Oxford. His interest grew in the field of psychology whereby Stephenson studied and worked alongside Charles Spearman (the inventor of factor analysis), and Cyril Burt, an educational psychologist and statistician.

Q-methodology provides a structured means to explore a given phenomenon or topic of concern by allowing patterns of subjective meaning to emerge from participants' thoughts, beliefs, and perspectives (McKeown & Thomas, 1988).

As such, it is essentially a hybrid qualitative-quantitative research method. Its core foundation is based upon categories that are operant; in other words operant categories are clusters of subjectivity that have been determined by the participants and not pre-imposed by the researcher.

Q-methodology is characterised by two particular elements that set it apart from traditional factor analysis methods. First, a characteristic of Q-methodology is its capacity to determine categories set by the participants rather than categories that have been pre-imposed by the researcher. In more traditional forms of factor analysis, categories would be imposed by the researcher and developed as an a priori element of the research protocol, usually using a Likert scale or other ranked scoring system. In contrast, Q-methodology begins with preliminary qualitative data collection as a way of defining subsequent categories. A variety of collection techniques can be drawn upon to collate the information required for concourse development; Interviews, focus groups, textual analysis of media outputs and popular literature. The concourse is further explained in this Chapter at 4.5.8.1

The second defining characteristic of Q-methodology is the level at which factor analysis is focused; it is a modification of traditional factor analysis, which analyses (cluster) variables at the level of the group rather than the individual as is the case in more traditional methods. As such, Brown (1980) states that the Q-methodology findings are based on factor scores and will reflect the agreement and disagreement (perceptions) related to the individual Q-sort statements.

4.5.3 Justification

This study aims to understand the attitudes of people who have used commercial weight loss products and services, in order to inform NHS policy and practice. I hope that the findings from my research can increase understanding about the complex relationships between behaviour (choice of CWLPS) and beliefs, which may in the future inform the further development of these interventions. It was therefore important to choose a method of data collection for my research which allowed participants own beliefs to emerge, rather than impose my beliefs on the participants. Q-methodology has been chosen for this particular research topic as other forms of subjective research often rely upon categories that the researcher has determined. This method was employed to limit the probability of researcher bias of qualitative interpretation of subjective opinion and feelings, and to limit obsequiousness bias. The utilisation of a Likert scale would increase researcher bias; the questions would be imposed by the researcher, purely agreeing or disagreeing. In this study, Q- methodology has been chosen in order to gain an understanding of the attitudes associated with commercial weight loss products and services. This is a relatively novel method of choice within health and, in this particular field of interest (obesity), only one other study has used the application of Q-methodology. This study examined weight-control self-efficacy beliefs in obese women, linked to outcomes of a weight-loss program (Dennis & Goldberg, 1996).

4.5.4 Criticisms of Q-methodology

Due to the small sample size required for a Q-methodology study, this method has been criticised for its reliability, and the generalisability of findings (Danielson, 2009). However, proponents of the method point out that any topic will only have a handful of viewpoints. A carefully structured Q-methodology study will reveal the full range of viewpoints (but not the popularity of these viewpoints), as long as the participants come from a variety of different sources (e.g. males and females, have tried different CWLPS, etc.). A Q-methodology study focuses on the specific subjectivities about a given topic that are operant, and does not focus upon the distribution of participants to each factor.

4.5.5 Variables

Q-methodology is different to traditional factor analysis, and the two methods can easily be distinguished. In Q-methodology, the subjects and variables are inverted; in other words the subjects take the place of the statements, and the variables take the place of the participants, particularly their Q-sorts. In traditional factor analysis, participants are the subjects, and the questions asked are the variables. Researchers using traditional factor analysis will look at the data for patterns in responses across the variables and whether there are any relationships between variables in the same individual. Q-methodology looks at the data the other way around.

4.5.6 Determinants of sample size

In Q-methodology, a sample size of 10 or over is considered large enough to reveal underlying factors (Brown, 1980). Seven to twenty participants were involved at one or more stages of my Q-method study.

4.5.7 Focus groups and interviews

4.5.7.1 Aims

The purpose of focus groups and interviews is to develop an in-depth understanding of the specific topic in question, which in my case were the weight loss experiences of participants who had used CWLPS. In my study, the main objective of conducting focus groups and interviews was to inform the development of the subsequent Q-method (described at 4.5.8.1) which sought to examine the relative importance of the decision-making factors regarding the choice, etc., of commercial weight loss products and services.

4.5.7.2 Choice of method

The focus group and interviews which I conducted were informed by the theoretical framework offered by Q-methodology as described in Chapter 3. Indeed, this is the recommended method for Q-methodology. The literature on Q-methodology argues that it is important to ensure knowledge of the full breadth of data on the research topic (in my case, the possible viewpoints on CWLPS from those who had used them) in advance in order to conduct a full

and complete interrogation of each decision-making factor. Kitzinger (1995) suggests that the focus group method offers the optimum method to achieve this aim by virtue of bringing together relatively large numbers of people with a range of demographics and experiences.

Although I had planned and would have very much liked to have restricted my research at this stage to focus groups, I found it very difficult to organise such groups across the wide geographical area of the NE. Although some people were keen to take part in the study, they were not willing to travel too far and/or meet up at set times. Therefore, I used, in addition to focus groups (held at Durham City and Queen's campus), some one-to-one face-to-face interviews, and in a few cases one-to-one telephone interviews. Although I understand that using one to one interviews, particularly by telephone, was not ideal, I conducted them in a way which tried to maximise data depth and quality. I was reluctant, initially, to conduct interview by telephone, but after reading the relevant literature, I was reassured that it would be a satisfactory method of data collection to use. For example, Aneshensel et al (1982) observed no important differences between data generated using telephone and face to face interviews in a study of 546 people. However, more recent research suggests that telephone interviewing does not allow for visual cues and this may affect the level of intimacy and responses from participants (Opdenakker, 2006). Others have argued that telephone interviewing may offer a level of anonymity that might elucidate more personal or embarrassing information (Wilson et al, 1998). There is also a debate about the relative utility of the focus group method which can involve additional costs, researcher time, and participant burden. The potential of response bias is a contested concept in qualitative research and

there is no consensus about the optimum method in the more general (non-Q-method) literature.

Although I was disappointed, initially, to have to use one-to-one face-to-face and telephone interviews, after reading the relevant literature I was of the opinion that combining the results from different methods (focus groups, one-to-one face-to-face interviews and one-to-one telephone interviews), may offer a greater breadth and depth of data. I applied the principles of data saturation in my data collection (using all 3 methods) until no new themes emerged.

4.5.7.3 Recruitment

Participants who had stated in their survey consent form that they were happy for the researcher to contact them at a later date (n=80) were sent information sheets (Appendix 16), consent forms (Appendix 14), a pre-paid envelope to be returned back to the researcher, and a registration form (Appendix 15) to ask which venues, and times, would be most suitable for them. A range of venues and times (including evenings) were offered, and participants had the opportunity to request alternative times or venues.

After receiving the completed registration and consent forms, focus groups (n=3; 12 participants), telephone interviews (n=5), and one-to-one interviews (n=1) were conducted over a period of three months. One participant had already been involved in the pilot focus group (n=2), though wished to be

involved in the actual study. In total, data from 19 participants were used for analysis.

4.5.7.4 Focus group conduct

A pilot focus group was conducted in order to assess the process of data collection, to ensure familiarity of the process with the neophyte researcher (i.e. me!), and acceptability of the experience for participants, as well as 'testing out' the pragmatics of the verbal introductions and questions, and data recording. I felt that it was important to conduct a pilot focus group to ensure that the equipment was working correctly, all questions were phrased accurately, and to develop questioning skills in order to build my confidence. Two participants attended, one who had previously used a CWLPS, and the second who was reflecting upon the experiences of a family member. All questions were acceptable, however the script required some refining to ensure that there was a good linkage between questions.

Arguments for and against using pilot data in the final analysis were considered by me and my supervisors. Given that the interview schedule was not changed significantly between the pilot and full study, it was decided that we could analyse the pilot data with the data from the fully study. This process taught me a lot about the importance of doing a pilot study, regardless of what type of method you are using, and why you need to think carefully about whether or not you should combine pilot data with the data from a full study.

All focus groups were held in an easily accessible venue with disabled access within Durham University (at both the Durham City campus and Queen's campus). All participants were asked for their permission for the focus group to be recorded. Two small electronic Dictaphones were used during each focus group, one as back up if the other one failed. Each focus group began me outlining what the focus group would cover, housekeeping rules and explaining the main objective of the focus group, which was to capture as many viewpoints about the reasons for using commercial weight loss products and services as possible. Because of the potentially sensitive nature of the topic, a set of ground rules were discussed and agreed which focused on the need for mutual respect, allowing each person to speak, confidentiality, a request not to discuss the content of the focus group with anyone, and a reminder that any disclosures of harm or potential harm would be acted upon by the researcher (me).

Prior to the focus group I developed a set of potential general questions on three key areas, namely weight loss, obesity, and experiences of CWLPS (Appendix 11). Questions were open, enabling participants to think about the reasons they chose CWLPS, and which CWLPS. The script was only used as a guide, and sometimes a lively discussion developed which meant the questions were not answered in the order I had planned. I tried to facilitate but not lead the discussions, but did try and steer the conversations at certain point so that all of the questions I wanted answers to were covered.

All participants were given the opportunity to ask questions, thanked for attending, and the Dictaphones were stopped.

4.5.7.5 Interviews

The majority of interviews were conducted via telephone (n=5); one was conducted face-to-face. The conduct of the one-to-one face-to-face interview followed the same protocol as the focus group (described above), but of course there was only one participant.

Prior to the commencement of the telephone interviews, all participants were asked whether they had had time to read the participant information sheet (Appendix 16), and asked whether they had any questions about their involvement in the telephone interview. One participant wanted to know exactly what the telephone interview would involve, and was keen to know more about the research. Similar to the conduct of the focus groups, I read from the script outlining what the interview would cover, and explained that the main objective of the interview was to capture their viewpoints regarding the reasons they used commercial weight loss products and services (Appendix 11).

Participants were then asked whether they had any further questions prior to recording the telephone interview (using two Dictaphones). The interview was recorded by having the telephone on loudspeaker, and a Dictaphone either side of the mouthpiece. I conducted the telephone interviews in a private room, so nobody else could hear the conversation.

4.5.7.5.1 Telephone interviews

4.5.7.5.1.1 Advantages

- Telephone interviews can occur at a time that is most convenient for the participant. Including telephone interviews as part of the data collection might mean that the study includes people who are generally very busy, have chaotic lifestyle, and/or are very shy, and would not wish to take part in a focus group. Therefore, I believe that including telephone interviews in my study increased the chance that I included the views of a wide range of people who choose to use CWLPS.
- Participants can feel relaxed and respond openly when answering questions related to their own personal experiences of weight loss and commercial weight loss methods utilised, knowing that only the researcher is listening. In a group setting, a participant might not feel comfortable in discussing these issues with strangers.

4.5.7.5.1.2 Disadvantages

- The researcher cannot detected body language and signs of miscommunication or misinterpretation, which could cause a breakdown in the flow of communication
- The participant might forget to mention certain points, which may have otherwise been promoted by comments from others if they were part of a focus group.

4.5.7.6 Focus groups

4.5.7.6.1 Advantages *(in addition to the 'flip-side' of those statements for interviews, listed above)*

- Participants might feel that sharing their experiences with others (in addition to the researcher), who could be considered their peers, provides them with an added benefit of taking part in the study.
- Data can be collected on a number of participants at the same, thus saving researcher.

4.5.7.6.2 Disadvantages *(in addition to the 'flip-side' of those statements for interviews, listed above)*

- It can be difficult to find a time and venue for the focus group which is convenient to participants, particularly if they are from a wide geographical area and are expected to come to one central location.
- Transcribing data from focus groups can be a more complex process for the researcher, especially if many participants attend the focus group.
- If any one participant is particularly dominant in the group, this can disrupt the flow of the focus group and stop the other participants speaking out. This is where the skills of the researcher are particularly important.

4.5.8 Q-methodology stages

A Q-methodological study involves the following steps: (1) definition of the concourse; (2) development of the Q sample; (3) selection of the P set; (4) Q sorting; and (5) analysis and interpretation.

4.5.8.1 Definition of the concourse

Brown (1980) draws upon the definition of a concourse in a Q-methodology study, stating that it is “the flow of communicability surrounding any topic”. A verbal concourse was derived from qualitative research; focus groups, and telephone or face-to-face interviews. The researcher examined the emerging data to ensure all aspects relevant to the discourses were apparent. The gathered material from weight loss company websites, researcher knowledge, and qualitative data collection was representative of the opinions relevant to the choice of CWLPS. Key quotes relevant to the Q-sorting stage were extracted from focus groups and interviews transcriptions to form statements. I refined statements for readability purposes, and quotes that were less than four words required additional text to form a statement. After looking at commercial loss company websites, the researcher felt that additional statements needed to be created, to encompass all relevant aspects of all the discourses.

4.5.8.2 Development of the Q-set

The concourse involved inductive analysis of the focus group and interview transcripts. Codes were applied to the emerging themes and subthemes; second level coding resulted in a handful of meaningful and representative

categories that was a miniature version of the concourse through the application of a deductive sampling method. Five broad themes were identified; personal, emotional, mental, social and physical. All themes were examined to assess duplication, and whether any statement needed to be refined for readability purposes. After careful consideration, 111 statements were compiled before inductive analysis occurred

Once the researcher felt that no more emerging themes were coming through, and data saturation had occurred, the Q-set was refined to a manageable set of 59 statements for piloting. Duplications were removed, and one final statement was added by my primary supervisor.

Q-methodology involves distinct stages whereby participants are involved; the concourse development stage was the only stage whereby telephone interviews were employed.

4.5.8.3 Selection of the P-set

In Q-methodology, the P-set is not selected randomly. Participants are chosen (from those who took part in the focus groups and interviews) based upon the theory that they will have a clear and distinctive viewpoint about the area or topic being investigated. It is expected that four or five persons should define a specific viewpoint; called a factor.

At this stage, I had already selected the respondents for the P-set. I contacted the survey participants who had consented that they were happy for me to contact them at a later date within their survey consent form. Separate consent

forms were required for the development of the concourse, pilot study, and Q-sort; process consent (Appendices 14, 17 &18). This was necessary due to the time required for each phase to be completed; I could have found that participants had said 'Yes' to all three stages at the outset, but due to other commitments during the course of the study they found themselves able to only commit to the development of the concourse, and withdrawing from the study after this stage.

4.5.8.4 Pilot study-Q-set

To ensure that all statements reflected the reasons why participants choose CWLPS, and were readable, a pilot study was conducted. The purpose of the pilot was not only to text the statements for readability, but also to test the statements for overlap (and try and reduce the size of the Q-set). Several revisions of statements usually occur before the Q-sorting phase is completed.

4.5.8.4.1 Recruitment

All participants who had stated that they were happy for the researcher to contact them at a later date within their survey consent form (n=80, or 81) were sent in the post; information sheets (appendix 18), respective consent form (appendix 17), registration form (appendix 19) to state which venues (Durham University; Main campus, Durham University; Queens Campus, and Teesside University), and times (Monday; 7-8pm, Wednesday; 2-3pm or Friday; 10-11am) would be more suitable for the participants. Participants also had the

opportunity that state other times or venues, and pre-paid envelope to be returned back to the researcher.

After receiving the completed registration and consent forms, the researcher organised two focus groups, each of six participants. Two separate focus groups were conducted at a time and date that was suitable for the participants. Initially one focus group was organised, however, at the last minute four participants could not attend this focus group, including one participant who was ill on the day. Therefore, only two people attended this focus group. I then sent the pilot exercise by post to those participants were unable to attend the focus groups. Within the information sent to these participants, they had the option to write down the statements which they felt required further work, and say if there were any statements that were missing. Four of six participants attended the second focus group, and those who did not attend were sent the information in the post. All participants were asked (verbally or by letter) to read the instruction sheet, and think about the one CWLPS that they were most positive about. This was essential as the majority of participants had used one or more CWLPS in the past 12 months. I wanted the participants to concentrate on one CWLPS instead of thinking which CWLPS applied to selecting agree, disagree and neural from the Q-set. Participants were asked to write their favoured CWLPS down, carefully look at all 59 statements, and write down whether they agreed, disagreed or had no opinion or felt that the statement was not relevant to them (neutral). An audio device (Dictaphone) was used to record the feedback given by the participants about the statements.

4.5.8.4.2 Piloting the q-set: phase one

Eleven participants piloted the 59 statements. Statements that were split between agree and neutral, or disagree and neutral, were removed from the Q-set (n=11 statements). Deleting these statements was essential; participants were not showing preference for polar opposites, or loading between three piles. Participants also expressed that they felt additional statements were required about the reasons why they chose CWLPS (n=13 statements), and four statements were separated as the participants felt that the statements were asking two separate questions about the reasons of choice.

4.5.8.4.3 Piloting the q-set: phase two

To ensure that the additional, and separated, statements were reflective of the reasons why participants chose CWLPS, another piloting exercise was required. In addition, I decided to include a statement that I had previously deleted.

"I wanted something where there was a consistent guide to weight loss that did not change, which I could get from this CWLPS".

This statement was originally deleted as; at that point, I felt that it did not show an agreement, disagreement or neutral preference. Instead, I decided to keep a similar statement to the deleted one in the q-set:

"I used this CWLPS as I got confused listening to the ever changing government guidelines on healthy eating, and I knew the CWLPS guidelines would not alter".

Upon observing participants take a longer amount of time in considering this statement, I decided that it would be better to revert to the original statement; participants also confirmed that this would be more appropriate.

Seven participants piloted 63 statements (52 original statements), and this number was further reduced to 60 statements (Appendix 23).

Senior researchers using Q-methodology do not pilot their Q-set before Q-sorting. It is my opinion that piloting ensures that all statements presented are as representative as they can be for the Q-sorting stage. Without piloting, it is my opinion that a miniature version of the concourse would not be provided for Q-sorting. Valuable information, about the reasons why participants chose CWLPS could have been missed without piloting. In Q-methodology, it is the Q-sort as a whole that is interpreted, not individual statements.

4.5.8.5 Q-sorting grid

As a Q-methodology novice, I felt that I required additional information in relation to the layout of the Q-sorting grid from members of a Q-methodology email network; Q-METHOD@LISTSERV.KENT.EDU. I explained that the P-set which I had been decided upon.

Van Exel and de Graaf (2005) explain that the distribution of the grid should be flat to provide more room for (dis) agreement between statements. Prior to administering the Q-sorts, I estimated that 46 statements would be used, and asked whether a 2,3,4,5,6,6,6,5,4,3,2 grid would be appropriate (Figure 14). Literature suggests that there is not a minimum or maximum number of

statements that could be given to a participant. However, a large Q-set could cause the participant to rush their decisions, because they felt they were taking too long to complete the task.

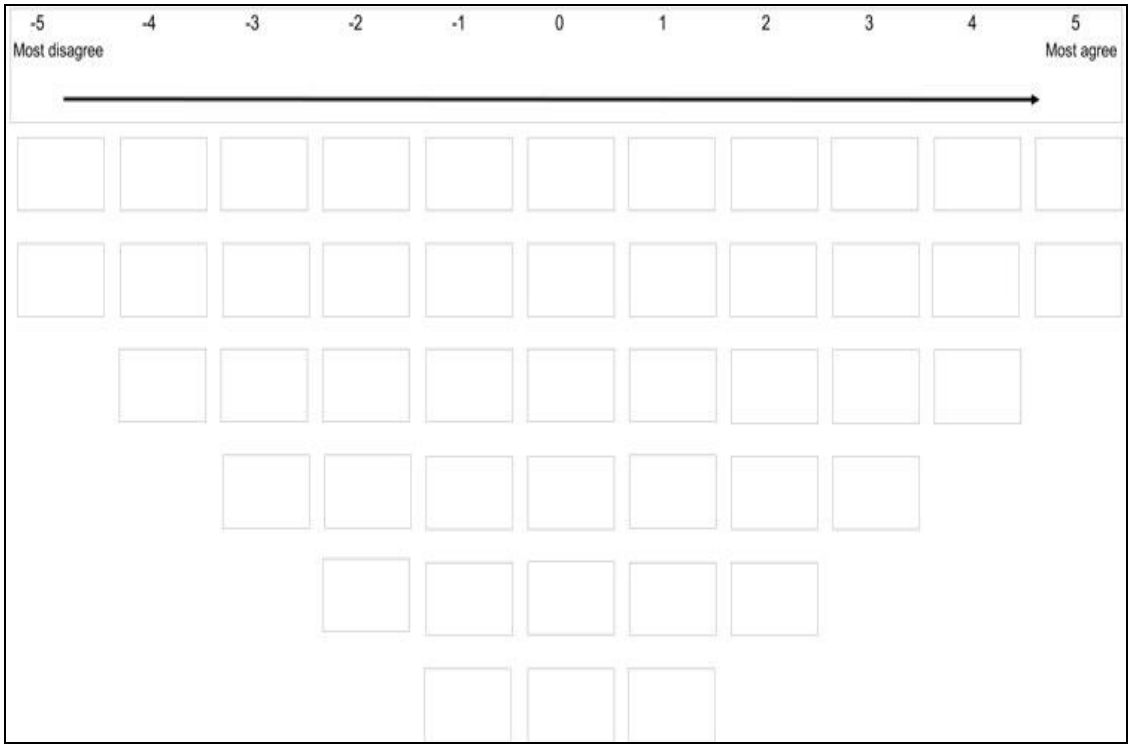


Figure 14: Q-sorting grid

Senior researchers using Q- methodology responded my email, stating:

"The platykurtic distribution described seems sensible enough".

"I am sure you'll get a range of responses to your question, but I think the main theme will be along the lines of "It makes no difference! From what I can gather (and I am relatively new to Q), the testing of different distributions has shown that they make no difference (perhaps, very little difference?) to the final factor scores. Having said that I think the two main tenets must be adhered to;

statement ordering is self-referential in that it refers to the thoughts of the participant, and that decisions are made in reference to the other statements in the Q-set, i.e. there IS an order. Presumably that means you could just have a continuum of statements from 1 to 50, but their order must reflect the participant's view of statement x being more 'important' than statement y etc"

This information was extremely useful. Although I anticipated using only 46 statements, I decided to 60 statements for Q-sorting after I received advice from others. After piloting the q-set several times, 60 statements could not be narrowed down any further; all participants felt that 60 statements were manageable. The distribution of the grid (Figure 15) was slightly altered from what I had originally intended, but a flatter distribution was still utilised to ensure that the participants had more room for the agree/disagreement statements.

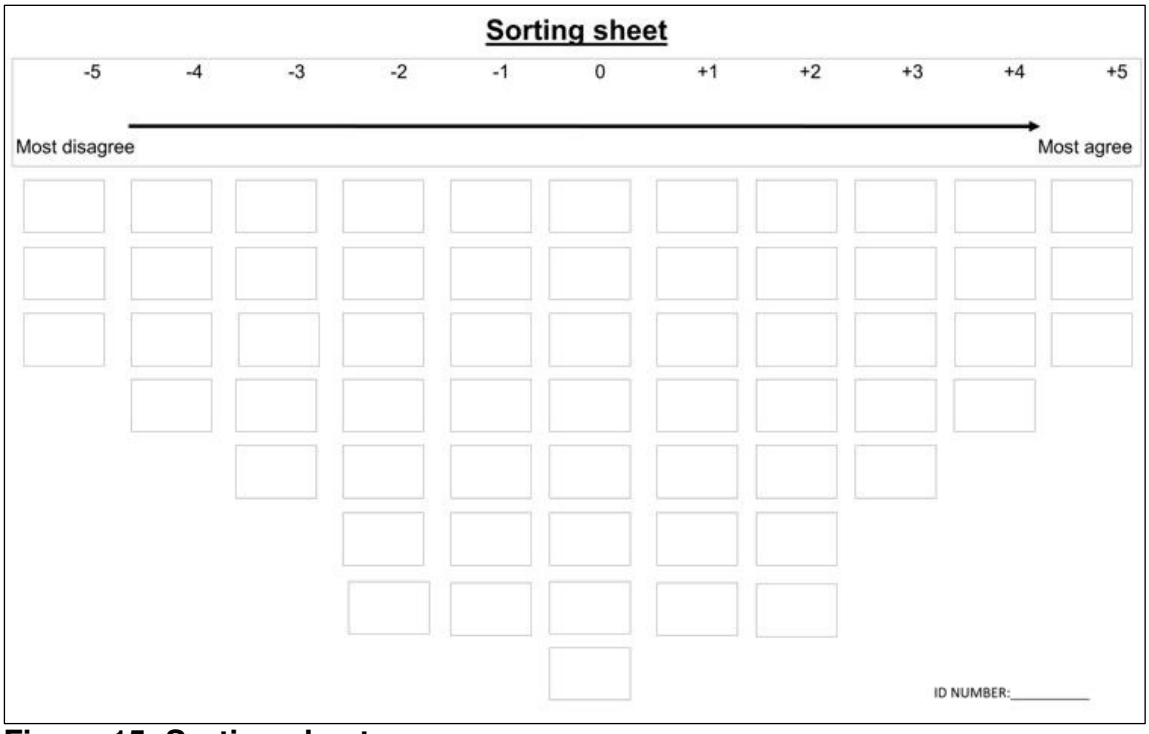


Figure 15: Sorting sheet

Irrespective of the structure of the grid, and the selection of statements, the participant employs a meaning to the statements.

4.5.8.6 Recruitment

All participants who had stated that they were happy for the researcher to contact them at a later date within their survey consent form (n=80, of 81) were sent information sheets (Appendix 20) and consent forms (Appendix 22) in the post, with a pre-paid envelope to be returned back to the researcher, and a registration form (Appendix 21) asking which venues (Durham University; Main campus, Durham University; Queens Campus, or Teesside University),and times (Monday;7-8pm, Wednesday; 2-3pm or Friday; 10-11am) which would be most suitable for them. Participants also had the opportunity to state other times or venues.

4.5.8.6.1 Q-sorting

The Q-sample systematically rank-orders each of the statements along a Q-sorting sheet. This process differs from Likert scales as the statements are rated against one another, instead of on an individual basis. The overall process of Q-sorting reveals individual subjective opinion about the subject being investigated. Q-methodology does not assume what is an appropriate response; instead, as there are no right or wrong answers in relation to a participant's viewpoint, interpretation relies on where the statements are placed on the Q-sorting grid.

4.5.8.6.2 Face-to-face

The Q-sorting process was designed to instruct participants to review the entire set of statements according to a condition of instruction. This condition of instruction was *"why did you choose this particular CWLPS?"*, and also the participant needed to review a pack of randomly numbered, individually typed statements on business sized cards (n=60). The participant was asked to divide the statements into three piles; agree, disagree and neutral, according to the condition of instruction. After the process of sorting, the agree pile was taken, and the participants was asked to think about which three statements they agreed with the most, and these were placed under the +5 on the Q-sorting sheet (Appendix 12). They were then asked which four statements they agreed with slightly less than +5, and placed these under +4. This process was continued until there were no more agree statements to be sorted and placed. The same process was undertaken with the disagree pile, but they were asked three (not four) statements that they disagreed with the most, and place them under the -5 on the Q-sorting sheet. The next four statements which they disagreed with the most (of those left in the pile) were then taken and placed under -4, and this process was continued until there were no more disagree statements. The neutral pile was then taken, placing the rest of the statements where the participant felt they were most appropriately positioned on the Q-sorting sheet.

During the exercise, the participant had the opportunity to move the statements on the Q-sorting grid to where they felt would be more appropriately placed. Once each of the participants was satisfied that his or her sort was complete, I recorded the results on their Q-sort answer sheet. After the Q-sort, I asked the

participant to comment about the placement of the statements at polar opposites to the Q-sorting grid, recorded on a Dictaphone to gain additional qualitative data. This enabled a profile to be built of each participant's beliefs and opinions. Interviews also allowed for the interpretation of factors during data analysis.

4.5.8.6.3 Postal

Participants who were not able to attend the face-to-face Q-sorts, though had expressed their interest in wanting to take part in the Q-sorting exercise, were given the opportunity to be involved in postal Q-sorts. An instruction sheet, Q-sorting grid, an example of a Q-sorting grid, statements and marker cards were forwarded to the participants, with pre-paid envelopes. Participants were asked to send their completed Q-sorting grid, indicating where they had placed their statements, back to me.

4.5.8.7 Analysis and interpretation

Statements were then subject to correlation and factor analysis, whereby persons were correlated against one another, rather than by tests. Individual likes and dislikes were factorised of significant clusters and correlations. In order to assess whether there were factors that were highly correlated or uncorrelated with one another, factors were rotated objectively using varimax rotation until I was satisfied that the relationships were true to the study. Theoretical rotation could have been used. However, this method is used when the researcher has a pre-conceived idea or theory. I did not want to confirm an

idea or a theory, and therefore I used varimax rotation instead. Objective or theoretical rotation modifies the perspective from which the Q-sorts or relationships between Q-sorts are observed. Retained factors had an eigenvalue of more than one. Factor analysis reduced the data set of larger numbers of correlation variables to a simple structure of factors (McKeown & Thomas, 1988). Whilst the researcher chooses the statements, the Q-sort is self-referent, and the placement of statements was chosen by the participants.

Data from the Q sorts was analysed using the PQMethod 2.11. This computer program allows the researcher to enter each participant's Q-sort in accordance with where the statements were placed on the grid.

4.6 Cochrane review

4.6.1 Background

Prior to the commencement of the systematic review, a title and application was submitted to the Effective Practice of Care (EPOC) Review Group. A proposal which included details of the types of studies, participants, distribution of workload, and co-authors, were included in this application.

The editor of the review group (Alain Mayhew) did not feel that the review was appropriate as an EPOC review, and felt that it was better suited to the Cochrane Endocrine and Metabolic Disorders review group. Alain forwarded the review proposal to the editor of the Endocrine and Metabolic Disorders review group. Before the title registration form could be fully accepted, amendments in relation to international perspective, definition of CWLPS, types of studies, outcomes, and roles and responsibilities of co-authors (see next paragraph), were required, and corrected. I successfully corrected the information on the title registration for and the systematic review title was accepted by Cochrane Endocrine and Metabolic Disorders review group.

Additional co-authors who had an extensive knowledge of commercial weight loss products and services were invited to join the review team, on the recommendation of the Endocrine and Metabolic Disorders review group. Professor Frank Greenway, Chief of Outpatient Clinic, Pennington Biomedical Research Center, USA, and Tance Sonnier who works with Professor Greenway, accepted my invitation. I also invited Professor Harry Rutter,

Director of the National Obesity Observatory UK to join the review team, and he kindly accepted.

I attended two Cochrane run courses; Developing a Protocol for a Review, and Introduction to Analysis, at York University, prior to progressing any further with the systematic review. I found these a great help.

After completing of the courses, I was much more confident in conducting a systematic review and using the specific programme which I needed to use as part of the process (RevMan). I then developed the protocol for the systematic review, and contacted all co-authors for their comments. I wrote the search strategies for Medline and Embase, and these were checked by Karla Bergerhoff who is the Trials Search Coordinator of the Cochrane Metabolic and Endocrine Disorders Group. I needed to make a few revisions, and this was a very useful learning process. I also compiled search strings for the Cumulative Index to Nursing and Allied Health Literature (CINAHL) database, and PsycInfo database.

I submitted the protocol to Endocrine and Metabolic Disorders review group and their reviewers come back with a number of queries and comments. Most of their comments related to outcome measures and the definition of CWLPS. The review group suggested that the initial diagnostic criteria of weight and BMI was too restrictive, and this was amended (as suggested) to include a variety of markers for obesity. The Cochrane review group also suggested that we collect data on a wide range of relevant secondary outcomes, and these are now included (as suggested) in the revised protocol. One of the most difficult issues I had with the Cochrane review group was trying to define CWLPS. CWLPS in

any context and setting were included within this review (e.g. face-to-face, group settings, and online). However, I wanted to restrict my review to CWLPS which focussed on diet and/or physical activity only, and I did not include studies of weight loss drugs, hypnotherapy or hypnosis, or nutriceuticals. The original definition of CWLPS which I submitted was changed, and a detailed explanation describing the types of products and services that would and would not be included within the review is now included in the protocol.

I submitted a revised version, and this was accepted pending a small number of changes. I submitted a further revised version of the protocol (Appendix 13) in March 2013, and at the time of submitting my PhD thesis I am still waiting for confirmation that the protocol has been accepted.

Although I understand that the process of doing a Cochrane review is important, and the steps which you must follow are there to ensure that the review attempts to answer an important question and is of high quality, it does take a long time.

In April 2012 I made the decision, in discussion with my PhD supervisor Professor Carolyn Summerbell, that I would conduct the systematic review using Cochrane principles, but do it as a stand-alone systematic review (I refer to this as my PhD refer, below). I made this decision because I was worried that if we conducted it with the Cochrane review group that I would not be able to complete it in time. I was originally planning to submit my PhD in January 2013. However, as soon as I have submitted my PhD I will start to work on the Cochrane review.

4.6.2 Search strings

The search strategy which was written for the Cochrane protocol produced a limited number of RCT's and CCT's (controls could be placebo, usual care, or another commercial weight loss product or service) which could be included in the review. At that point, I decided to include additional study designs (CBA's and BA's, and studies of shorter duration) in my PhD review, to capture the essence and breadth of intervention studies which evaluated the impact of commercial weight loss products and services. The Endocrine and Metabolic Disorders review group only accepts RCT's and CCT's in their reviews.

I do understand that studies which do not have control groups are prone to bias results, and they should be viewed with caution. I do understand that most people who are obese who go on a weight loss diet which they believe will work will probably lose weight, regardless of what sort of diet it is. However, I also believe that good evaluations of interventions which do not have a parallel control group can provide useful information; although the results from these studies cannot be ‘lumped’ with the results form RCT's and CCT's. The result from RCT's and CCT's is the difference in change over time between the intervention and control group. The result from evaluations of interventions (CBA's and BA's) is just change over time in the intervention group. Because people in control groups do want to lose weight (otherwise they would not have agreed to take part in the study or stay in the study) and usually get some sort of weight loss advice, and lots of measurements during the study, they usually lose weight. Therefore, results from evaluations are likely to be greater than results from studies with parallel control groups.

Within the Cochrane protocol, only studies of 6 months, 1 year (weight change at 1 year is the primary outcome) and longer are included. This was a recommendation of one of the Cochrane reviewers. However, due to the fact that I was particularly interested in including studies which had evaluated 12-week commercial weight loss interventions which PCT's had commissioned in the UK over recent years, I decided to include studies of 12 weeks or longer in my PhD review. However, I kept weight change at 1 year as the primary outcome for my PhD review.

I do understand that, typically, people who go on weight loss diets lose weight initially, but then (at about 2 or 3 months) it starts to go back on again, and by six months the weight lost from the start is minimal. Perhaps this is why commercial weight loss companies offer PCT's 12-week courses, and often just present their results at 3 months.

In addition, I only included studies from 1980 only in my PhD review. This specific year was chosen as the 1980's saw a boom in the commercial weight loss industry, and it was about then that doctors informed the public that obesity was a risk to health.

In the Cochrane protocol, participants in studies must be 18 or older. However, in my PhD review I have included people aged 16 years or older. I decided it was a good idea to reduce the age to 16 year olds since this is the minimum age for people who can attend commercial weight loss groups such as Slimming World and Weight Watchers.

Finally, for my PhD review, I did not collect and report the plethora of outcome measures which are listed in my Cochrane protocol. I have restricted the outcomes measures to measures or estimates of body weight and body fatness.

4.6.3 Cochrane title

Commercial weight loss products and services for overweight and obese people (Crayton et al, 2013).

4.6.4 Cochrane protocol

On March 28th 2013, the Cochrane protocol (Appendix 13), was checked into the Cochrane Library for editorial comments. I am not expecting any further editorial comments. After I have submitted my PhD thesis, and after the review has been 'unlocked', and I have received the approval to start the review, I will run the searches again from August 2012 to present, and will assess the additional hits for duplication and relevance. I am hopeful that I will be able to complete the Cochrane review quickly, and submit the review to Cochrane by summer 2013.

Chapter Five

Results

5.1 Introduction

This section reports the findings of the first component (of three) of my research, the survey. Demographics of those participating in the survey, the popularity of CWLPS, and the relationship between the cost of CWLPS and socioeconomic status of those who used them, are described in this chapter.

Results from the Q-methodology study (the second component of my research) follow the results of the survey. The third component of my research is a systematic review, which was conducted in line with Cochrane methodology, with a couple of exceptions. The Cochrane review protocol (included as an Appendix to my thesis) has been accepted by the Cochrane Metabolic and Endocrine review group. For the purposes of this thesis, the systematic review, which I report here, includes a more inclusive inclusion criterion, as compared with the Cochrane review. For example, in addition to RCT's and CCT's, I included CBA's and ITS studies in my PhD systematic review. In addition, I included studies in my PhD systematic review with a minimum duration of 12 weeks (to reflect the same referral periods used in the NHS) and people from aged 16 years; in my Cochrane review the minimum duration of study is 6 months, and minimum age is 18 years.

5.2 Survey

5.2.1 Participants

Participants who were involved in the survey research (n=81), were primarily recruited through local publications, which have large online and print readerships (Evening Gazette, Northern Echo, and Darlington and Stockton times). As shown in Table 9, most of the participants were female (91%) and Caucasian (99%). About a third of the participants were in receipt of a postgraduate or graduate degree (37%), and over half of them were married (51%). The mean age of participants was 44.4 (SD 13.6).

Table 9: Survey participant's (n=81) demographics

	Mean (SD)	
Age	44.4 (13.6)	
	Number of Participants (%)	
Gender		
Female	74	(91%)
Male	7	(9%)
Ethnicity		
White	80	(99%)
Other	1	(1%)
Highest level of educational achievement		
Secondary School	6	(7%)
BTEC/SCOTVEC	1	(1%)
NVQ	10	(12%)
HNC or HND	2	(3%)
CSE	2	(3%)
Degree	18	(22%)
GCSE	10	(12%)
Postgraduate degree	11	(14%)
AS or A Level	10	(12%)
Occupation		
Full time employment	39	(48%)
Full time education	8	(10%)
Homemaker	3	4%)
Other	1	1%)
Part-time employment	14	(17%)
Retired	10	(12%)
Self-employed	4	(5%)
Unemployed	2	(3%)
Religion		
Buddhism	2	(3%)
Catholic	1	1%)
Christianity	38	(47%)
Church of England	3	(4%)
None	23	(28%)
Roman catholic	13	(16%)
Wiccan	1	(1%)
Marital status		
Co-habiting	19	(24%)
Divorced/separated	5	(6%)
Living with parents/guardians	7	(9%)
Married	41	(51%)
Other (widowed)	3	(4%)
Single	6	(7%)

5.2.2 Supermarket purchases

Participants were asked where they did their bulk food purchases. Asda was clearly the most popular supermarket, followed by Tesco's (Table 10).

Table 10: Bulk food shopping purchases amongst survey participants

Name of the supermarket	Number (%)	
Aldi	1	1(%)
Asda	29	(36%)
Lidl	1	(1%)
Local shops	1	(1%)
Morrison's	13	(16%)
None	1	1(%)
Sainsbury's	14	(17%)
Tesco	21	(26%)

5.2.3 Cost and duration of CWLPS purchased

The cost and duration of use of CWLPS by the survey participants varied widely (Table 11).

Table 11: Total cost and duration of use of CWLPS by the survey participants

Total cost of CWLPS purchased: range (mean)	 £5.00 - £3,717.48 per year (£399.97 per year; £1.09 per day)
Total duration of CWLPS purchased: range (mean)	14 – 1121 days (327 days)

5.2.4 Socio-economic status

As shown in Table 12, the majority of participants who wanted to take part in the survey were not from the most deprived areas of the North East.

Table 12: Participant IMD data

Lower layer super output (2010 data) index of multiple deprivation:	**Range** 3.03 - 68.72	**Mean** (20.04)

5.2.5 Popularity of CWLPS

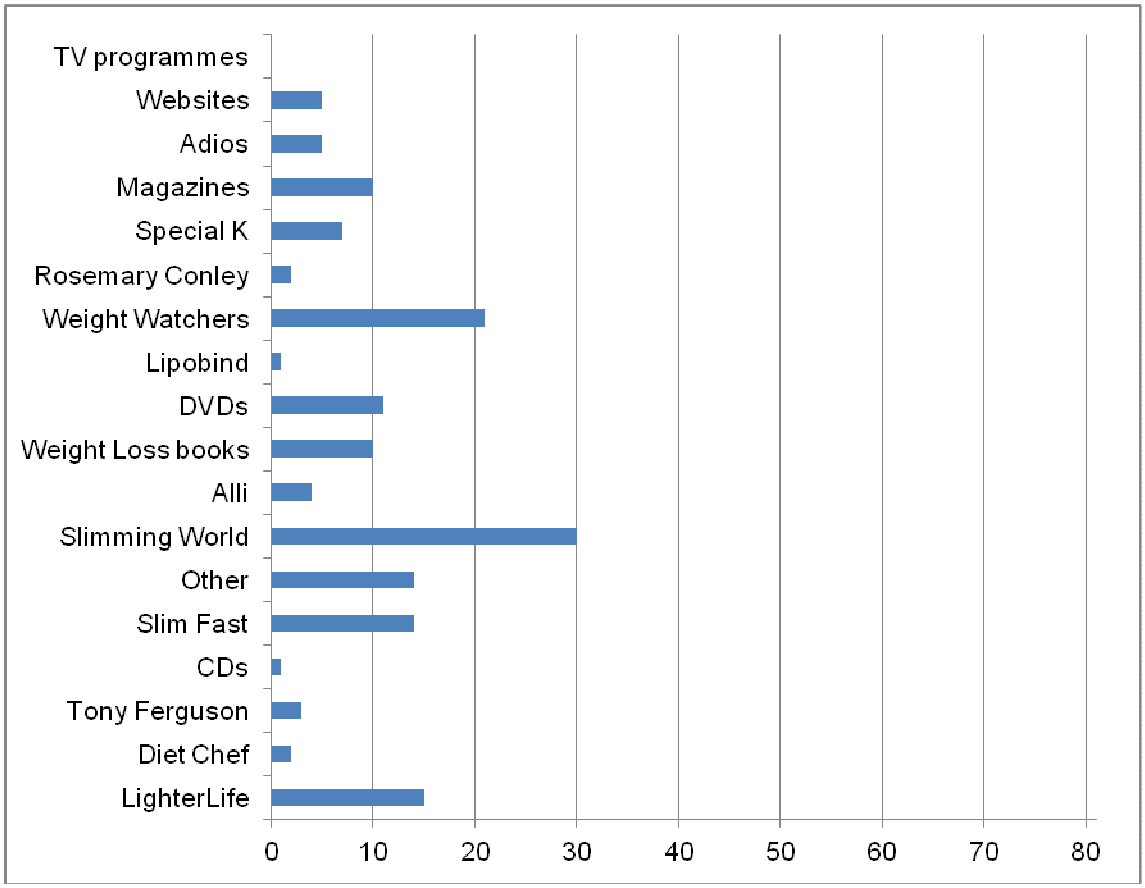


Figure 16: Popularity of CWLPS n=81

The most popular CWLPS amongst survey participants (n=81) was Slimming World (n=30), followed by Weight Watchers (n=21), LighterLife (n=15), Slim Fast (n=14), Other (n=14), DVDs (n=11), Weight Loss books (n=10),Magazines (n=10), Special K (n=7), Adios (n=5), Websites (n=5), Alli (n=4), Tony Ferguson (n=3),Diet Chef(n=2), Rosemary Conley (n=2), CDs (n=1), Lipobind (n=1), and TV programmes (n=0).

Others included Cambridge weight plan (n=6), Tesco ultra slim replacement (n=1), flabelouse machine (n=1), actislim ultra tablets (n=1), all about w8 (n=1), The Zoe Harcombe Diet (n=1), weight watchers meals (n=1), Paul McKenna (n=1), phentermine at slimming clinic (n=1).

Figure 16 shows the popularity of CWLPS chosen by survey participants. Slimming World and Weight Watchers were the favoured CWLPS. In addition to looking at the popularity of CWLPS, I also assessed whether there were any participants who had used a combination of CWLPS, and if there were any participants who had only used one CWLPS. Less than half of the participants (n=37) used a combination of CWLPS over a 12 month period. For those who used only one CWLPS (n=44), this equated to an average spend of £250.42 per participant, while those who used a combination of CWLPS spent more overall, on average £566.89 per participant.

Table 13: CWLPS cost per week and suggested duration of the course

CWLPS	Cost per week	Suggested length of the course
Slimming World	£9.95	Until goal weight is reached
Weight Watchers	£5.50	Until goal weight is reached
LighterLife	£74.00	Until goal weight is reached
Rosemary Conley	£5	Until goal weight is reached
Diet Chef	£47.53	unknown
Tony Ferguson	£33.39	Unknown
Alli	£8.74	Unknown
Slim Fast	£21.70	Unknown
Special K	£2.69	Unknown
Lipobind	£5.69	Unknown
Adios	£2.43	Unknown
Weight Loss book(s)	£7.69 based upon the top selling weight loss book from Amazon (I Can Make You Thin by Paul McKenna)	Unknown
DVD(s)	£7.44 based upon the top selling weight loss DVD from Amazon (Yoga For Weight Loss for Beginners DVD ~ Maggie Rhoades)	Unknown
Magazine(s)	£2.54	Unknown
Website(s)	free	Unknown
TV Programmes	free	Unknown
CD(s)	£24.99 based upon customer rating from Amazon (Virtual Gastric Band Hypnosis - Lose Weight Fast!)	Unknown
Other Cambridge weight plan Tesco ultra slim replacement The Zoe Harcombe Diet Flabelouse machine Actislim ultra tablets Phentermine at slimming clinic All about W8 Weight Watchers meals Paul McKenna	 £44.10 £2.57 £1.49 £20.83 £14.95 £9.83 £49 £56.00 £9.99	Unknown

Table 14: Rank ordering of CWLPS according to cost and popularity

CWLPS rank by cost (highest to lowest)	Rank by popularity (most to least popular)
LighterLife	Slimming World
Diet Chef	Weight Watchers
Tony Ferguson	LighterLife
CDs	Slim Fast
Slim Fast	Other
Other	DVDs
Slimming World	Weight Loss books
Alli	Magazines
Weight Loss books	Special K
DVDs	Adios
Lipobind	Websites
Weight Watchers	Alli
Rosemary Conley	Tony Ferguson
Special K	Diet Chef
Magazines	Rosemary Conley
Adios	CDs
Websites	Lipobind
TV programmes	TV programmes

TV programmes was the only CWLPS that matched according to ranking of cost and popularity. The most popular CWLPS amongst survey participants was Slimming World; however, this CWLPS was ranked as 7th according to cost.

Further analysis was undertaken in relation to the most popular CWLPS; Slimming World. The total (of all participants) duration which this product was taken (6488 days) and accounted for 24.8% of overall CWLPS usage (26143 days), though it only accounted for 10% of the total money which the participants spent on CWLPS during the survey period (£34129.58). Survey

Participants spent a considerable amount of time using CWLPS; equating to 71.8 years.

If one groups the different CWLPS used by the participants into; programmes, weight loss tablets, meals, education, it is clear that programmes are the most popular (Table 15).

Table 15: Duration and cost of CWLPS

CWLPS	**Total duration (days)**	**Total cost (£)**
Programmes (Slimming World, Weight Watchers, LighterLife, Rosemary Conley, Diet Chef, Tony Ferguson	14241	28848.54
Weight loss tablets (Alli, Lipobind, Adios)	434	630.00
Meals (Slim Fast, Special K,	1355	999.14
Education (Weight Loss book(s), DVD(s),Magazine(s),Website(s),CD(s)	8222	1429.42
Others Cambridge weight plan, Tesco ultra slim replacement, The Zoe Harcombe Diet, Flabelouse machine , Actislim ultra tablets, Phentermine at slimming clinic, All about W8, Weight Watchers meals, and Paul McKenna	1891	2204.48

Of those 44 participants who used only one CWLPS, 19 used Slimming World and eight used Weight Watchers. One of the aims of my research was to try and find out why some CWLPS were more popular than others.

5.2.6 Age; Survey response and CWLPS choices

Figure 17 shows the profile of age for the participants who took part in the survey.

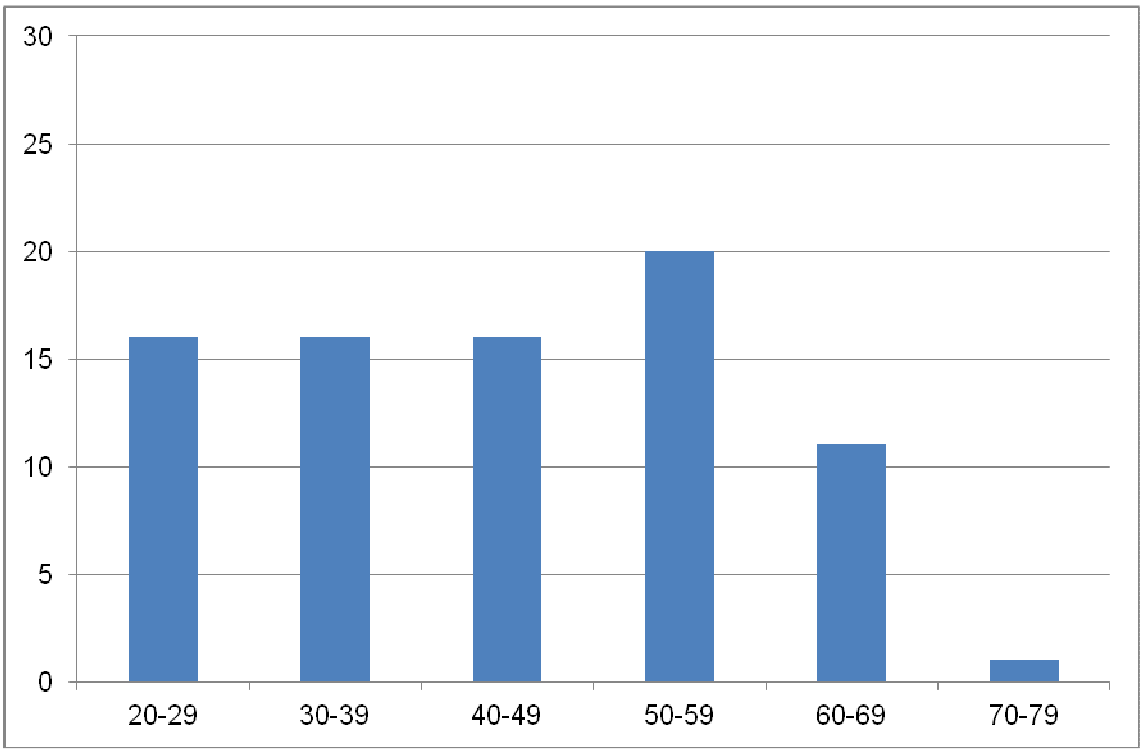


Figure 17: A bar chart showing the age distribution of participants of the survey

The use of CWLPS varied by age in the participants of the survey; 16% of the participants who were in their 20's had only used one (rather than a combination of) CWLPS in the previous year, compared with 62% of those in their 50's.

Table 16: Total cost of CWLPS bought by 20-29 year olds (n=16), and 50-59 year olds (n=21), in one year (between 2010 and 2011)

	Cost Range (mean)	
20-29year olds	£25.00-£397.00	(£144.40p)
50-59 year olds	£49.50-£3717.48	(£578.90p)

Participants in their 20's spent less on CWLPS, compared with those in their 50's; £144.40 vs. £578.90, respectively.

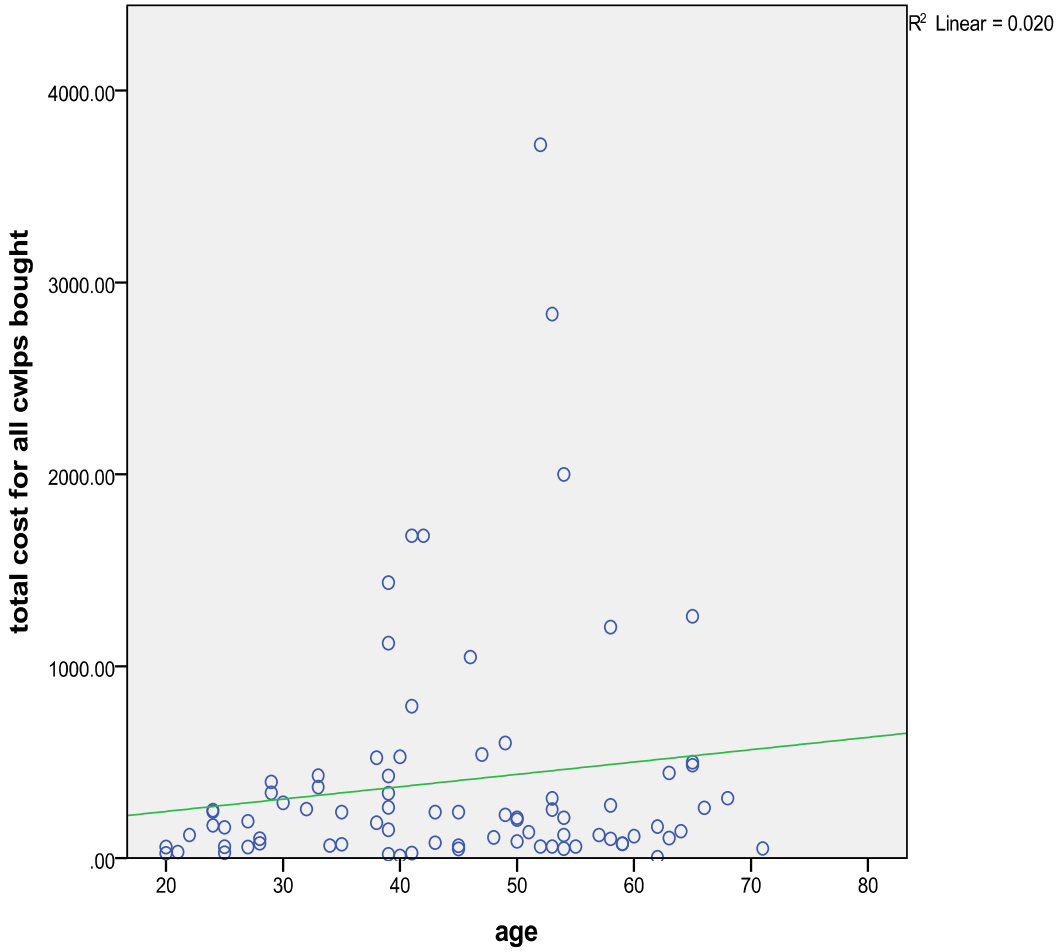


Figure 18: A scatter plot to demonstrate the relationship between age and total cost of commercial weight loss products and services purchased (2010-2011) n=81

Although it appears that there is a positive relation between age and total cost of all CWLPS purchases, when looking at the statistics, there was no positive linear trend for age and CWLPS. The figure explains .020% (R^2) of the variability of the response data around its mean. Also when observing the output data, there was no significance shown (see appendix 44).

Table 17: Total duration (days) of CWLPS bought by 20-29 (n=16), and 50-59 year olds (n=21) from 2010-2011

	Range (mean)		Median
20-29year olds	14-1092.75	(361.8)	266
50-59 year olds	84-1120.75	(356.2)	364.25

Participants in their 50's spent more money on CWLPS, and used the CWLPS for a shorter amount of time, compared with participants in their 20's.

Table 18: Socioeconomic factors (IMD and household net income)

	Range (mean		Median
Lower layer super output (2010 data) index of multiple deprivation: range (mean)	3.03-68.72	(20.04)	16.43
Average annual household net income,(after housing costs)	£14560-£26520	(£20324.94)	19760

Table 18 illustrates participant's deprivation from IMD scores and their possible annual household net income (after housing costs). Mean IMD participant data shows that the population involved was not deprived, and the average household net income (after housing costs) for this sample of participants was higher than the median North East average household net income (after housing costs) of £17,004 (Office for National Statistics, 2012). On average participants spent 2.10% of their average annual income on CWLPS. (£34129.58/81=£421.40;£421.40/£20324.94*100=2.10%)

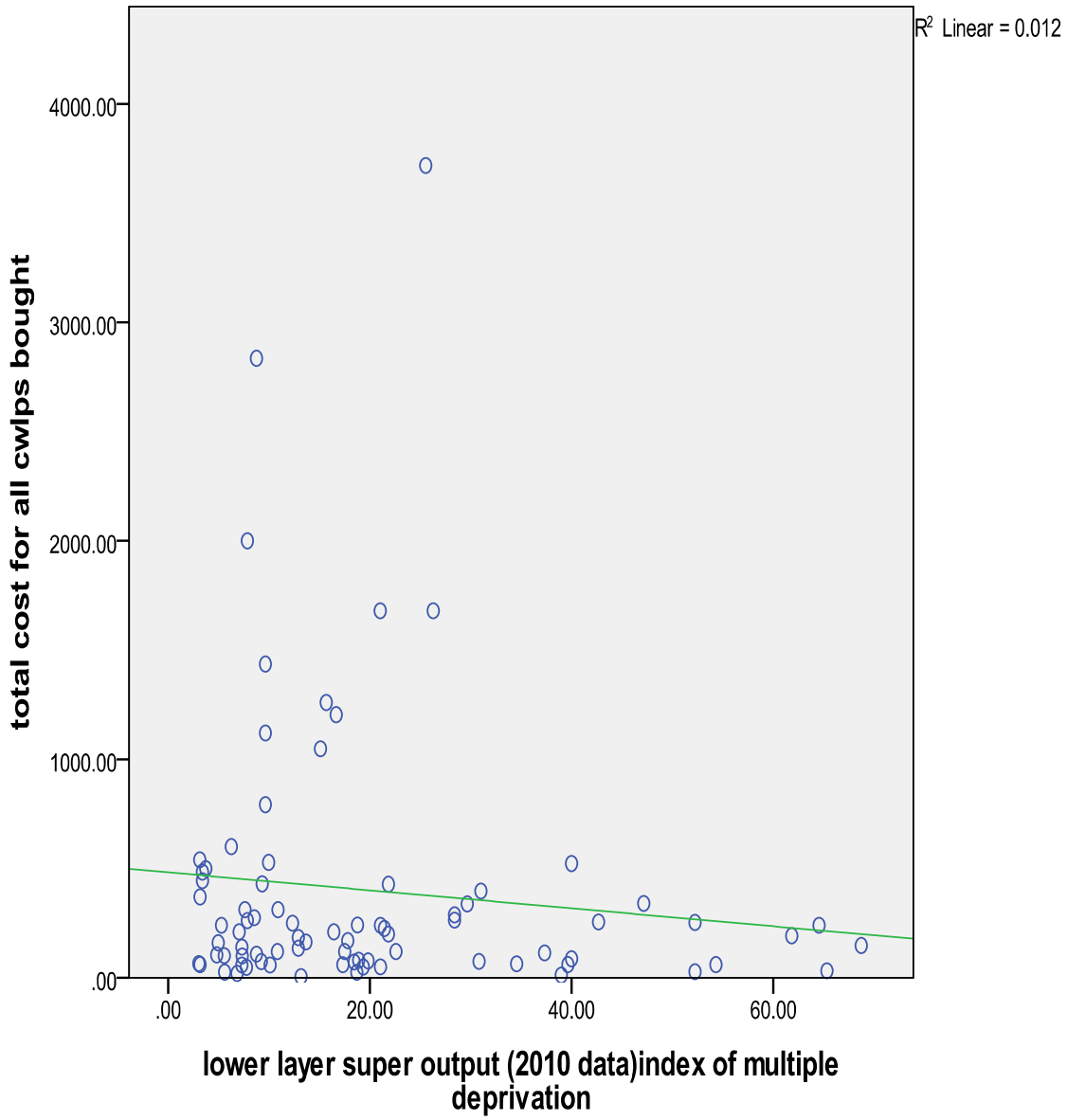


Figure 19: A scatter plot showing the relationship between IMD data, and total cost of CWLPS purchased (2010-2011) n=81

In general the higher the score within a domain the more deprived the SOA. Therefore, participants within this sample are not deprived, or very few would be classified as deprived.

Although it appears that there is a positive relation between age and total cost of all CWLPS purchases, when looking at the statistics, there was no positive linear trend for age and CWLPS. The figure explains .012% (R^2) of the variability of the response data around its mean. Also when observing the output data, there was no significance shown (see appendix 44).

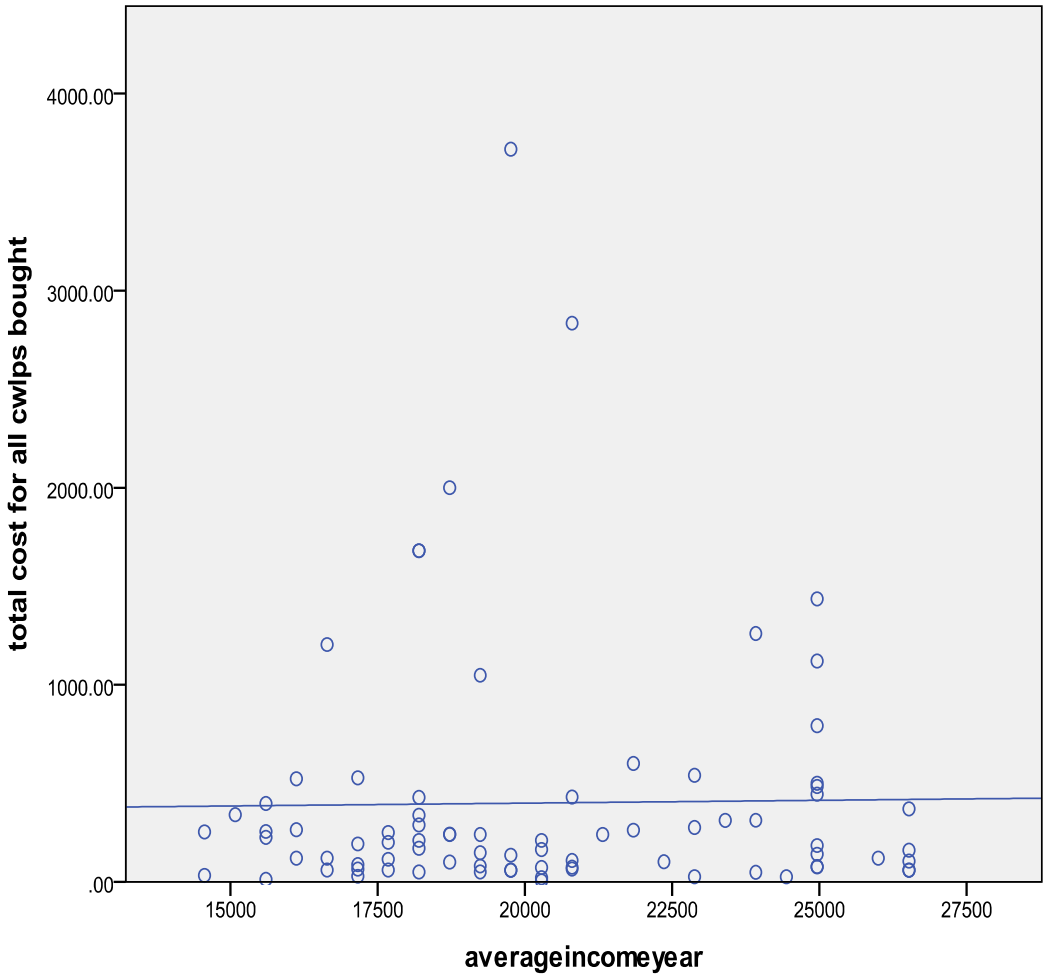


Figure 20: A scatter plot to show the relationship between Average Weekly Household Net Income Estimate, and total cost of commercial weight loss products and services purchased (2010-2011) n=81

Using household income data as a proxy for deprivation, rather than IMD, Figure 20 shows that there is no relationship between the amount of money a participant spent on CWLPS and household income data.

5.2.7 Summary

Weight loss programmes such as Slimming World and Weight Watchers were clearly the most popular CWLPS used by the participants in my survey. Saying that, there was a wide range of CWLPS used by the participants in my survey.

The survey clearly demonstrates that age plays an important part in relation to the purchase of CWLPS, especially between the ages of 20-29 and 50-59. The amount of money spent on CWLPS is significantly different between 20-29 year olds and 50-59 year olds; older participants spent more money on CWLPS. Also, older participants were more likely to choose just one CWLPS, rather than try different ones over a one-year period.

The analysis did not show any correlations between the amount of money a participant spent on CWLPS and the socioeconomic status of the participants, but this was primarily because there were very few participants in the survey who were deprived. Therefore, it was necessary to establish whether cost was an important factor in relation to a person's socioeconomic status through an additional piece of research exploration, the Q-methodology study.

5.3 Q-methodology analysis

5.3.1 Description of Study Sample

As previously described in 4.5.6, seven to twenty participants were involved at one or more stages of my Q-method study. Participants who had stated that they were happy for the researcher to contact them at a later date within their survey consent form (n=80, of 81) were sent information sheets (Appendix 20) and consent forms (Appendix 22) in the post, with a pre-paid envelope to be returned back to the researcher, and a registration form (Appendix 21) asking which venues (Durham University; Main campus, Durham University; Queens Campus, or Teesside University), and times (Monday;7-8pm, Wednesday; 2-3pm or Friday; 10-11am) would be most suitable for them. Participants also had the opportunity to state other times or venues. Twenty participants replied, stating where and when would be suitable for them to complete the Q-sorting exercise. This sample size was adequate enough to reveal underlying factors in relation to the reasons for choosing CWLPS.

Five subjects were male, and 15 were female. Subjects ranged in age from 21 to 65; the mean age of participants was 45 years. All subjects were identified as Caucasian (100%). Complete demographic information for can be found in Table 19.

Table 19: Sample (n=20) Q-methodology characteristics

	Mean (range)	
Age (years)	45 (21-65)	
	Frequency (%)	
Gender		
Male	5	(25%)
Female	15	(75%)
Ethnicity	20	(100%)
White		
Occupation		
Employed fulltime	11	(55%)
Employed part-time	1	(%)
Fulltime education	2	(10%)
Retired	3	(15%)
Self-employed	1	(5%)
Homemaker	1	(5%)
Other	1	(5%)
Marital status		
Co-habiting	5	(25%)
Married	8	(40%)
Divorced/separated	1	(5%)
Living with parents	1	(5%)
Single	3	(15%)
Other (widow)	2	(10%)
Highest level of educational achievement		
AS or A level	6	(30%)
Degree	2	(10%)
GCSE	2	(10%)
HNC or HND	1	(5%)
Other	2	(10%)
Postgraduate degree	4	(20%)
Secondary school	3	(15%)
Religion		
Christianity	12	(60%)
Buddhism	1	(5%)
Roman catholic	1	(5%)
Wiccan	1	(5%)
None	5	(25%)

Table 20: Socioeconomic data and CWLPS usage of participants who took part in the Q-method study

	Range (mean)	
Average Weekly Household Net Income (after housing costs)	£14,560 - £26,520	(£20,618)
IMD	3.14 - 65.31	(19.62)
CWLPS purchased	£28 - £1,260	(£321)
Duration of CWLPS purchased (days)	14 - 1121	(353)

5.3.2 Review of Methods

Key quotes in relation to the reasons why participants chose CWLPS were taken from focus groups and interviews to form statements. Prior to the commencement of the Q-sorting phase, the statements were piloted twice (see 4.5.8.4.2 and 4.5.8.4.3) for readability, overlapping purposes, and to try and reduce the amount of statements.

Individualized Q-Sorts were completed by 20 participants, who each rank-ordered the Q-Set statements according to how much they agreed or disagreed with the statements when thinking about their favoured CWLPS. Due to time constraints by the participants, face-to-face (n=12) and postal (n=8) Q sorts were required. Participants were asked to elaborate on her/his point of view, expanding on the most salient statements that were placed at both extreme ends of the continuum on the score sheet. This information was gathered via a Dictaphone, or written on the postal Q-sorts. This information was extremely helpful for the interpretation of factors.

5.3.3 Correlation matrix

The first step in the Q-analysis was to create a correlation matrix from the 20 Q-sorts, whereby each participant's sort was correlated with every other participant's sort (Table 21). A correlation matrix is essential in organising the data to identify the underlying dominant factors.

Table 21: Correlation Matrix Between Sorts

Sorts	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1	100	34	19	25	7	48	35	37	28	11	26	42	23	41	19	36	23	17	15	27
2	34	100	34	18	30	29	58	40	36	-16	11	15	33	37	42	21	39	17	16	37
3	19	34	100	38	34	18	49	59	23	-11	1	8	44	48	37	24	-8	2	45	-4
4	25	18	38	100	34	39	42	32	34	20	25	9	51	30	28	37	1	14	28	14
5	7	30	34	34	100	20	47	11	13	-17	19	6	32	6	11	9	-13	5	22	13
6	48	29	18	39	20	100	27	42	30	34	46	36	44	42	18	53	26	43	39	34
7	38	58	49	42	47	27	100	51	36	-8	16	25	62	43	46	18	16	14	41	12
8	37	40	59	32	11	42	51	100	48	-1	19	20	39	63	43	45	18	7	36	13
9	28	36	23	34	13	30	36	48	100	18	17	26	36	37	32	35	31	4	8	15
10	11	-16	-11	20	-17	34	-8	-1	18	100	27	19	1	11	-8	15	27	30	-8	-4
11	26	11	1	25	19	46	16	19	17	27	100	50	21	11	15	37	22	37	12	6
12	42	15	8	9	6	36	25	20	26	19	50	100	30	16	-4	27	22	27	31	-21
13	23	33	44	51	32	44	62	39	36	1	21	30	100	31	46	18	-2	8	56	7
14	41	37	48	30	6	42	43	63	37	11	11	16	31	100	33	34	29	27	37	13
15	19	42	37	28	11	18	46	43	32	-8	15	-4	46	33	100	10	5	17	18	10
16	36	21	24	37	9	53	18	45	35	15	37	27	18	34	10	100	32	36	10	23
17	23	39	-8	1	-13	26	16	18	31	27	22	22	-2	29	5	32	100	33	0	14
18	17	17	2	14	5	43	14	7	4	30	37	27	8	27	17	36	33	100	5	1
19	15	16	45	28	22	39	41	36	8	-8	12	31	56	37	18	10	0	5	100	11
20	27	37	-4	14	13	34	12	13	15	-4	6	-21	7	13	10	23	14	1	11	100

5.3.4 Interpretation of the correlation matrix between sorts

Table 21 shows all 20 Q-sorts and which participants show the agreement or disagreement between the factors; the closer the value to 100, the higher the agreement or disagreement between participant Q-sorts.

Q-sorts 8 and 14 show high agreement between the factor scores, Q-sorts 12 and 20 show a slight disagreement between the factor scores.

5.3.5 Factor analysis

The second step was to perform a factor analysis on the correlation matrix, using an unrotated factor matrix (Table 22), resulting in the identification of underlying factors, or clusters of groupings.

Table 22: Unrotated Factor Matrix

Sorts	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	Factor 7	Factor 8
1	0.5788	0.2339	0.1399	0.0218	0.1218	0.3402	-0.2263	0.0008
2	0.6115	-0.1656	0.4623	0.1698	0.4028	-0.1141	0.2020	-0.0279
3	0.5859	-0.4892	-0.1039	-0.2556	-0.1378	0.0382	0.1446	0.2837
4	0.5933	-0.0959	-0.2373	0.2016	-0.4591	-0.2385	-0.1271	0.0189
5	0.3701	-0.3576	-0.2562	0.5569	0.1379	-0.1777	-0.0520	0.3082
6	0.6994	0.3763	-0.1106	0.2319	-0.1749	0.2192	0.1223	-0.1243
7	0.7304	-0.3568	-0.0225	0.0456	0.2618	-0.1692	-0.0307	-0.0574
8	0.7342	-0.1587	0.1702	-0.3383	-0.1453	0.1431	-0.0448	0.1862
9	0.5807	0.0636	0.2201	-0.1781	-0.1085	-0.2548	-0.5314	-0.0398
10	0.1394	0.6193	-0.1783	-0.1212	-0.3709	-0.2622	-0.0483	-0.3037
11	0.4390	0.4828	-0.3421	0.2102	0.1602	-0.1221	-0.0360	0.1171
12	0.4370	0.3920	-0.4484	-0.1864	0.4722	0.1883	-0.2564	0.0144
13	0.6823	-0.3113	-0.3336	0.0346	-0.0065	-0.0781	-0.0666	-0.3478
14	0.6794	-0.0151	0.2196	-0.3592	-0.1344	0.1578	0.2329	0.0335
15	0.5212	-0.3081	0.1814	-0.1236	0.0156	-0.4075	0.1871	-0.2049
16	0.5678	0.3810	0.0981	0.0639	-0.2576	0.1128	-0.0151	0.4667
17	0.3388	0.5073	0.4336	-0.1295	0.2658	-0.1264	0.0299	-0.0986
18	0.3582	0.5153	-0.0734	0.0587	0.1216	-0.2573	0.5956	0.0973
19	0.5218	-0.2803	-0.3623	-0.0534	0.0288	0.4371	0.2219	-0.3070
20	0.2733	0.0212	0.5171	0.6194	-0.1967	0.2930	0.0016	-0.2190
Eigenvalues		5.9546	2.4660	1.6002	1.2973	1.1536	1.0687	0.9598
% expl.Var.		30	12	8	6	6	5	5

5.3.6 Varimax rotation

The third and fourth step was to conduct, using a computer-automated rotation, varimax, selecting which subjects to assign to each factor and how many factors to be considered for final analysis Table 23). Varimax produces the factor solution that maximizes the amount of variance explained on as few factors as possible. Varimax rotation was utilised. As a novice Q-methodologist, I felt that this analysis would be straightforward and transparent, and it is widely used in Q circles. I could not have used the second form of rotation in Q-methodology for this study; judgmental rotation. Judgemental rotation looks for confirmation of an idea or a theory, a theoretical rotation for an acceptable vantage point by statistical criteria (Van Exel & de Graaf, 2005). My research did not set out to confirm an idea or a theory in relation to CWLPS.

Various factor analyses and factor rotations were performed to identify the most powerful representation of factors. A four-factor solution was performed for this study; three and five factor solutions were also examined. This was determined by assessing the factor loadings for each sorter, and evaluated for statistical significance ($f > 0.33$, $p < 0.01$). Factor loadings for each Q-sorter using a three, four a five factor solution were examined using the formula $2.58(1/\sqrt{60})$. The auto flag feature within the Varimax option was used for subject selection, and to decide upon the final factor solution. Auto flagging of subjects is based on the rule that the rotated factor loadings must be significant at $p < 0.05$ and the subject must explain more than half of the common variance for that given factor.

After examining the data for factors three, four and five, I assessed which solution uncovered and revealed more insight into my research question.

5.3.7 Five factor solution

Upon assessment of correlations between factor scores, I felt that there was some commonalty between the factors (0.1381-0.4519). Ideally the correlation between factor scores should be low, to increase the confidence that the factors are more different than alike. Also, a significant number of participants were loading on multiple factors (n=6). Therefore, these participants would have required their Q-sort to be unflagged to sharpen the meaning and distinctiveness of the factor, and would not be included in the final analysis. However, after examining the unflagged solution, factor arrays and correlations between factor scores, I felt that the factors were not revealing significant reasons why participants' chose their favoured CWLPS.

5.3.8 Three factor solution

After examining the factor arrays, correlations between factor scores, and confounding Q-sorts, I felt that this solution was not sufficient in demonstrating the differences between the factors; correlations between factor scores were 0.2999-0.5164. Therefore, there were significant similarities between the factors. However, to account for confounding Q-sorts it would have been essential to unflag eight Q-sorts, to show clear distinctions among the factors. However, I was conscious of one particular participant who had the highest Q-sort loading on factor 4.This particular participant had chosen Slimming World

for men only, and I felt that this participant was unique and interesting, and therefore using a three factor solution would not highlight his views.

5.3.9 Four factor solution

This factor solution provided the most insight as to why people chose their favoured CWLPS, using 16 Q-sorts for the final analysis. Eight Q-sorts were confounding; however, four of these were far enough apart between the factors to not be considered as confounding (.1219-.3098). One Q-sort was unflagged as it was between one or more factors (there were a variety of reasons why this person chose their favoured product, or service. They did not have a clustering of reasons on one factor), and the remaining Q-sorts (n=3) were not included in the analysis as their confounding between factors was too high.

Before, finally deciding upon a four-factor solution, I also consulted Webler et al's (2009) Q-methodology study into environmental research, whereby a detailed explanation on deciding upon the final set of factors is given.

1. **Simplicity**: All else being equal, fewer factors are better, as it makes the viewpoints at issue easier to understand. Of course, simplicity should not be taken so far that you lose important and interesting information about differences in people's views.
2. **Clarity**: The best factor solution is one in which each sorter loads highly on one, and only one, factor. You should try to minimize the number of "confounders" (people who load on multiple factors) and "non-loaders" (people who do not load on any factor). If a few confounders persist, that indicates that those people have truly hybrid views.

3. **Distinctness**: Lower correlations between factors are better, as highly correlated factors are saying similar things. Nevertheless, it is not necessarily bad to have high correlations, as long as the factor is otherwise satisfactory. It may be that two factors agree on many issues, but their points of disagreement are particularly important (e.g. if they disagree about a remedy that is being proposed as the next step at your site).

4. **Stability**: As you compare the results of using different numbers of factors, you will notice certain groups of people tend to cluster together. This is an indicator that those individuals really do think similarly.

Table 23: Factor Matrix with an X Indicating a Defining Sort

	Loadings			
QSORT	1	2	3	4
1	0.0922	0.4382	0.4022	0.2180
2	0.1681	0.0492	0.5717	0.5352
3	0.4926	-0.1265	0.6145X	-0.1495
4	0.5598X	0.2767	0.2343	0.1151
5	0.7288X	-0.0165	-0.0594	0.3250
6	0.3138	0.6943X	0.2397	0.2423
7	0.5656	0.5670	0.5616	0.1572
8	0.2045	0.1465	0.8227X	-0.0730
9	0.0513	0.2603	0.5808X	0.1170
10	0.1768	0.6214X	-0.0516	-0.1713
11	0.2650	0.7163X	-0.0529	0.0309
12	0.2194	0.6345X	0.1309	-0.3355
13	0.7034X	0.1491	0.3934	-0.0560
14	0.0687	0.2270	0.7634X	-0.0012
15	0.2505	-0.0661	0.5777X	0.1188
16	0.0557	0.5703X	0.3217	0.2224
17	-0.3968	0.4683	0.3740	0.2457
18	-0.0118	0.6260X	0.0749	0.0712
19	0.5926X	0.0992	0.3077	-0.1708
20	0.0510	0.6700	0.0769	0.8445X
% expl.Var.	14	16	19	8

Table 23 illustrates four Q-sorts by factor 1, five by factor 2, four by factor 3, and one Q-sort by factor 4. The factor 4 solution accounted for 57% of the total variance (factor 1; 14%. factor 2; 16%, factor 3; 19% and factor 4; 8%).

Table 24: Correlations between Factor Scores

Correlations between Factor Scores

	1	2	3	4
1	1.0000	0.3291	0.4863	0.1517
2	0.3291	1.0000	0.3469	0.1027
3	0.4863	0.3469	1.0000	0.1364
4	0.1517	0.1027	0.1364	1.0000

5.3.10 Factor scores and arrays

After I had identified a four factor solution, each statement (see appendix 23) in the Q sample (n=60) were converted to z-scores via the Q-methodology software, and weighted so that the relative importance of each statement would be reflected in composite Q sorts representing the four factors. Webler, Danielson, and Tuler (2009) suggest that a Z-score is a good measure of salience, and allows the researcher to establish how far a statement lies from the middle of a distribution. For example a statement with a z-score of -1.408 is 1.408 standard deviations below the mid-point of the distribution. Based on their Z-scores, the statements were ranked within each factor from the strongest positive z-scores to the strongest negative z-scores, demonstrating an ideal or hypothetical Q-sort for each factor indicating the relative importance of each statement in the composite. Statements ranked in high disagreement (-5), and those ranked in high in agreement (+5) offered an insight into the reasons why participants chose their favoured CWLPS. A weighting of the appropriate sorts

elicits the factor arrays. An example of the resulting factor arrays for a three-factor solution (based on z-scores) can be found in Appendix 24.

Distinguishing statements also identified which statements distinguished the factors from one another, and aided the interpretation of the factors, and the consensus statements that are not distinguished amongst the factors.

5.3.10.1 Interpretation of the factors

5.3.10.1.1 Factor 1- "Effortless self-management".

The Q-sorts of 4 participants all showed statistically significant loadings on factor 1, all of whom had chosen different favoured CWLPS when conducting the Q-sort; LighterLife, Special K, Slim fast, and Weight Watchers online.

Proceeding tables demonstrate the highest and lowest ranked statements, as well as the highest ranked distinguishing statements with z-scores for Factor 1. The z-scores of statements are the normal distribution curve of each array turned on its side, resulting in a composite (or idealised) Q sort for each factor. Proceeding tables represent how a hypothetical respondent with a 100% loading on that factor would have ordered all the statements of the Q-set for factor 1. Hypothetical respondents of factor 1 would have chosen their favoured CWLPS based upon payment motivation, targets set by the individual and wanting the weight loss to be rapid too.

Participants represented in Factor 1 ranked the following statements as "+5"; statements that I agree why I chose my favoured CWLPS:

Table 25: +5 ranking of statements for factor 1

Number (ranking)	Statement	Z-scores
51 (+5)	I chose this CWLPS, as I wanted to lose weight quickly.	2.013
56 (+5)	I chose this CWLPS, as it looked easy to follow.	1.926
43 (+5)	I chose this CWLPS as I could set my own realistic weight loss target to aim for.	1.890

The following were ranked in factor 1 as "+4"; statements that I agree why I chose my favoured CWLPS:

Table 26: +4 ranking of statements for factor 1

Number (ranking)	Statement	Z-scores
28 (+4)	I chose to pay for this CWLPS, as I knew that paying for it would motivate me into losing weight.	1.588
38 (+4)	I chose to pay for this CWLPS because it is my responsibility to lose weight. If I do mess up, I fail.	1.585
60 (+4)	I chose this CWLPS based upon the endorsement from friends who had successfully tried it themselves.	1.466
48 (+4)	I chose this CWLPS based upon convenience.	1.436

At the other end of the composite Q sort array, Factor 1 participants placed these cards next to the positions marked "-5", statements which they disagreed were not based upon the reasons why they chose their favoured CWLPS.

Table 27: -5 ranking of statements for factor 1

Number (ranking)	Statement	Z-scores
7 (-5)	I chose this CWLPS as it was of a case of all or nothing.	-2.144
30 (-5)	I chose this CWLPS as it was the last resort for me.	-2.115
15 (-5)	I chose this CWLPS based upon the endorsement from celebrities who had successfully tried it themselves.	-1.408

The following were ranked in factor 1 as "-4", statements which they disagreed with were 'the opposite' of the reasons why they chose their favoured CWLPS.

Table 28: -4ranking of statements for factor 1

Number (ranking)	Statement	Z-scores
54 (-4)	54 I chose this CWLPS, as I did not want to talk about food at all.	-1.405
59(-4)	59 I chose this CWLPS, as I wanted the camaraderie from others who were also following the same CWLPS as me.	-1.242
10 (-4)	I chose this CWLPS, as it was particularly important for me to be with others in a group setting, which I could get from this CWLPS.	-1.203
46 (-4)	I chose this CWLPS, as I wanted to understand why I overeat so that I could change my relationship with food.	-1.203

Seven statements were distinguishing at $p<0.01$(Table 29). Therefore, statement scores on two factors have exceeded the difference score at $p<0.01$.

Table 29: Distinguishing statements for factor 1

Number	Statement	Rank	Z-scores
56	I chose this CWLPS, as it looked easy to follow.	+5	+5
41	I chose this CWLPS because I saw it advertised (online, TV, newspaper, radio).	+3	+3
12	I chose this CWLPS, as I wanted to buy the meals, and snacks provided by the commercial weight loss company that produces this CWLPS.	+3	+3
20	I chose this particular CWLPS as I thought it would encourage me to do new activities to help me lose weight (Great North Run, joining a gym).	+2	+2
49	I chose this CWLPS, as I did not want to try and lose weight with other people; I wanted to do it alone.	+1	+1
10	I chose this CWLPS, as it was particularly important for me to be with others in a group setting, which I could get from this CWLPS.	-4	-4
59	I chose this CWLPS, as I wanted the camaraderie from others who were also following the same CWLPS as me.	-4	-4

Table 30 demonstrates the consensus statements that were not distinguished amongst the factors at $p>0.01$, with respective z-score and ranking.

Table 30: Consensus statements for Factor 1

Number	Statement	Rank	Z-scores
11	I chose this CWLPS, as I wanted to be able to buy the products associated with this CWLPS (scales, books).	0	-0.23
15	I chose this CWLPS based upon the endorsement from celebrities who had successfully tried it themselves.	-5	-1.41
47	I chose this CWLPS as it would help me to maintain my weight loss.	3	1.30

Participants who subscribed to this factor chose their favoured CWLPS as it was simple, and it appeared that they had considered other others prior to choosing this CWLPS. The key statement that was distinguishing and also highly ranked (+5) amongst individuals who subscribed to "Effortless self-management" was in relation to the CWLPS's method of delivery:

(56) I chose this CWLPS, as it looked easy to follow.

5.3.10.1.2 Factor 1; Post-sort interviews

Qualitative data from the post-sort interviews strengthens the statements listed in the tables above, further explaining the reasons why the subscribers of this factor chose their favoured CWLPS.

5.3.10.1.3 Factor 1; Interpretation

Participant 20, 114 and 100 clearly explained their reasons why they placed statements 43, 56, and 51 at +5. Even though these were not distinguishing statements for this factor, it is apparent that these statements were the core

reasons for choosing their favoured CWLPS; they were also highly ranked and common in the factor arrays too.

"could motivate myself, I just wanted something as a guide really, so it let me set my target of what I wanted to lose, and I could chart it on a weekly basis, if I wanted too" (Participant 20: weight watchers online; statement 43; I chose this CWLPS as I could set my own realistic weight loss target to aim for.)

"Hectic lifestyle like most people seem to have these days, erm I'm working long hours, 12 hour shifts, sometimes split shifts, and things like that so it basically didn't need any extra decision making from myself in order to know what I was supposed to be eating….that's it you can't have anything else other than your black coffee or your water or whatever…your food packs you know" (Participant 114:LighterLife, statement 56; I chose this CWLPS, as it looked easy to follow.)

"diet is quick and easy. It doesn't involve any faffing around and is simple to pick up". (Participant 100: special k; statement 51: I chose this CWLPS, as I wanted to lose weight quickly.

Even though statements 30 and 7 were not distinguishing statements for this factor at -5, it is apparent that these statements were not the reasons why participants (114, 100 and 20) subscribing to this factor chose their favoured CWLPS; they were also highly ranked and common in the factor arrays too.

"I didn't think it was a last resort, I mean I'm fairly healthy anyway. If I wanted to do it that much and this wasn't available, then I would of just had to increase the exercise and decrease the calorie intake, this obviously was a little bit more extreme" (Participant 114:LighterLife; statement 30; I chose this CWLPS as it was the last resort for me.)

" to be honest I wasn't at an extreme of being massively overweight it was just wanting to nip it in the bud, I was a little bit overweight, so it wasn't a last resort" (Participant 20;weight watchers online; statement 7;I chose this CWLPS as it was of a case of all or nothing.)

5.3.10.2.1 Factor 2- Lifestyle adjustment counselling

The Q-sorts of 6 participants all showed statistically significant loadings on factor 2, 5 of whom had chosen a very-low calorie diet (LighterLife & Cambridge diet), only one person was the exception to the choice of CWLPS for factor 2;weight watchers.

Proceeding tables demonstrate the highest and lowest ranked statements, as well as the highest ranked distinguishing statements with z-scores for Factor 2. The z-scores of statements are the normal distribution curve of each array turned on its side, resulting in a composite (or idealised) Q sort for each factor. Proceeding tables, represent how a hypothetical respondent with a 100% loading on that factor would have ordered all the statements of the Q-set for factor 2. Hypothetical respondents of factor 2 would have chosen their favoured

CWLPS based upon rapid weight loss, being healthier, and maintenance advice after discontinuing with the CWLPS.

Participants represented in Factor 2 ranked the following statements as "+5"; statements that I agree why I chose my favoured CWLPS:

Table 31: +5 ranking of statements for factor 2

Number (ranking)	Statement	Z-scores
51 (+5)	I chose this CWLPS, as I wanted to lose weight quickly.	2.197
21 (+5)	I chose this CWLPS as I wanted to be healthier - improving my appearance was not the main reason for choosing this particular CWLPS.	1.870
52(+5)	I chose this CWLPS, as I wanted the 'coping/rebound' advice after I came off the CWLPS.	1.725

The following were ranked in factor 2 as "+4"; statements that I agree why I chose my favoured CWLPS.

Table 32: +4 ranking of statements for factor 2

Number (ranking)	Statement	Z-scores
53 (+4)	I chose this particular CWLPS because I hoped the counselling would help me get to the root cause of why I overeat.	1.533
47 (+4)	I chose this CWLPS as it would help me to maintain my weight loss.	1.414
3 (+4)	I chose this CWLPS as I wanted something where there was a consistent guide to weight loss that did not change, which I could get from this CWLPS.	1.383
60 (+4)	I chose this CWLPS based upon the endorsement from friends who had successfully tried it themselves.	1.366

At the other end of the composite Q sort array, Factor 2 participants placed these cards next to the positions marked "-5", statements which they disagreed were not based upon the reasons why they chose their favoured CWLPS.

Table 33: -5 ranking of statements for factor 2

Number (ranking)	Statement	Z-scores
14 (-5)	I chose this CWLPS, as I wanted to be able to compare my progress with others who were also using the same CWLPS as me.	-0.673
11 (-5)	I chose this CWLPS, as I wanted to be able to buy the products associated with this CWLPS (scales, books).	-0.533
13 (-5)	I chose this CWLPS, as I was aware that it would provide me with the element of competition about weight-loss between others who were also using the same CWLPS as me.	-0.514

The following were ranked in factor 2 as "-4", statements which they disagreed were not based upon the reasons why they chose their favoured CWLPS.

Table 34: -4 ranking of statements for factor 2

Number (ranking)	Statement	Z-scores
49 (-4)	I chose this CWLPS, as I did not want to try and lose weight with other people; I wanted to do it alone.	-0.497
28(-4)	I chose to pay for this CWLPS, as I knew that paying for it would motivate me into losing weight.	-0.416
16 (-4)	I did not choose this CWLPS based upon the endorsement from other people (group leaders and case studies of 'real life' people) who had successfully tried it themselves.	-0.411
41 (-4)	I chose this CWLPS because I saw it advertised (online, TV, newspaper, radio).	-0.367

Seven statements were distinguishing at p<0.01(Table 35). Therefore, statement scores on two factors have exceeded the difference score at p<0.01.

Table 35: Distinguishing statements for Factor 2

Number	Statement	Rank	Score
52	I chose this CWLPS, as I wanted the 'coping/rebound' advice after I came off the CWLPS.	5	1.73
53	I chose this particular CWLPS because I hoped the counselling would help me get to the root cause of why I overeat.	4	1.53
46	I chose this CWLPS, as I wanted to understand why I overeat so that I could change my relationship with food.	3	1.22
30	I chose this CWLPS as it was the last resort for me.	3	1.13
40	I chose this CWLPS to lose weight for an event (wedding, holiday etc.).	0	-0.23
39	I chose this CWLPS as someone suggested that I could do with losing some weight.	-2	-0.77
22	I chose this CWLPS, as I was aware that it would not be a massive lifestyle change in following it.	-4	-1.24

Table 36 demonstrates the consensus statements that were not distinguished amongst the factors at p>0.01, with respective z-score and ranking.

Table 36: Consensus statements for Factor 2

Number	Statement	Rank	Z-scores
11	I chose this CWLPS, as I wanted to be able to buy the products associated with this CWLPS (scales, books).	-1	-0.57
15	I chose this CWLPS based upon the endorsement from celebrities who had successfully tried it themselves.	-5	-1.45
47	I chose this CWLPS as it would help me to maintain my weight loss.	4	1.41

Participants who subscribed to this factor chose their favoured CWLPS based upon core counselling techniques, used for behaviour cognitive therapy. The key statement that was distinguishing and also highly ranked (+5 and +4) amongst individuals who subscribed to “lifestyle adjustment counselling” was in relation to the CWLPS’s cognitive behaviour therapy techniques:

52) I chose this CWLPS, as I wanted the ‘coping/rebound’ advice after I came off the CWLPS.

53) I chose this particular CWLPS because I hoped the counselling would help me get to the root cause of why I overeat.

5.3.10.2.2 Factor 2; Post-sort interviews

Qualitative data from the post-sort interviews strengthens the statements listed in the tables above, further explaining the reasons why the subscribers of this factor chose their favoured CWLPS.

5.3.10.2.3 Factor 2; Interpretation

Participants 109, 11, 0, 57 and 110 clearly explained their reasons why they placed statements 51, 21, and 52 at +5. Even though these were not distinguishing statements for this factor, it is apparent that these statements were the core reasons for choosing their favoured CWLPS; they were also highly ranked and common in the factor arrays too.

"I think when you are very obese, I mean I was about five stones overweight, and you know and I got to the stage, because it's a big decision to make because it is a lot of money, and I thought right I'm going to crack this and it does come off quickly, and you get lots of compliments pretty quickly because people are seeing the results and your clothes are fitting, and you think 'oh yes' I'll keep going here". (Participant 0; LighterLife: statement 51 I chose this CWLPS, as I wanted to lose weight quickly).

LighterLife participant 57 chose this product, as they wanted the 'coping/rebound' advice after they came off the CWLPS to

"Nail it" for the "long lasting effect"

Participant 11, was an interesting subscriber, as they believed that all statements fell below the +5 column when Q-sorting. Therefore, even though this participant had a significant loading onto this factor, I am wary of their data, due to their postal explanation of the placement of +5 and -5 statements.

"Most of the question warrant answering correctly and most of all the answers were truly below 5+"

Even though statements 14,11 and 13 were not distinguishing statements for this factor at -5, it is apparent that statement 13 was not one of the reasons why participants (109, 110 and 0) subscribing to this factor chose their favoured CWLPS; they were also common in the factor arrays too.

Participants (110,109 and 0) did not choose their CWLPS based upon an element of competition (statement 13 I chose this CWLPS, as I was aware that it would provide me with the element of competition about weight-loss between others who were also using the same CWLPS as me), this was one of the key factors that did not interest the subscribers to factor 2

"you need an element of competition, sometimes it can be counterproductive really, if someone's losing weight faster than you, and if someone's not losing it, and all you think, well all you think is she's not doing it properly or the persons not doing it properly". (Participant 110; LighterLife).

"Not interested in competition about weight loss, it's about myself, my own targets my own health, competition not an issue whatsoever." (Participant 109; LighterLife)

"No, that wasn't there, not at all" (Participant 0; Cambridge diet)

5.3.10.3.1 Factor 3- Celeb support

The Q-sorts of five participants all showed statistically significant loadings on factor 3, five of whom had chosen a programme based commercial weight loss intervention (Weight Watchers and Slimming World).

Proceeding tables demonstrate the highest and lowest ranked statements, as well as the highest ranked distinguishing statements with z-scores for Factor 3. The z-scores of statements are the normal distribution curve of each array turned on its side, resulting in a composite (or idealised) Q sort for each factor. Proceeding tables represent how a hypothetical respondent with a 100% loading on that factor would have ordered all the statements of the Q-set for factor 3. Hypothetical respondents of factor 3 would have chosen their favoured CWLPS based the support given from this CWLPS, maintenance, and knowing that choosing the CWLPS would not affect their lifestyle.

Participants represented in Factor 3 ranked the following statements as "+5"; statements that I agree why I chose my favoured CWLPS.

Table 37: +5 ranking of statements for factor 3

Number (ranking)	Statement	Z-scores
6 (+5)	I chose this CWLPS, as I knew it would give me the support that I needed in assisting me to lose weight.	1.766
47(+5)	I chose this CWLPS as it would help me to maintain my weight loss.	1.595
22 (+5)	I chose this CWLPS, as I was aware that it would not be a massive lifestyle change in following it.	1.547

The following were ranked in factor 2 as "+4"; statements that I agree why I chose my favoured CWLPS.

Table 38: +4 ranking of statements for factor 3

Number (ranking)	Statement	Z-scores
3 (+4)	I chose this CWLPS as I wanted something where there was a consistent guide to weight loss that did not change, which I could get from this CWLPS.	1.434
1 (+4)	I chose this CWLPS, as I wanted a better choice of clothes that I would be able to buy, in losing weight from this particular CWLPS.	1.332
57 (+4)	I chose this CWLPS, as I wanted regular weigh-ins.	1.299
43 (+4)	I chose this CWLPS as I could set my own realistic weight loss target to aim for.	1.247

At the other end of the composite Q sort array, Factor 2 participants placed these cards next to the positions marked "-5", statements which they disagreed were not based upon the reasons why they chose their favoured CWLPS.

Table 39: -5 ranking of statements for factor 3

Number (ranking)	Statement	Z-scores
45 (-5)	I chose this CWLPS, as I wanted advice from celebrities to help me make better choices.	-1.994
39 (-5)	I chose this CWLPS as someone suggested that I could do with losing some weight.	-1.780
4 (-5)	I chose this CWLPS, as I did not want to get to the stage whereby I would be needing weight-loss surgery.	-1.610

The following were ranked in factor 2 as "-4", statements which they disagreed were not based upon the reasons why they chose their favoured CWLPS.

Table 40: -4 ranking of statements for factor 3

Number (ranking)	Statement	Z-scores
15 (-4)	I chose this CWLPS based upon the endorsement from celebrities who had successfully tried it themselves.	-1.522
29 (-4)	I chose this CWLPS as I thought it would be more socially accepted amongst my peers.	-1.485
7 (-4)	I chose this CWLPS as it was of a case of all or nothing.	-1.419
30 (-4)	I chose this CWLPS as it was the last resort for me.	-1.366

Three statements were distinguishing at $p<0.01$(Table 41). Therefore, statement scores on two factors have exceeded the difference score at $p<0.01$.

Table 41: Distinguishing statements for factor 3

Number	Statement	Rank	Z-scores
42	I chose this CWLPS as I thought it would help me to give my family a healthier diet too.	2	0.78
39	I chose this CWLPS as someone suggested that I could do with losing some weight.	-5	-1.78
45	I chose this CWLPS, as I wanted advice from celebrities to help me make better choices.	-5	-1.99

Table 42 demonstrates the consensus statements that were not distinguished amongst the factors at $p>0.01$, with respective z-score and ranking.

Table 42: Consensus statements for Factor 3

Number	Statement	Rank	Z-scores
11	I chose this CWLPS, as I wanted to be able to buy the products associated with this CWLPS (scales, books).	-2	-0.53
15	I chose this CWLPS based upon the endorsement from celebrities who had successfully tried it themselves.	-4	-1.52
47	I chose this CWLPS as it would help me to maintain my weight loss.	5	1.60

The key statement that was not distinguishing but was highly ranked (+5) amongst individuals who subscribed to celeb support was in relation to the changes that were required to their lifestyle:

22) I chose this CWLPS, as I was aware that it would not be a massive lifestyle change in following it.

5.3.10.3.2 Factor 3; Post-sort interviews

Qualitative data from the post-sort interviews strengthens the statements listed in the tables above, further explaining the reasons why the subscribers of this factor chose their favoured CWLPS.

5.3.10.3.3 Factor 3; Interpretation

Participants 67 and 51 clearly explained her reasons why they placed statement 22 at +5. Even though these were not distinguishing statements for this factor, it is apparent that these statements were the core reasons for choosing their favoured CWLPS, were also highly ranked and common in the factor arrays too.

"it was more or less a normal way of eating, you just needed to be more aware of how much…your quantities really" "its just being organised really, and having a bit more of a plan of what I'm going to eat, and generally it tends to work" (Participant 67)

Slimming world participant 51 did not clearly explain why they ranked statement 22 so highly (+5), however, they did clearly justify the placement of statements 6 (+5) and 3 (+4).

*"The diet was straightforward (not counting calories) rather eating a lot of a wide range of foods. The support from slimming world was vital in the first months. Now it is second nature though. I enjoy the food and have kept to the healthy eating plan. My tastes have changed completed e.g. I actually crave fruit when hungry" (*Slimming world; participant 51)

Participant 11, was an interesting subscriber, as they believed that all statements fell below the +5 column when Q-sorting. Therefore, even though this participant had a significant loading onto this factor, I am wary of their data, due to their postal explanation of the placement of +5 and -5 statements.

""Most of the question warrant answering correctly and most of all the answers were truly below 5+"

Statements 39 and 45 were distinguishing statements for this factor at -5, and were also common in the factor arrays too. In relation to the z-scores of statements 45 and 39, statement 45 was -1.99, 1.99 standard deviations below the mid-point of the distribution, and statement 39 was -1.78, 1.78 standard deviations below the mid-point of the distribution. Based upon the rank ordering of these statements (Table 41), participants did not choose their favoured CWLPS based upon celebrity advice, or someone telling them that they needed to lose weight.. Typically, a celebrity does not offer advice for a CWLPS, a celebrity will endorse a CWLPS after their success and how they stuck to the CWLPS. Celebrities would not give advice that was not related to the CWLPS. However, subconsciously, a participant could have purchased their favoured CWLPS, based upon the advertising of the CWLPS via a celebrity's success.

Participants (67, 92 and 51) did not choose their CWLPS due to someone saying that they needed to lose weight (statement 39; I chose this CWLPS as someone suggested that I could do with losing some weight). Also celebrity endorsement was not a factor for participant 88 in choosing their favoured CWLPS (statement 45; I chose this CWLPS, as I wanted advice from celebrities to help me make better choices.)

"No one suggested I needed to lose weight" (Participant 51; statement 39; I chose this CWLPS as someone suggested that I could do with losing some weight).

"Nobody's told me I need to lose some, but maybe in the past someone should have "(Participant 67; statement 39; I chose this CWLPS as someone suggested that I could do with losing some weight).

*"No one's ever said that to me in my life, because I would kill them *laughs ".* (Participant 92; statement 39; I chose this CWLPS as someone suggested that I could do with losing some weight).

"That's the least its more about my healthy, and how I look and buying nice clothes" CWLPS" (Participant 88; statement 45; I chose this CWLPS, as I wanted advice from celebrities to help me make better choices.)

5.3.10.4.1 Factor 4- Men don't get help

The Q-sorts of 1 participant showed a high statistically significant loading on factor 4 (0.8445), choosing Slimming World for men.

Proceeding tables demonstrate the highest and lowest ranked statements, as well as the highest ranked distinguishing statements with z-scores for Factor 4. The z-scores of statements are the normal distribution curve of each array

turned on its side, resulting in a composite (or idealised) Q sort for each factor. Proceeding tables represent how a hypothetical respondent with a 100% loading on that factor would have ordered all the statements of the Q-set for factor 4. Hypothetical respondents of factor 4 would have chosen their favoured CWLPS based upon it being gender specific, being healthier, and the GP being of little assistance in relation to losing weight.

Participants represented in Factor 4 ranked the following statements as "+5"; statements that I agree why I chose my favoured CWLPS.

Table 43: +5 ranking of statements for factor 4

Number (ranking)	Statement	Z-scores
21 (+5)	I chose this CWLPS as I wanted to be healthier - improving my appearance was not the main reason for choosing this particular CWLPS.	1.835
27 (+5)	I chose this CWLPS, as my GP was not helpful in providing any weight loss advice.	1.835
50 (+5)	I chose this CWLPS as it was gender specific (men only or women only).	1.835

The following were ranked in factor 2 as "+4"; statements that I agree why I chose my favoured CWLPS.

Table 44: +4 ranking of statements for factor 4

Number (ranking)	Statement	Z-scores
6 (+4)	I chose this CWLPS, as I knew it would give me the support that I needed in assisting me to lose weight.	1.468
18 (+4)	I chose to use this particular CWLPS because I could see other people (group leaders and case studies of 'real life' people) who had been through the process themselves, and could understand what I was going through.	1.468
39 (+4)	I chose this CWLPS as someone suggested that I could do with losing some weight.	1.468
48 (+4)	I chose this CWLPS based upon convenience.	1.468

At the other end of the composite Q sort array, Factor 2 participants placed these cards next to the positions marked "-5", statements which they disagreed were not based upon the reasons why they chose their favoured CWLPS.

Table 45: -5 ranking of statements for factor 4

Number (ranking)	Statement	Z-scores
30 (-5)	I chose this CWLPS as it was the last resort for me.	-1.835
40 (-5)	I chose this CWLPS to lose weight for an event (wedding, holiday etc.).	-1.835
17 (-5)	I chose to use this particular CWLPS because I could see celebrities who had been through the process themselves and could understand what I was going through.	-1.835

The following were ranked in factor 2 as "-4", statements which they disagreed were not based upon the reasons why they chose their favoured CWLPS.

Table 46: -4 ranking of statements for factor 4

Number (ranking)	Statement	Z-scores
57 (-4)	I chose this CWLPS, as I wanted regular weigh-ins.	-1.468
24 (-4)	I did not chose this CWLPS because of seeing advertisements which showed lots of people who have succeeded from this CWLPS.	-1.468
42 (-4)	I chose this CWLPS as I thought it would help me to give my family a healthier diet too.	-1.468
37 (-4)	I chose this CWLPS to educate me about what exercise I was supposed to do.	-1.468

Five statements were distinguishing at $p<0.01$(Table 47). Therefore, statement scores on two factors have exceeded the difference score at $p<0.01$.

Table 47: Distinguishing statements for factor 4

Number	Statement	Rank	Z-scores
27	I chose this CWLPS, as my GP was not helpful in providing any weight loss advice.	5	1.84
50	I chose this CWLPS as it was gender specific (men only or women only).	5	1.84
18	I chose to use this particular CWLPS because I could see other people (group leaders and case studies of 'real life' people) who had been through the process themselves, and could understand what I was going through.	4	1.47
43	I chose this CWLPS as I could set my own realistic weight loss target to aim for.	-3	-1.10
40	I chose this CWLPS to lose weight for an event (wedding, holiday etc.).	-5	-1.84

Table 48 demonstrates the consensus statements that were not distinguished amongst the factors at $p>0.01$, with respective z-score and ranking.

Table 48: Consensus statements for Factor 4

Number	Statement	Rank	Z-scores
11	I chose this CWLPS, as I wanted to be able to buy the products associated with this CWLPS (scales, books).	-3	-1.10
15	I chose this CWLPS based upon the endorsement from celebrities who had successfully tried it themselves.	-2	-0.73
47	I chose this CWLPS as it would help me to maintain my weight loss.	3	1.10

The only participant who subscribed to this factor chose their favoured CWLPS as it was gender specific. The key statements that was distinguishing and also highly ranked (+5) amongst this individual who subscribed to "Men don't get help" was in relation to negative experiences at a GP's, and it being for men only.

27) I chose this CWLPS, as my GP was not helpful in providing any weight loss advice.

50) I chose this CWLPS as it was gender specific (men only or women only).

5.3.10.4.2 Factor 4; Post-sort interviews

Qualitative data from the post-sort interviews strengthens the statements listed in the tables above, further explaining the reasons why the subscriber of this factor chose their favoured CWLPS.

5.3.10.4.3 Factor 4; Interpretation

Participant 1 clearly explained his reasons why they placed statements 50 and 27 at +5, which were also distinguishing statements for this factor, it is apparent that these statements were the core reasons for choosing their favoured CWLPS, were also highly ranked and common in the factor arrays too.

"I found that slimming world were the only ones that had done a gender specific class, aimed solely at men, and that's the reasons why I chose that product"

(Participant 1; statement 50 I chose this CWLPS as it was gender specific (men only or women only).

"When I saw my GP I got no help, and from the sleep clinic at James Cook, they just give you the machine and say get on with it, there is no advice with regards to diet, exercise things like that "

(Participant 1; statement 27; I chose this CWLPS, as my GP was not helpful in providing any weight loss advice.)

Distinguishing statement 40 for this factor at -5, was one of the reasons why participant 1 subscribing to this factor did not choose their favoured CWLPS, and were also common in the factor arrays too.

"It wasn't for a specific event; it was purely for health reasons"

(Participant 1; statement 40 I chose this CWLPS to lose weight for an event (wedding, holiday etc.).

5.3.11 Summary

The Q-methodology study identified a variety of reasons why the participants of my study chose purchase of CWLPS, and which CWLPS they chose to purchase.

Participants (n=4) of Factor 1 had chosen different favoured CWLPS when conducting the Q-sort; LighterLife, Special K, Slim fast, and Weight Watchers online. These CWLPS vary in price and method of delivery. If an ideal intervention was to be produced for the respondents of Factor 1, the key components of it would need to be a) ease of use, b) setting specific individuals targets, and b) quick weight loss. Realistically the NHS could commission a weight loss programme for respondents who load onto Factor 1.

The majority of participants of Factor 2 had chosen a very low-calorie diet (n=5); one had chosen a commercial weight loss programme that would be more suited to Factor 3 (weight watchers). Lighterlife and the Cambridge diet are 'high end' CWLPS, and known for rapid weight loss. If an ideal intervention was to be produced for the respondents of Factor 2, the key component of it would need to be a focus upon cognitive behaviour therapy techniques, specifically in relation to the maintenance advice after discontinuing with the CWLPS. These participants also wanted to be healthier, and to lose weight quickly. Realistically the NHS could not implement a weight loss programme that mirrors participant

loadings of Factor 2; counsellors trained in weight loss would be required, other health professionals would be required to ensure that the patient is in ketosis and that blood pressure is normal. As discussed in chapter 2 (2.10.4) rapid weight loss can lead to problems, including psychological distress which would require a psychologist to be involved if this intervention was utilised.

All participants of Factor 3 (n=5) had chosen a programme-based commercial weight loss intervention (Weight Watchers and Slimming World). If an ideal intervention was to be produced for the respondents of Factor 3, it would need to a) be support based, b) not involve a massive lifestyle, and c) factor in weight maintenance after discontinuation. Realistically the NHS already utilises this weight loss intervention in their 12 week referral schemes. Referral would only work for respondents that load onto Factor 3, a patient that wanted to lose weight quickly and did not want to talk about calories (Factor 2) would not benefit from referral to a commercial weight loss programme.

Only one participant loaded onto factor 4.However, this gentleman's loading onto factor 4 (0.8445X) was too high to ignore. This gentleman had chosen Slimming World for men as his favoured CWLPS. If an ideal intervention was to be produced for respondents that load onto Factor 4, the key component would be in relation to the intervention being delivered in single sex groups. Realistically the NHS could provide male only weight loss interventions through their 12 week referral scheme (Slimming World for men). Or another alterative option would be for the NHS to pay for individuals to use Weight Watchers

online, and to take baseline, end point and follow up measures to assess maintenance.

In relation to the Q-methodology study it is apparent that there is not one specific reason why the participants involved chose their favoured CWLPS. Dependent upon a person's circumstance, and how much weight they want to lose, delivery of the CWLPS, and what support they require varies from person to person. No two people sorted the statements identically, which further shows that there is not *one size that fits all.* There is a considerable number and range of CWLPS for people to choose from, each varying in cost and characteristics. However, unless the person chooses an intervention which includes the most important components which suit them, they are unlikely to comply with the diet and lose weight. My findings show that people are very different in what they want from a CWLPS, and perhaps that it why there are so many products and services available.

As a neophyte researcher I had assumptions about what I would find out from my study; I felt that marketing and cost would be the key features why participants chose their favoured CWLPS. However, my assumptions were proven incorrect, marketing and cost were not the key influencers for a person choosing their favoured CWLPS. I believe that marketing could have been one of the influencing factors for the choice of a participants CWLPS, though this was in the participant's subconscious. If marketing did not play a part in the choice of CWLPS, commercial weight loss companies would not spend so much on advertising their product/service. Commercial weight loss companies

know their consumers very well, and spend vast amounts of money on when (before Christmas, and before summer), and where (prime time TV and Groupon) to marketing their CWLPS. Cost was secondary, in the sense that participants felt that if they were paying for it, they would make the most out of it; it was a motivator. Again, I believe that cost was a factor in the choice of CWLPS, as a participant would not spend all of their monthly outgoings (mortgage, council tax, water, TV licence, gas, electric etc.) on a CWLPS, a participants would chose a CWLPS that would be within their budget.

In relation to health inequalities, it could be argued that the sample of Q-methodology participants (high SES) could afford to lose weight and look after their health, in comparison to lower SES individuals. However, this is an assumption, and not based upon evidence. Table 20 shows that the participants involved in the Q-methodology study spent on average 1.6% of their annual earnings on CWLPS alone, and spent 96.9% of their year using a CWLPS. As previously mentioned in 2.9.6, education plays an important role in relation to obesity prevalence, and also effects income. 60% of the participants involved in the Q-methodology study were in receipt of a postgraduate degree, degree or AS/A levels. However, it could be questioned why these individuals were using CWLPS, when research (Cutler and Lleras-Muney, 2006) suggests that additional schooling reduces the likelihood of obesity and overweight status. One can only assume that the individuals involved in the Q-methodology study gained their job prior to becoming overweight or obese, as their wage would be lower than it is, and they possibly would be able to afford CWLPS, and would not be involved in my research. As mentioned earlier in 2.8.2, an obese

person could suffer a wage penalty in the range of 0.7%-6.3% Baum and Ford (2004). Therefore, individuals in the Q-methodology study potentially could be using a CWLPS as they know that 'thinner' colleagues have a higher wage than them. However, I believe that that is not true as their average annual wage (£20,618 after housing costs) is £3614 higher than the North East average (Office for National Statistics, 2012).

Additional research amongst a variety of socioeconomic groups is required to establish whether cost influences the choice of CWLPS amongst high and low SES individuals.

5.4 Cochrane Review

5.4.1 Results of the search

The database searches for my review were conducted in September 2012. All hits were downloaded into Endnote on the 24th September 2012.

The results of my searches in different databases yielded 25,484 hits before de-duplication and 23,723 after de-duplication. I screened all titles of these hits, and 92 of them appeared relevant to the review. After assessing the abstracts of these 92 studies, I excluded 55 of them quite easily against my inclusion and exclusion criteria of my review. These studies were excluded because of the

type of participants (under 16), type of study design (not evaluations), or type of intervention (not using a CWLPS). I ordered full papers for the remaining 26 hits.

5.4.2 Excluded studies

After reading the full papers of 26 hits, I excluded 9 papers (Bye et al, 2005; Furlow et al, 2009; Goldstein et al,1996; Hamilton and Greenway, 2004; Hession et al, 2009; Hyman et al, 1993; Mycroft, 2008; Pallister et al, 2009; Tsai et al, 2005) against my inclusion and exclusion criteria for various reasons; the date of publication (before 1980), not a CWLPS (self-help), type of study design (not evaluations), and CWLPS focusing on other outcomes (not weight related).

I included 17 studies in my review (Anderson et al, 1991; Anderson et al, 1994a; Anderson et al, 1994b; Ditschuneit et al, 1999; Djuric et al, 2002; Gold et al, 2007; Gosselin and Cote, 2001; Heshka et al, 2003; Heshka et al, 2000; Jolly et al, 2011; Lowe et al, 2001; Morgan et al, 2008; Rippe et al, 1998; Rock et al, 2007; Rolland et al, 2009; Truby et al, 2006; Womble et al, 2004).

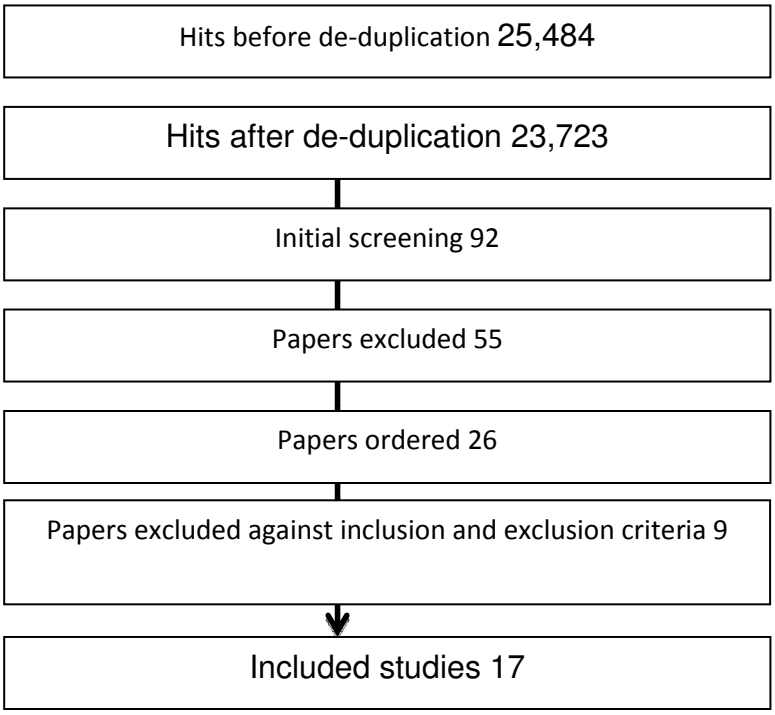


Figure 21: Flowchart of the selection process for included studies

5.4.3 Description of included studies

See Appendices 25-41 for a full description and summary of each of the 17 studies which were included in my review. The data extraction sheet which was used for my review (Appendix 42) was based on that which was recommended by Cochrane.

5.4.5 Risk of bias in included studies

The majority of studies had a high risk of bias, especially those which were funded by a commercial weight loss company. The majority of studies were RCT's (n=13); the other studies were controlled before and after studies (n=4).

5.4.6 Allocation and blinding

Due to the type of intervention assessed (CWLPS) all participants in the RCT'S knew which intervention they were assigned to and were not blind to the intervention. This is the case for most dietary intervention studies. However, it is possible to blind the outcome assessor for dietary intervention studies, and this should be done if at all possible. Only one study which I included in my review did this (Jolly et al, 2011). One study reported that participants were instructed not to mention their participation in the study to others (Heshka et al, 2000).

5.4.7 Drop out and compliance

Three CBA's (Anderson et al, 1994b; Gosselin and Cote, 2001; Lowe et al, 2001) did not list whether there had been any dropouts in their studies. In one RCT (Womble et al, 2004), a significant amount of participants dropped out of the study (65% in the ediets group and 67% in the LEARN group). Where drop out was reported, this ranged from 17.74%-94.3%. Three studies resulted in a >50% dropout rate; a CBA of a meal replacement drink (Anderson et al, 1991); a multicentre RCT with 5 arms - two commercial face to face weight loss groups (Weight Watchers and Rosemary Conley), a low carbohydrate diet (Atkins), a liquid meal replacement (Slimfast) and a control group (Morgan et al, 2008); and an RCT of a commercial internet weight loss programme (Womble et al, 2004).

In the multicentre RCT (Morgan et al, 2008) the highest dropout rate was observed in the Atkins group (81.8%) and the lowest dropout rate was observed in the weight watchers group (69%).

Anderson et al (1991) did not comment on the high dropout rate (51%) in their study.

One could argue that studies which include a high burden for the participant (for example in a lot of assessments being required during the study period) or studies which fail to engage with the participant (e.g. online programmes) may result in higher dropout rates. This will be discussed further in Chapter 6.

Womble et al's (2004) RCT of a commercial internet weight loss programme did report the reasons for drop out at 52 weeks (study end point). Participants in the ediet group dropped out due to family issues (n=1), and lack of interest/unknown (n=7). Participants in the LEARN group dropped out due to lack of interest/unknown (n=5), medical reasons (n=2), and family issues (n=1). However, this study did not report the reasons why dropout occurred at 16 weeks. It is unknown whether the participants dropped out as they were bored, had severe side effects (which is not reported) and were not able to continue with the programme, or whether the research team could not get in contact with the participants.

It is extremely important that studies report dropout rates. No study stated that anyone had died from using a CWLPS; however side effects were reported in

some studies, but not all. The reasons why dropout occurred is significant to any study, even more so in relation to the CWLPS that are prescribed on referral through the NHS (Slimming World/Weight Watchers). Studies that have used Weight Watchers and/or Slimming World as the intervention and not reported the reasons for dropout (Heshka et al, 2000; Heshka et al, 2003; Morgan et al, 2008) have shown that the intervention was effective in relation to weight loss. However, the dropouts of these studies could have had severe reactions to the diet, did not understand the diet, felt weight loss was not significant enough and stopped, or got tired of the intervention. Within studies of this nature, it is vital to report the differences between groups and reasons for drop out between the groups.

One study (Jolly et al, 2011) included a qualitative component to their study which provides some insight into reasons for dropout. Jolly et al's (2011) study team sent participants who had dropped out of their allocated programme an open ended question asking for their views about the weight loss programme to which they had been allocated, participants allocated (n=10) to Rosemary Conley reported difficulties with completing the exercise part of the classes due to arthritis and other musculoskeletal problems. Participants could have dropped out due to their physical problems.

5.4.8 Other factors which affect the quality rating of studies

5.4.8.1 Analysis

Only 35% of the studies included in my review used an intention to treat analysis.

5.4.8.2 Power

Only four studies reported the statistical power of their study, and how they calculated this (Heshka et al, 2003; Jolly et al, 2011; Rolland et al, 2009; Womble et al, 2004); two further studies reported that they had calculated statistical power, but did not provide any information on how they had calculated it (Morgan et al, 2008; Rock et al, 2007).

5.4.9 Funding source

Nine of the 17 included studies were funded by industry (Ditschuneit et al, 1999; Djuric et al, 2002; Heshka et al, 2000; Heshka et al, 2003; Morgan et al, 2008; Rippe et al, 1998; Rock et al, 2007; Rolland et al, 2009; Truby et al, 2006), seven of which were all or in part funded by a commercial weight loss company whose product was being researched (Ditschuneit et al, 1999; Djuric et al, 2002; Heshka et al, 2000; Heshka et al, 2003; Rippe et al, 1998; Rock et al, 2007; Rolland et al, 2009).

Table 49: Funding source

Study	Funding source
Anderson et al, 1991	Authors do not report this
Anderson et al, 1994a	Supported in part by Health Management Resources and the HCF Nutrition Research Foundation in Lexington, Kentucky.
Anderson et al, 1994b	Authors do not report this
Ditschuneit et al, 1999	Slim fast
Djuric et al, 2002	This study was supported in part by grant RO3 CA89761 from NIH, The Weight Watchers Group, Inc, Farmington Hills, Michigan, and the Ford Motor Company Fund.
Gold et al, 2007	This study was supported by U.S. Department of Agriculture Hatch Act Funds (Grant VT-NS-00,904)
Gosselin and Cote, 2001	Author do not report this
Heshka et al, 2000	Supported by a grant from the Weight Watchers Foundation.
Heshka et al, 2003	This study was supported by a grant from Weight Watchers International (Woodbury, NY) to the New York Obesity Research Center at St Luke's/ Roosevelt Hospital.
Jolly et al, 2011	The study was funded by NHS South Birmingham.
Lowe et al, 2001	Authors do not report this
Morgan et al, 2008	British Broadcasting Corporation
Rippe et al, 1998	Weight Watchers International.
Rock et al, 2007	This study was supported by Jenny Craig, Inc.
Rolland et al, 2009	LighterLife UK
Truby et al, 2006	British Broadcasting Corporation
Womble et al, 2004	Pilot Study Grant from the North American Association for the Study of Obesity (to Dr. Womble) and by NIH Grant K24-DK-065,018 (to Dr. Wadden).

Four studies did not report who funded their study (Anderson et al, 1994b; Anderson et al, 1991; Gosselin and Cote, 2001; Lowe et al, 2001).

Of interest, the studies which I included in my review which had the smallest (n=40; Anderson et al, 1994a) and the largest (n=1002; Lowe et al, 2001) sample sizes did not report who funded their research. The funding of an

evaluation of a CWLPS, by that CWLPS, could be considered a conflict of interest.

5.4.10 Patient outcome incentives

Gosselin and Cote (2001) reported that a penalty of $7 would have been charged at weighing sessions if the participant in their study had gained weight. This form of incentive is not uncommon in weight loss programmes, and it could improve patient compliance and the final results. Participants who wanted to be involved in the study conducted by Lowe et al (2001) were given an incentive of $25 at the end of the study if they turned up for all of their measurement assessment appointments, regardless of whether or not they had lost weight. This latter type of assessment is much better in terms of trial design in that, in real life, people do not get incentivised to lose weight. Results from studies where patients get incentivised to lose weight when they are on a CWLPS diet, compared with patients in a control group who do not receive incentives, are not a true reflection of how the diet might work in real life.

5.4.11 Confounders

Jolly et al (2011) reported that a small percentage of patients in their trial were using weight loss drugs at baseline (between 1 and 4 %). The authors do not state whether these drugs were continued throughout the duration of the study. The use of weight loss drugs could have impacted on the results.

5.4.12 Effects of interventions

Although the studies included in my review varied in the type and number of outcome measurements taken and reported, and the methodological quality of the studies, all studies favoured the CWLPS intervention vs. control. However, when studies assessed whether one CWLPS intervention was better or worse compared with another, some types of CWLPS were clearly better than others.

5.4.13 Types of interventions

Table 50: Studies included and type of intervention

Comparison	N	Included studies
CBA study (patents were their own control)	4	Anderson et al, 1991 Anderson et al, 1994b Gosselin and Cote, 2001 Lowe et al, 2001
RCT's: Intervention A vs. Intervention B	5	Anderson et al,1994a Ditschuneit et al, 1999 Gold et al, 2007 Rolland et al, 2009 Womble et al, 2004
RCT's: Intervention vs. control	4	Heshka et al, 2000 Heshka et al, 2003 Rippe et al, 1998 Rock et al, 2007
RCT's including more than 2 arms and more than 1 intervention group	4	Djuric et al 2002 Jolly et al, 2011 Morgan et al, 2008 Truby et al, 2006

5.4.13.1 CBA studies (n=4)

Four of the included studies in my review were CBA studies (Anderson et al, 1991; Anderson et al, 1994b; Gosselin and Cote, 2001; Lowe et al, 2001). Two of these studies included participants that had taken part in a commercial weight loss programme previously, and presented the follow up/maintenance results (Gosselin and Cote, 2001; Lowe et al, 2001).

Five to eleven years after discontinuation of the Mincavi programme, Gosselin and Cote (2001) found that 29.1% of women who started the programme had maintained a weight loss of at least 5%, while 14.3% had maintained a loss of at least 10%. The Mincavi programme is similar to other commercial weight loss programmes, but is more 'hands-on'; sampling takes place, and specific topic subjects are covered in the programme sessions. Clients are also able to gain support from a dietician and psychologist via using a free phone line and internet link. In this programme, clients were penalised if they gained weight, by needing to pay $7. 291 participants took part in this study, but measured weights were only available for 31 of these participants; the rest (n=260) had to have their weight adjusted (+2.9%) as it was self-reported via the telephone, and so there is a potential element of error in the findings of this study.

Lowe et al (2001) randomly selected male and female participants (n=1002) who had completed a Weight Watchers programme in the past, and found that they had regained (after they had lost weight during the programme) between 31.5% and 76.5% of their weight after one to five years. However, 42.6% had

maintained a loss of 5%, 18.8% had maintained a loss of 10%, and 70.3% were below their initial weight, when assessed at follow up.

Anderson et al (1991 & 1994b) conducted studies to test the effectiveness of a commercial weight loss product called Slimfast. Although I have included them as two studies (of 17) in my review, one might view them as just one study. The 1991 paper reported the results at the end of the intervention, and the 1994b paper reported the follow up results at two years post intervention. Given that the 1991 paper was assessing weight loss during the intervention, and the 1994b paper was assessing follow-up/maintenance, I decided to keep these papers as separate studies. All patients (n=80) were obese at baseline, and 62% of females and 69% of males had reduced their weight at the end of the intervention to a point where they were no longer obese (Anderson et al, 1991). 36% of females and 39% of males maintained their weight loss at 1 year follow up (Anderson et al, 1994b), and 19.7% maintaining their weight loss at two year follow up.

The participants in the in the Slimfast studies (Anderson et al, 1991; Anderson et al, 1994b) had a variety of co-morbidities at baseline; hypertension (n= 68), hypercholesterolemia (n=28), degenerative joint disease (n =21), hypertriglyceridemia (n =15), and type II diabetes (n=10). Anderson and colleagues do not report whether participants were receiving drugs to manage their co-morbidities during the course of the intervention or follow up.

5.4.13.2 RCT: Intervention vs. intervention (n=5)

Five studies assessed the effectiveness of one CWLPS against another (Anderson et al, 1994a; Ditschuneit et al, 1999; Gold et al, 2007; Rolland et al, 2009; Womble et al, 2004).

Ditschuneit et al (1999) compared the effects a controlled diet vs. slim fast meal replacements. I found it difficult to assess what the results of this study were from reading the paper. The two arms of the study, I think, remained separate for 3 months (Phase 1). Those participants using slim fast (n=50) lost 7.1 kg ± 3.5 kg, and those in the controlled diet group (n=50) lost 1.3 kg ± 2.2 kg. In terms of % weight loss, participants using slim fast lost 11.3% ± 6.8%, and those in the controlled diet group lost 5.9% ± 5.0%. During Phase 2 (where I think both groups were prescribed Slim fast), both groups lost, on average, an additional 0.07% of their initial body weight. Both male and female participants were involved in this study. Attrition rates were quite high; 62% of participants in the slim fast group finished the study, compared with 64% of the control participants.

Gold et al (2007) compared the effects of two online diets programmes; the VTrim diet vs. the eDiets.com diet. Both males and females were recruited to this study. Participants in the VTrim group lost significantly more weight than those in the eDiets.com group at 6 months (8.3 ± 7.9 kg vs. 4.1± 6.2 kg), and maintained a greater weight loss at 12 months (7.8 ± 7.5 kg vs. 3.4 ± 5.8 kg). In

terms of dropout, 77.4% of participants in eDiets.com group, and 64.5% of participants in the VTrim group, remained in the study until the end.

One of the most expensive CWLPS is a VLCD called LighterLife. Rolland et al (2009) compared Lighterlife (n = 38) against a low carbohydrate, high protein diet (LCHP) (n = 34). Both men and women were recruited to the study. A greater weight loss was observed for participants in the LighterLife group vs. the LCHP diet at 3 months (11.6 ± 12.9 kg vs. 2.8 ± 4.5 kg) and 9 months (15.1 ± 21.1 kg vs.1.9 ± 5.0 kg), $p<0.0001$ for both. However, only 41.2% of participants in the LighterLife group, and 52.6% in the LCHP, completed the study. Therefore, although Lighterlife appeared to work very well for those participants who remained in the study, for the majority of them (59%) it did not work.

Another relatively small study (n=47, all females), conducted by Womble et al (2004), compared the effects of a weight loss manual vs. ediets. The manual featured information about diet and recommended the consumption of 1200-1500 kcal per day, and physical activity. Those in the weight loss manual group lost more weight than those in the ediets group. At week 16, participants in eDiets.com lost 0.9% ± 3.2% of their initial weight compared with those in the manual diet group who lost 3.6% ± 4.0%. At week 52, losses were reported to have increased a little to 1.1% ± 4.0% (ediets group) and 4.0% ± 5.1% (manual group), and I think these weights must have been the last weight recorded for each participant. The authors state that only eight participants remained in each group at 16 weeks, and all participants were lost to follow up at 52 weeks.

Participants in Anderson et al (1994a) study, another relatively small study (n = 40), compared a 800 kcal dietary supplement diet with the same 800 kcal dietary supplement diet plus an evening meal. Both arms received an intensive behavioural education program. Weight loss for the two groups is not clearly stated in the paper, but the authors report that the weight loss did not differ significantly between the two groups, and that the average weight loss for all participants was 15.7kg. Both male (n=21) and female participants (n=19) took part in this study, and drop out was minimal (92.5% of participants completed the study). Of note, Anderson et al (1994a) report the co-medications that the participants were taking during the study, including insulin (n=5), insulin and oral hypoglycaemic agents (n=3), oral hypoglycaemic agents (n=24), and diet alone (n=7). These medications could have had an effect on the results of this study.

5.4.13.3 RCT's: One CWLPS vs. control (n=4)

Four RCT's assessed the effectiveness of a CWLPS vs. controls (Heshka et al, 2000; Heshka et al, 2003; Rippe et al, 1998; Rock et al, 2007). Three of these studies assessed the effectiveness of Weight Watchers as the CWLPS, and the other study assessed the effectiveness of the Jenny Craig programme (Rock et al, 2007).

I have included the two studies by Heshka and colleagues (2000 and 2003) as separate studies, although they might be viewed as just one study. The studies

were funded by Weight Watchers. Heshka and colleagues report the findings of their study at 26 weeks (2000 paper) and at 2 years (2003 paper); both demonstrated significant decreases in body weight and BMI for both the control and intervention group (Weight Watchers). However, at 26 weeks, Weight Watchers participants (n=211) lost more weight, and reduced their BMI more than the control participants (n=212); -4.8 ± 5.6 kg vs. -1.4 ± 4.7 kg, and -1.7 ± 1.9 vs. -0.5 ± 1.6 kg/m², respectively, in intention-to-treat analyses. Female (n=358) and male (n=65) participants took part in the study, and dropout rates were average; 17.5% in the Weight Watchers group and 18.9% in the control group.

After 2 years, attrition was low (Heshka et al, 2003); 71% of Weight Watchers participants and 75% of control participants remained in the study at 2 years. Weight Watchers participants lost more weight than the control participants at one year; 4.3 ± 6.1 kg vs. 1.3 ± 6.1 kg, and two years 2.9 ± 6.5 kg vs. 0.2 ± 6.5 kg. At 2 years, BMI decreased more in the Weight Watchers group than the control group; 1.6 ± 0.2 vs. 0.5 ± 0.2 kg/m².

Another study which assessed the effectiveness of Weight Watchers was conducted by Rippe et al (1998). This study only included female participants (n=80), who were randomised to a control or intervention (Weight Watchers) group for 12 weeks (thus mirroring the standard 12 weeks GP referral system in England). The intervention group (Weight Watchers) lost significantly more body weight (kg) and body fat (%) compared with controls (-6.07 ± 4.01 kg vs. 1.31 ± 1.28 kg; 36.8% ± 32.5 vs. 36.2% ± 36.0%). However, one should be cautious

when reading these results. Three times more participants remained in the intervention group (75%) at study end vs. control participants (35%). If an ITT had been conducted, conclusions could have been more accurate.

Rock et al (2007) assessed the effectiveness of the Jenny Craig programme. This study gave pre-packaged foods to the participants, along with programme materials, and extra support which addressed food-related components (mind, body, and food issues). Of note, this CWLPS also included advice to complete 30 minutes of physical activity on 5 or more days of each week. Only female participants (n=70, 35 in each group) took part in this study. This study had minimal dropout rates; 5.7% control vs. 8.6% in the intervention group. Using an intent-to-treat (ITT) analysis, at six months, weight loss was 7.2 ± 6.7 kg and 7.8% ± 7.2% in the intervention group vs. 0.3 ± 3.9 kg and 0.3% ± 4.5% in the control group. Using ITT analysis, at one year, weight loss was greater in the intervention group (n=32) 7.3 ± 10.4 kg vs. controls (n=33) 0.7 ± 5.6 kg, as was % weight loss, 7.8% ± 11.1% in the intervention group vs. 0.7% ± 6.2% in the control group.

5.4.13.4 RCT's including more than 2 arms and more than 1 intervention group (n=4)

Four studies compared the effect of one CWLPS with at least two other groups (Djuric et al 2002; Jolly et al, 2011; Morgan et al, 2008; Truby et al, 2006).

Djuric et al (2002) conducted a relatively small study in 48 female patients with Stage I or II breast cancer who had been diagnosed within the past 4 years, and a physician had confirmed that they were free of any recurrence. Chemotherapy or radiation therapy was to have been completed at least 3 months previously. The study had three arms; Weight Watchers with counselling (the Comprehensive group), an individualised arm (dietetic support, monthly group meetings, a monthly package of written information on various weight-loss topics), and a control group.

The greatest weight loss (at 12 months of intervention) was found in the comprehensive group; 9.4 ± 8.6 kg compared with 8.0 ± 5.5 kg in the individualised group and 0.85 ± 6.0 kg in the control group. Weight loss relative to control was statistically significant in the comprehensive group at 3, 6, and 12 months after randomisation, whereas weight loss in the individualised group was significant only significantly greater than controls at 12 months .Overall, the comprehensive group demonstrated the greatest improvements; a weight loss of 10% or more of initial body weight was observed in six of the 10 women in this group at 12 months.

This study did not report the dropout rates per group, but an overall dropout rate and reason for drop out were given. 81% of participants remained in the study until the end. Two participants were asked to leave the study for non-compliance after 3 and 6 months, respectively. Reasons for drop out were; medical problems (n = 1), too busy (n= 2), emotional distress (n =3), and lost interest (n = 1). Attendance at the sessions was higher in the comprehensive

group compared with other groups; 93% (baseline to three months), 79% (3 months to six months), and 52% (six to 12 months).

The results of this study should be viewed in context, given that the participants in this study were breast cancer survivors and their medication could have had an impact on the overall results of the study. For example, three women were taking oestrogen replacement therapy and, of these, one was taking both tamoxifen and hormone replacement therapy. Three other participants were taking diabetes medication.

Jolly et al (2011) conducted a trial with a number of programme arms; Weight Watchers, Slimming World, Rosemary Conley, Size down, General Practice, Pharmacy, Choice, and a control group. The study was funded by Birmingham PCT. 640 intervention, and 100 control participants took part in the study; both males and females were recruited to the study. At 12 weeks, participants in all programmes achieved significant weight loss, ranging from an average of 1.4 kg in the General Practice group to 4.4 kg in the Weight Watchers group. At one year, participants in all arms, except the General Practice and Pharmacy groups, had significant weight loss. At one year, only those in the Weight Watchers group had significantly greater weight loss (3.5kg) compared with the control group (1.1kg); mean difference 2.5 kg, 95% CI 0.8 to 4.2. Overall, participants in the commercial weight loss programmes lost significantly more

weight than the primary care programmes (mean difference 2.3 kg, 95% CI 1.3 to 3.4).

In this study conducted by Jolly et al (2001), a few participants in all of the groups were taking weight loss drugs; 3% Weight Watchers, 4% slimming world, 3% Rosemary Conley, 2% Size down, 1% General Practice, 4% Pharmacy, 3% choice, and 3% control. The study does not report whether the weight loss drugs were continued for the duration of the study.

Morgan et al (2008) conducted a study with a number of programme arms; Weight Watchers, Rosemary Conley, Slim Fast, Atkins, and a control group. Participants (n=293) were stratified by gender (30% of participants were male) and randomly allocated to one of the five groups. Significant weight loss was achieved by those in all programmes (an average of between 5 and 9 kg at 6 months), but no significant difference was observed between weight loss at 6 months. 28% of participants dropped out of the study at six months.

The BBC funded the study which was conducted and reported by Truby et al (2006). It is identical in design to the study of Morgan et al (2008) mentioned above, but Truby et al (2006) used ITT analysis. 71.7% of participants, including control participants, finished the study. Using ITT, all diet programmes resulted in a significant loss of body fat and weight over six months compared with the control group, but the loss of body fat and weight between programme groups was not significantly different; average weight loss was 5.9 kg and average fat

loss was 4.4 kg over six months. The Atkins diet resulted in significantly higher weight loss during the first four weeks, but by the end of the study it was not significantly more effective than the other programmes.

The Atkins and Rosemary Conley groups appeared to perform best; average weight loss in the Atkins group was 6.3 kg, and 6.1 kg in the Rosemary Conley group. However, those in the Rosemary Conley group had the greatest % weight loss (6.6%), and greatest % fat loss (3.5%), at 6 months. Those in the Atkins group had a greater average reduction in their waist circumference compared with those in the Rosemary Conley group; 7.4 cm vs. 7.2 cm.

5.4.14 Summary

17 studies were included in this review, all of which had similar aims; some of the studies which I included were in fact papers from the same study that had presented results at different time points (e.g. at end of intervention and at follow up) and/or different analysis. When I convert my review into a Cochrane review I will discuss with my co-authors how best to manage these data. Sample size, design, quality, duration, and types of outcome measures varied considerably amongst the studies I included in my review. Because of the heterogeneity between studies, I did not conduct a meta-analysis. However, the majority of studies reported that the CWLPS they were testing performed better than the control. In the table below (Table 51), I have summarised the main weight loss results of the included studies. It is clear that the CWLPS interventions, particularly commercial weight loss programmes perform the best.

Where the effectiveness of commercial weight programmes have been compared within the same study, Weight Watchers appears to perform the best.

Table 51: Summary of main weight loss findings from the 17 included studies

Study	Main results
Anderson et al, 1991	Of the 100 subjects, 49 stayed on the diet until reaching their desired weight. The average weight loss was 19.2 kg for females and 18.6 kg for males. At the end of the study period, 62% of the females and 69% of the males had reduced their weight to the point that they were no longer obese. At follow-up, 36% of females had maintained their weight loss and 39% of males had maintained their weight loss.
Anderson et al, 1994a	Both groups lost significant amounts of weight, and weight losses did not differ significantly between groups. Weight loss averaged 15.7 kg.
Anderson et al, 1994b	35kg was lost at 25 weeks. 20 kg was maintained of their weight loss at 2 year follow up.
Ditschuneit et al,1999	The study favoured group B (meal replacement). Group B lost 11.3% (± 6.8) vs. Controls 5.9% (± 5.0%) (as a percentage of initial body weight ($p < 0.0001$). During phase 1, mean weight loss in group B ($n = 50$) was 7.1 ± 3.5 kg. Group A patients ($n = 50$) lost an average of 1.3 ± 2.2 kg. During phase 2, both groups lost on average an additional 0.07% of their initial body weight every month ($p < 0.01$).
Djuric et al, 2002	The most successful group (at 12 months of intervention) was Weight Watchers combined with counselling (the comprehensive group) -9.4 ±8.6 kg, then the individualised group -8.0 ± 5.5kg. Weight loss relative to control was statistically significant in the comprehensive group 3, 6, and 12 months after randomisation, whereas weight loss in the individualised group was significant only at 12 months. Weight loss of 10% or more of initial body weight was observed in 6 of the 10 women in the comprehensive group at 12 months
Gold et al, 2007	The participants in the VTrim group lost significantly more weight than those in the eDiets.com group at 6 months (8.3 ± 7.9 kg vs. 4.1 ± 6.2 kg) and maintained a greater loss at 12 months (7.8 ±7.5 kg vs. 3.4 ±5.8 kg). More participants in the VTrim group maintained a 5% weight loss goal; 65% vs. 37.5% at 12 months
Gosselin and Cote, 2001	Five to eleven years after they had participated in the Mincavi programme 29.1% of all women maintained a weight loss of at least 5%, while 14.3% maintained a loss of at least 10%. The percentage of women who maintained at least 5% of their initial weight loss are as follows; 2 years = 43.6% (n = 55), 3

	years = 33.3% (n = 42), 4 years = 23.8% (n = 42), 5–6 years = 38.2% (n = 55), 7–8 years = 29.4% (n = 51), and 9–11 years; 19.6% (n= 46).
Heshka et al, 2000	After 26 weeks, subjects in the commercial program (weight watchers), as compared with those in the self-help program, had greater decreases in body weight (-4.8 ± 5.6 kg vs. -1.4 ±4.7 kg) and BMI (-1.7 ± 1.9 vs. -0.5 ± 1.6 kg/m2), both p< 0.001, in intention-to-treat analyses.
Heshka et al, 2003	In ITT analysis, mean (SD) weight loss of participants in the commercial group (weight watchers) was greater than in the self-help group at 1 year (4.3 ± 6.1 kg vs. 1.3 ± 6.1 kg) and at 2 years (2.9 ± 6.5 kg vs. 0.2 ± 6.5 kg). BMI also decreased more in the commercial group (1.6 ± 0.2 vs. 0.5 ± 0.2) compared with the self-help group.
Jolly et al, 2011	Participants on all programmes achieved significant weight loss from baseline to programme end; range 1.37 kg (general practice) to 4.43 kg (Weight Watchers), and all except general practice and pharmacy provision resulted in significant weight loss at one year. At one year, only the Weight Watchers group had significantly greater weight loss than the control group (2.5 kg, 95% CI 0.8 to 4.2). The commercial programmes achieved significantly greater weight loss compared with the primary care programmes at programme end (mean difference 2.3 kg, 95% CI 1.3 to 3.4.
Lowe et al, 2001	Based on corrected weights, weight regain from 1 to 5 y following weight loss ranged between 31.5 and 76.5%. At 5 years, 19.4% were within 5 lb. of their goal weight, 42.6% maintained a loss of 5% or more, 18.8% maintained a loss of 10% or more, and 70.3% were below initial weight.
Morgan et al, 2008	Significant weight loss was achieved by all dieting groups (Atkins, Weight Watchers, Slimfast, Rosemary Conley); (5–9 kg at 6 months) but no significant difference was observed between the different diets at 6 months.
Rippe et al, 1998	The intervention group (Weight Watchers) lost significantly more body weight (kg) and body fat (%) compared with controls (-6.07 ± 4.01 kg vs. 1.31 ± 1.28 kg; 36.8% ± 32.5 vs. 36.2% ± 36.0%).
Rock et al, 2007	At 6 months, change in weight using ITT analysis was 7.2 ± 6.7 kg and 7.8% ± 7.2% in the intervention group (Jenny Craig) vs. 0.3 ± 3.9 kg and 0.3% ± 4.5% in the control group (n =35 for each; p <0.01). One-year ITT analysis revealed significantly greater change in weight, present weight, BMI, and waist and hip circumferences in the intervention vs. control group. Completers at 1 year exhibited weight loss of 7.3 (±10.4) kg for the intervention group (n =32) vs. 0.7 ± 5.6 kg for controls (n =33), p < 0.01, and 7.8% ± 11.1% weight loss for the intervention group vs. 0.7% ± 6.2% for controls, p < 0.01.
Rolland et al, 2009	Significantly greater weight loss was seen for patients using LighterLife compared with the Low Carbohydrate High Protein group at 3 (11.6 ± 12.9 vs. 2.8 ± 4.5 kg) and 9 months (15.1 ±

	21.1 vs. 1.9 ± 5.0 kg), both p < 0.0001.
Truby et al, 2006	All diets resulted in significant loss of body fat and weight over six months. Groups did not differ significantly but loss of body fat and weight was greater in all groups compared with the control group. In an intention to treat analysis, average weight loss was 5.9 kg and average fat loss was 4.4 kg over six months. The Atkins diet resulted in significantly higher weight loss during the first four weeks, but by the end was no more or less effective than the other diets.
Womble et al, 2004	At week 16, participants in eDiets.com lost 0.9 ±3 .2% of their initial weight compared with 3.6 ± 4.0% for women assigned to the weight loss manual. At week 52, losses increased to 1.1 ± 4.0% and 4.0 ± 5.1%, respectively. Results of a last-observation-carried-forward analysis found that women in the manual group lost significantly (p< 0.05) more weight (at both time points) than those using eDiets.com. (Results, however, of baseline-carried-forward and completers analyses did not reach statistical significance.)

I did not formally assess the quality of the studies in my review, but I will do that as part of the conversion process for the Cochrane review. However, I do understand the concept of quality, and the different ways in which it can be assessed. When I have done this informally for the studies I included in my review, four of the studies stood out as being of good quality; Heshka et al 2000; Heshka et al 2003; Jolly et al, 2011; Truby et al, 2006.

Finally, approximately half of the studies included in my review were funded by a commercial weight loss company, or a non-academic based organisation. About a quarter of the studies were funded by a research grant, and about a quarter of studies did not state the source of funding.

Chapter Six

Discussion and Conclusions

6.1 Introduction

In this chapter I have explained what I set out to achieve by doing this research, what I have learnt along the way, and the findings from my research.

I set out to find out about the use, popularity and efficacy of CWLPS, particularly in relation to health inequalities. Much of what I have learnt by doing this research relates to methods. I learnt a lot about the various issues associated with recruiting people to a study like mine, including the issues associated with recruiting people from deprived areas. I also learnt about Q-methodology, which I found very exciting, and the Cochrane review process. I now appreciate the value of using a mixed methods approach. In addition, I learnt a lot about the issues involved with sensitive commercial data.

My research did produce findings which help better understand the choice and efficacy of CWLPS. The novel use of Q-methodology to this topic area revealed some very interesting findings. Sadly, I found out very little about the use and efficacy of CWLPS in relation to health inequalities from the survey and the review, but I did find out some useful facts about whether the cost of a CWLPS influences the decision as to whether to buy it, or a cheaper CWLPS, in my Q-method study.

At the end of this chapter, I make some suggestions for further research in this area

6.2 What I set out to achieve

The primary aim of my research was to establish why people chose certain CWLPS over others, and whether this depends on how much money they have. I also wanted to know about the efficacy of the different CWLPS, and whether this matched the views of the people using them. I was interested to know whether the choice of CWLPS was determined by their price. In theory, one could imagine that the most efficacious CWLPS might be the most expensive, and poorer people with less money may have no choice but to buy the cheaper CWLPS. If this was true, then the cost of CWLPS could contribute to health inequalities.

I understand that I was asking a difficult but important question. Given the complexity of the topic, I decided it would be best to try and approach the question using different methods, in the hope that I would get a richer set of findings which I could then look at. I used a mixed method study design using three components; a survey, Q-methodology, and a systematic review. Each method had distinctive but overlapping aims which mapped onto my research question.

6.3 Why I chose to investigate CWLPS

My interest in this topic came from a number of sources, including an interesting paper from Lowe et al (2001) which found that an increasing number of individuals who want to lose weight avoid clinical programmes, and instead seek assistance in commercial alternatives. This is not surprising, given the clever and persuasive marketing of CWLPS by commercial companies.

6.4 What I have learnt through my PhD: Methods

6.4.1 Recruiting people to the survey

As I set out on my PhD journey, I honestly thought that I would have no trouble at all in getting participants to take part in my survey (or Q-method study). I thought this because of the data in the literature on the numbers of people in the UK who, at any one time, are trying to lose weight. Although these numbers vary, they have been estimated at about almost 37% women were dieting most of the time, compared to around 18% of men (BBC, 2004). In addition, the amount of marketing and exposure of CWLPS in magazines, TV commercials, etc., led me to believe that a lot of people would be interested in taking part in my study. I could not believe it when I got such a poor response rate to the initial advert in the Middlesbrough Gazette.

Although I was disappointed with the level of interest, it did force me to think very carefully about recruitment, and different recruitment methods. I expanded the geographical area for recruitment, and went on the radio, which required additional ethical approvals (which caused a delay), and I learnt a lot from these

experiences. I have done a lot of reading on recruitment of participants to surveys and trials, and it does seem that, particularly for public health research (rather than clinical research), most studies struggle with recruitment issues these days. Before I did my PhD, I was a research assistant for a study called the 'Community Challenge Project' (CCP), and this study also had major problems in recruiting participants. I am co-author on a paper which we wrote about this issue (Hillier et al, 2011), and I intend to write a similar paper from my PhD work.

To be able to answer my research question, I not only needed to recruit enough participants, but also recruit enough participants from different SES groups. At the start of my PhD, I simply thought that by advertising in a local newspaper I would be able to do this. I now appreciate that a more targeted recruitment strategy would have helped me do this. During the CCP study, we certainly found that recruiting people from deprived areas of the North East was better done face to face, and best of all done by local champions who the participants knew and trusted. In hindsight, I think it is possible that many people who we invited to take part in the survey were suspicious about 'Ivory Tower' researchers, and perhaps cynical about what they, the participant, would get out of the study. I now realise that I probably shouldn't have told them I was a PhD student and needed the data for my PhD. It is possible that most potential participants for studies like mine are not very interested in helping a researcher in a University, but they may take part in a study if they think it is going to benefit them. I didn't offer potential participants any benefits, except the opportunity to talk to others in the same situation as them. I now realise that this was probably a mistake,

6.4.2 Q-methodology

Q-Methodology is not a novel method. It is a popular method of choice in some disciplines. However, to my knowledge it is not commonly used in health behaviour type research, and I have not been able to find a study using this method in the obesity research literature. I was a little nervous, but excited, about using this method. The Q-method part of my PhD work was certainly the part that I found most rewarding. One of the drawbacks of using a novel method is not being able to talk to others who have used it previously. However, I found out about, and joined, a discussion group for people doing Q-method, which was incredibly helpful. I also identified another (Fuse) PhD student at Newcastle University who was using it for her PhD, and also a lecturer at Teesside University; both were a great support. There was definitely something exciting about using a new method.

The method itself is quite complicated, but I thoroughly enjoyed the complex nature of the method. I had never done any qualitative work before my PhD, and I didn't think I was going to enjoy it. I couldn't have been more wrong.

6.4.3 The Cochrane review process

I now understand that Cochrane reviews are all of good quality because of the rigorous peer review process which Cochrane insists upon. However, it can take such a long time for the Review Group to respond to queries and process reviews. I had to wait more than 6 months at one stage to get comments back on my protocol, and each time it came back for edits I revised it and sent it back in, but had to wait for months for them to reply. I can now understand why it

would be too risky to say that you will do a Cochrane Review by X date, because you are not in control – they are – and you might miss a deadline.

In discussion with my supervisors, we made a decision during the course of my PhD that I would just get on and complete the review, and 'Cochranise' it after I had submitted my thesis. This was a good decision I think, but I am committed to Cochranise my review at a later date. I understand that the Cochrane Library is an important and valued source of best evidence, and can be accessed by people from all over the world. I particularly like the fact that it can be accessed free of charge by people from poor countries.

6.4.4 The value of using a mixed methods approach

One of the most important things I have learnt in doing my PhD is the value of asking the same question from different angles (using different methods). This provides a richer, and I would think truer, answer to the question. For example, I was particularly interested in the popularity and efficacy of CWLPS. From the survey (quantitative) results, there weren't any associations between the cost of a CWLPS and its popularity, particularly for poorer people. The primary reason for this was because very few of the participants in my survey were from low SES backgrounds. I also didn't find any useful (quantitative) data to help me answer the question from my review; included studies had not targeted particular groups by SES, or had presented analysis of effectiveness by SES.

However, the Q-method study, because it was a qualitative method, did allow me to drill down and ask questions about the cost of CWLPS and whether that has an influence of people's choice of CWLPS.

I think that a mixed methods approach may be particularly helpful when you are asking complex questions in a topic area where there isn't much existing evidence.

6.4.5 Issues involved with sensitive commercial data

I was initially very surprised at the negative response I got from commercial companies when I asked them for data about the use of and efficacy of their weight loss product or service. I did think that they would be very happy to give me this data. When I met representatives from these companies at conferences and meetings, they seemed very interested in my research, and very keen to be involved in some way. However, they were not. I now understand the sensitivities associated with data on use and efficacy of CWLPS. Personally, I don't think that this is right. These companies do hold a lot of data on their products and services, but they don't release it.

6.5 Findings from my research

6.5.1 The survey

The findings of the survey confirmed that there is a wide range of CWLPS which people in the UK use, and that slimming groups such as Weight Watchers and Slimming World are by far the most popular. However, what I was most interested to find out from the survey was whether the SES of an individual was

a factor in determining which CWLPS they used. Sadly, because of the profile of the sample, I was not able to answer this question.

6.5.2 The Q-methodology study

The Q-method study which I conducted produced a plethora of interesting information, which I did not expect. The participants told me about the many reasons they choose CWLPS which support why a variety of CWLPS should be available (and offered, in the NHS) to the public.

The Q-method study revealed four different groups of participants who had similar needs for their preferred weight loss product or service, which mapped onto the different types of CWLPS available; marketing and cost did not feature strongly in participant's choice of CWLPS.

The first group (Factor 1) I labelled as *'effortless self-management'*. This group of participants chose a CWLPS primarily because 1) it promised quick weight loss, 2) it was easy to follow, and 3) it allowed them to set their own realistic weight loss targets. Although the participants in this group chose different CWLPS, they each perceived the CWLPS they used as meeting these requirements.

The second group (Factor 2) I labelled as *'lifestyle adjustment counselling'*. This group of participants chose a CWLPS primarily because 1) it promised quick weight loss, 2) it was healthy, and 3) it provided advice on maintenance after the participant had stopped using the CWLPS. Although the participants in this

group chose different CWLPS, five (of the six) had chosen a VLCD. Each participant perceived the CWLPS they used as meeting these requirements.

The third group (Factor 3) I labelled as *'Celeb support'*. This group of participants chose a CWLPS primarily because 1) it offered support in losing weight, 2) it offered support in maintaining weight loss, and 3) sticking to the diet would not be a big change to their lifestyle. All participants in this group chose either Weight Watchers or Slimming World. Each participant perceived the CWLPS they used as meeting these requirements.

The fourth group (Factor 4) included just one person, a man, and I labelled this group as *'Men don't get help'*. This participant chose Slimming World for Men primarily because 1) it was gender specific, and 2) it was healthy. This participant perceived the CWLPS they used as meeting these requirements.

Within the NHS, there is little flexibility to match patients who seek to lose weight with programmes, products and services, because only a limited number of options are commissioned and thus on offer. Rather than focus future research on finding the one most effective weight loss method for everybody, I think it would be more useful to try and identify different groups of people based on their needs from a weight loss method, and look to see whether this matching produces better results for everybody. The simplest case in point, identified from my research, is the provision of gender specific weight loss services.

Certainly, in the studies included in the systematic review, there was a high dropout rate in most studies. I think it is more than possible that those who dropped out were not a random sample, but those whose needs for a weight loss method did not match the CWLPS to which they were allocated.

6.5.3 The review

The systematic review showed that the use of CWLPS resulted in weight loss, although attrition rates were sometimes quite high. Most of the studies included in the systematic review were underpowered, and very few could be considered as good quality. None of the studies reported SES within their analysis, or feature any in-depth qualitative analysis about the reasons for drop out and participant experiences of the CWLPS.

Where studies assessed the effectiveness of one type of CWLPS against a control diet, those in the CWLPS lost more weight over time. Where studies assessed the effectiveness of one type of CWLPS with another, results were mixed but slimming groups, such as Weight Watchers, appeared the most effective. A high quality study (Jolly et al, 2011) found that CWLPS such as Weight Watchers performed very well, compared with groups who were allocated to General Practice or Pharmacy weight loss service provision. A caveat needs to be attached to these results, in addition to the quality issues raised in the previous paragraph. One can only say something positive (or negative) about the effectiveness of a CWLPS if a study or trial has been conducted on this CWLPS. For many of the CWLPS which participants in my

survey listed as using, there are no CBA's or RCT's of effectiveness reported in the literature

The effectiveness of a CWLPS did not appear to be related to its cost and, because of a lack of data collected and reported in these studies, I was unable to assess whether the effectiveness of a CWLPS was related to the SES of those taking part in the studies.

6.6 Suggestions for further research in this area

a) Future research on public health should include work which identifies the best ways of recruiting people from low SES backgrounds to various studies.

b) Further research on mapping peoples preferred needs for their weight loss method with the available range of weight loss programmes; products and services (including CWLPS) would be helpful for both users and commissioners of services. The development of a screening to tool which facilitated a user being offered the most appropriate weight loss method would, most likely, improve an individual’s chances of success.

c) Future trials to assess the efficacy of CWLPS should ensure they are statistically powered and that participants from a wide range of social backgrounds, including people from low SES groups, are recruited. Analysis of effectiveness by SES should be conducted and presented in research papers. Qualitative research should also be included as part of these studies, which

should include the exploration of reasons why people dropped out of the trial, and views from both men and women.

6.7 Conclusions

It is clear that most CWLPS are used, preferred, and effective for some people, at least for a short period of time. However, different users have different needs for their preferred CWLPS. A screening tool, which identified the needs of somebody who is considering using a CWLPS, might be helpful in signposting them to a CWLPS which would best suits them.

From the data available to me, it appears that the cost of a CWLPS is not a critical factor in its use, popularity, or effectiveness. Also, I found no evidence that the cost of CWLPS fuels inequalities (i.e. that poorer people buy cheaper types of CWLPS, which in turn are less effective). However, the data available to me was limited; participants who took part in the survey (and Q-method) were mostly middle income, and the studies included in the systematic review did not target particular groups by SES, or present analysis of effectiveness by SES.

Additional research on the uptake of CWLPS and its impact upon health inequalities would be useful, given our current knowledge that obesity is associated with health inequalities. It is important to try and work out where and how obesity drives health inequalities, and there is some logic behind the hypothesis that the use of CWLPS may be a contributing factor. In theory, for

example, if an individual of low SES chooses to purchase and use a CWLPS to help them lose weight, rather than access support from the primary care team, then their available income would be reduced. We know that poverty is strongly associated with health inequalities (reference the nice book I lent to you), thus buying CWLPS could contribute to health inequalities via this route.

Research to better understand the uptake and reasons for choice of CWLPS across the socioeconomic spectrum should be conducted. Indeed, this is what I set out to do for my PhD, but sadly I was unable to recruit a large enough or socioeconomically diverse sample. Future research in this area should be designed using the learning from my research. Targeting particular groups in society, e.g. via community groups and talking to people face to face, might be a more effective sampling strategy. Other target groups might be community weight loss groups which could be visited in person by the researcher. Such a study would require a significant resource, and is beyond the scope of a PhD study.

Whilst undertaking my PhD I assumed that the cost of a CWLPS would play an important role in choice of CWLPS (with those individuals of greatest means been able to afford the more, and the most effective, CWLPS). The annual salary for the NE region in 2012 was £17,004. If an individual was to purchase the most expensive CWLPS from the survey (LighterLife), 25% of their salary would be accounted for on a CWLPS alone. Whilst I was intrigued to find, from my research, that the cost of a CWLPS did not appear to influence the choice of

CWLPS, my results should be interpreted with caution since most of the participants in my study were middle-income. The related issue of targeted marketing (to certain SES groups) of certain CWLPS is an issue which I have discussed with other academics during the course of my PhD, and one which I feel deserves further research. A study which identified, from magazines, newspapers, and TV adverts, whether certain CWLPS were targeted at certain SES groups, would be very useful in helping us to understand any relationship between the reasons of choice of CWLPS and SES was fuelled by company marketing strategies.

In addition, research to better understand the effectiveness of CWLPS commonly used would be useful. Currently, there is limited information, and the best evidence is restricted to just a few types of CWLPS. A best practice model whereby the company paid for the research, but the management of the trial and evaluation of the results was conducted independently by a research team (based in Universities), and peer reviewed by other researchers, should be championed. The rationale for funding such studies is perhaps unconvincing for some companies for two reasons. First, such studies are very expensive. Second, such studies run the risk of concluding that the CWLPS under investigation is not significantly effective compared with controls. Why, when the company can produce relatively cheap marketing based on compelling 'personal stories', would a company decide to spend a lot of money on a full trial. I understand the difficulties associated with the funding of good quality evidence in this area, and I think this needs addressing. One possible lever

might be for NICE to only include evidence on CWLPS where that company had funded such a trial.

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UPTAKE AND CHOICE OF COMMERCIAL WEIGHT LOSS PRODUCTS AND SERVICES BY ADULTS IN THE UK

VOLUME 2 (of 2)

ALISHA MICHELLE CRAYTON

Thesis submitted for
the degree of Doctor of Philosophy

School of Medicine, Pharmacy and Health
Durham University

May 2013

Appendix 1: Ethical approval

Durham University

Wolfson Research Institute
Improving health and well-being

Rebecca Perrett
Research and Development Manager, Wolfson Research Institute
Chair, School of Medicine and Health Ethics Committee

Tel: 0191 334 0425
Email: Rebecca.Perrett@durham.ac.uk

Alisha Crayton
Obesity Related Behaviours Group
School of Medicine and Health
The Wolfson Research Institute
Durham University Queen's Campus
Stockton-on-Tees
TS17 6BH
United Kingdom

23rd September 2010

Dear Alisha,

RE: Commercial Weight Loss Survey/Q-Weight Study

Ref: ESC2/2010/10

Thank you for sending your revisions to the above application to the School of Medicine and Health ethics committee. These have now been reviewed by a sub-committee of 2 members and we are satisfied that all of the points raised by the committee have been addressed. I am therefore able to grant you SMH ethics approval to conduct the study.

Please do not hesitate to contact me should you have any questions. I hope that the study goes well.

With best wishes

R H Perrett.

Rebecca Perrett

Appendix 2: Survey consent form

Durham University
School of Medicine and Health

Shaped by the past, creating the future

ID Number:

R-Weight

Consent Form

Please read the following consent form carefully then tick the **Yes** or **No** boxes, and **initial** all boxes. If you have ticked any of the **No** boxes to questions 1-7, your data will be securely destroyed when received. If you tick the **No** box to question 8, but tick the **Yes** boxes to questions 1-7 you will still be included in this survey.

	Yes	No	Initial
1. I confirm that I have read and understood the participant information sheet for this study (version 3.0) and am aware of what it will involve.	☐	☐	☐
2. I have been able to contact the researcher about any questions or concerns that I have about this study using the details provided in the information sheet.	☐	☐	☐
3. I understand that my participation is voluntary and that I can withdraw from the research at any point before 28th February 2011 when data analysis will be complete. I am aware that if I choose to withdraw I will not be required to give a reason.	☐	☐	☐
4. I am 16 years of age or older	☐	☐	☐
5. I have used a commercial weight loss product or/and service in the last twelve months	☐	☐	☐
6. I understand that the information that I provide will be anonymised, will be kept strictly confidential, and will be kept in locked filing cabinets and password-protected files on computers at Durham University in accordance with the Data Protection Act (1998). My information will not be shared with anyone who is not part of the research team. After the study has finished, data will be securely saved and destroyed before the 1st June 2015.	☐	☐	☐
7. I agree to take part in this study.	☐	☐	☐
8. I agree to be contacted to discuss my willingness to participate in the next stages of the overall study.	☐	☐	☐

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Appendix 3: Advertising recruitment

Volunteers needed to assess diet plans

10:48am Monday 3rd January 2011 in News

A UNIVERSITY research team is hoping to recruit volunteers to help in a study of weight-loss programmes.

With an estimated 14 million people across the UK about to embark on a new year diet, the scientists are hoping they will have no shortage of applicants.

The Durham University team is hoping to recruit 1,000 people to complete an anonymous 20-minute postal survey telling researchers about their experience of commercial diet and weight-loss programmes.

They hope to build up a scientific picture of which are popular and why, information which will be fed back to public health policy and may eventually lead to GPs having the option of referring patients to a diet plan, rather than a medical procedure.

Researchers, based at the university's school of medicine and health, in Stockton, want to recruit people from County Durham, Northumberland, Tyne and Wear and the Tees Valley.

The only stipulation is that they must be over the age of 16 and must have used a commercial weight-loss product in the past year, such as Slimming World, WeightWatchers, LighterLife, Rosemary Conley, Diet Chef and Slim- Fast, as well as weight loss books, DVDs and websites.

Lead researcher Alisha Crayton said: "There are so many commercial weightloss programmes available, but we don't yet fully know how effective they are, what people think of them, and whether they provide good value for money.

"In order for us to get a good idea of why people choose particular programmes and products, we are looking for at least 1,000 volunteers to complete the survey.

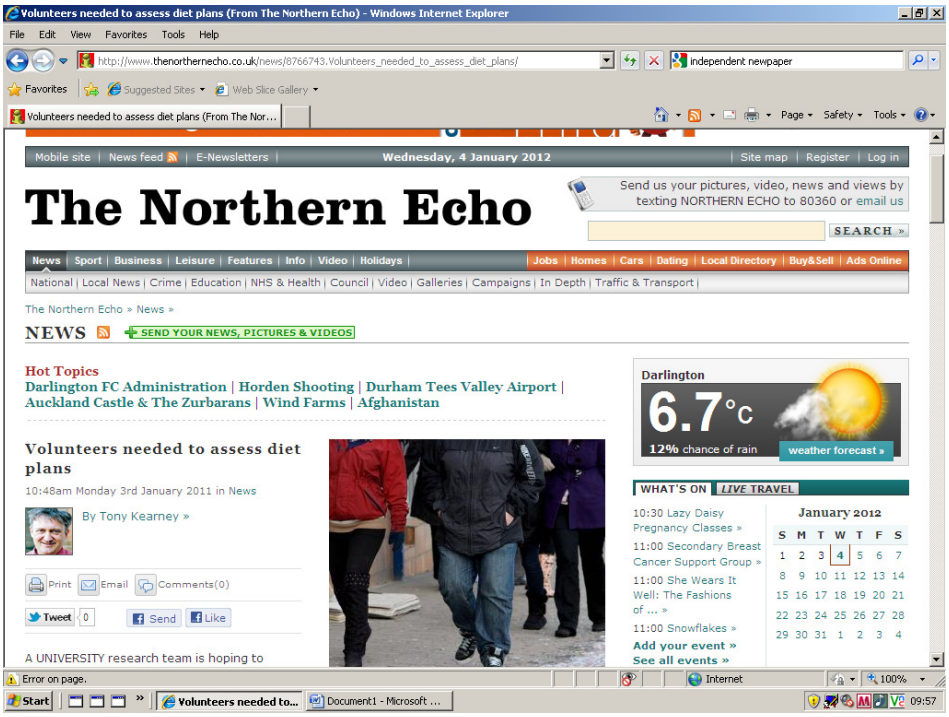
"That way, we can identify some patterns and get a good picture of the market place.

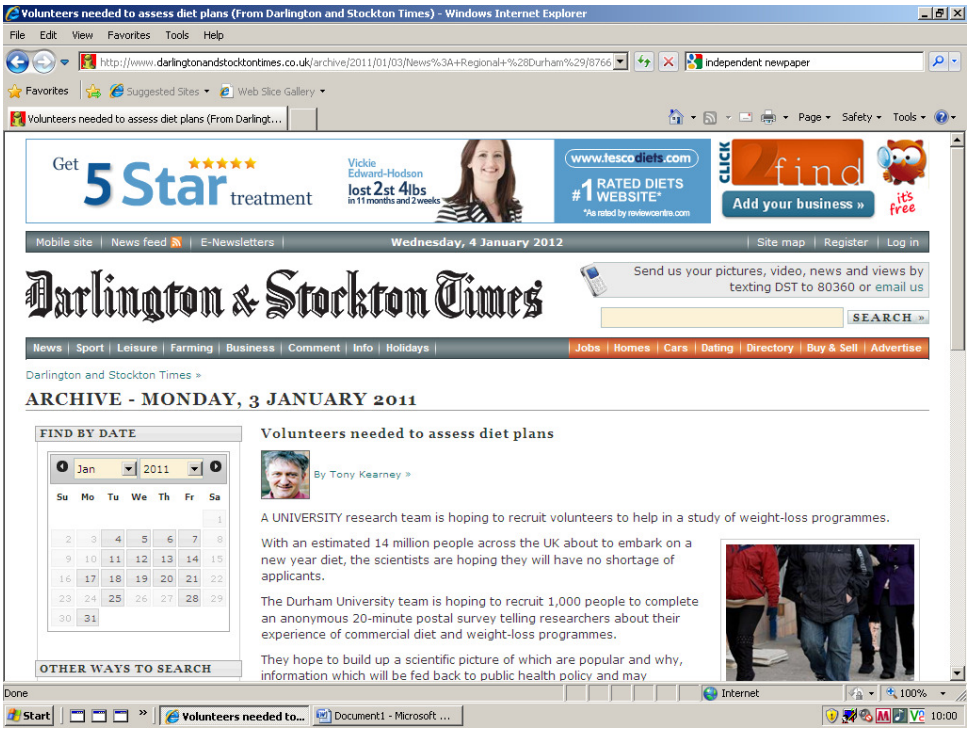
"We will then feed the findings into public health policy through primary care trusts."

Some of the volunteers will be invited to take part in a second stage of research, which will involve focus groups ranking programmes.

Anyone interested is asked to send their name and address, including their postcode, either by emailing cwl.orbresearchgroup@durham.ac.uk, calling 0191-334- 0820 or by writing to R-Weight, Obesity Related Behaviours Research Group, School of Medicine and Health, Durham University, Queens Campus, Wolfson Research Institute, Stockton-on-Tees, TS17 6BH.

Appendix 3: Advertising recruitment





Appendix 3: Advertising recruitment

Teessiders wanted for Durham University student's weight loss products survey

Nov 18 2010 by Sarah Judd, Evening Gazette

A GROUNDBREAKING study into the use of commercial weight loss products like meal supplement shakes and diet clubs is to take place on Teesside.

Volunteers are being sought for the research by Durham University PhD student Alisha Crayton, who is based at the Wolfson Research Institute on Stockton Riverside.

The research will form part of an international project to identify the effectiveness of products for consumers, while informing local health authorities - who could potentially offer them on the NHS - on the best weight loss methods available.

Alisha, who is carrying out the study alongside Durham University professor Carolyn Summerbell, believes local health trusts could benefit financially compared with the cost of treating obesity-related conditions.

Alisha was previously involved with the Evening Gazette's Get a Better Life Campaign, to encourage people across Teesside to improve eating and exercise habits, in conjunction with Teesside University and NHS Middlesbrough.

She said: "At the moment, we don't really know why some people choose commercial weight loss products. We want to get an idea of what products and services are being chosen on Teesside and what benefits people here see. In future, it could be that we put it to the Primary Care Trusts (PCTs) to say, 'these products and services are being used, what do you think?'"

The research, entitled R-Weight, is expected to be published across the world.

It takes the form of a simple survey.

Anybody who has used a commercial weight loss product or service in the past 12 months and is over 16 can take part by calling 0191 3340820, emailing **cwl.orbresearchgroup@durham.ac.uk** or writing to R-Weight, ORB research group, Durham University, School of Medicine and Health,

Appendix 3: Advertising recruitment

Queen's Campus, Wolfson Research Institute - E106, TS17 6BH, including a name, address and postcode.

Read More http://www.gazettelive.co.uk/news/teesside-news/2010/11/18/teessiders-wanted-for-durham-university-student-s-weight-loss-products-survey-84229-27670980/#ixzz1iU1LLKW9

Appendix 3: Advertising recruitment

Dieters wanted for uni study

RESEARCHERS are still recruiting dieters for a groundbreaking study into commercial weight loss products.

PhD student Alisha Crayton, based at Durham University's Wolfson Research Institute at Stockton Riverside, is analysing everything from meal supplement shakes to diet clubs. To take part, contact the research team with your name, address and postcode by email at cwl.orbresearchgroup@durham.ac.uk, telephone 0191 334 0820, or by writing to R-Weight, Obesity Related Behaviours Research Group, School of Medicine and Health, Durham University-Queens Campus, Wolfson Research Institute - E106, Stockton-on-Tees, TS17 6BH.

Read More http://www.gazettelive.co.uk/gazette-communities/ts17-ingleby-barwick-and-thornaby/ts17-ingleby-barwick-and-thornaby-news/2011/03/12/dieters-wanted-for-uni-study-84229-28331104/#ixzz1iU1fN4F8

Appendix 4: Survey; useful contact details

Durham University
School of Medicine and Health

R-Weight

Shaped by the past, creating the future

ID Number:

Useful contact details

If you are concerned about weight loss, eating disorders, or any other health related issues, seek advice from your GP. Alternatively please see below for general advice and support groups.

B-eat

Beat is the leading UK charity for people with eating disorders and their families, providing helplines for adults and young people, online support and a UK-wide network of self-help groups to help people beat their eating disorder.

Telephone: 0845 634 1414 Email: help@b-eat.co.uk

Eating Disorders Carers Group for Teesside, Co. Durham and North Yorkshire

Email goodwincath@googlemail.com

Alliance Psychological Services

Alliance Psychological Services is an independent provider of counselling and psychological solutions with a clinically proven record of delivering therapeutic and specialist services.

Tel: (01642) 352747
Fax: (01642) 614870
Email: info@alliancepsychology.com

Mind

The largest Mental Health Charity in the UK with branches all over the UK offering various services and support.

Website: http://www.mind.org.uk/ Telephone: 0845 766 0163

Samaritans

Samaritans provides confidential non-judgemental emotional support, 24 hours a day for people who are experiencing feelings of distress or despair, including those which could lead to suicide

Telephone: 08457 90 90 90.

Appendix 5: Survey; demographics information

Shaped by the past, creating the future

ID Number:

Additional Information

Please tick (✔) the questions that apply to you:

Gender
Male ☐ Female ☐

Date of birth (day/month/year) _____

Ethnicity - Which of the following best describes you?

White ☐ Black Caribbean ☐ Black African ☐ Bangladeshi ☐ Black other ☐ Asian other ☐
Chinese ☐ Indian ☐ Pakistani ☐

Other (please state) _____

Occupation - Which of the following best describes you?

Employed full-time ☐ Full-time education ☐ Employed part-time ☐ Full-time carer ☐
Self-employed ☐ Homemaker ☐ Unemployed ☐ Retired ☐

Other (please state) _____

Marital status - Which of the following best describes you?

Single ☐ Living with parent(s)/Guardian(s) ☐ Married ☐ Divorced/separated
Co-habiting ☐

Other (please state) _____

What is your highest level of educational achievement?

Secondary School ☐ BTEC/SCOTVEC ☐ NVQ ☐ HNC or HND ☐ CSE ☐ Degree
GCSE ☐ Postgraduate degree ☐ AS or A Level ☐

Other (please state) _____

What is your religion- Which of the following best describes you?

Judaism ☐ Muslim ☐ Sikh ☐ Buddhism ☐ Christianity ☐ Roman Catholic ☐ None ☐

Other (please state) _____

Where do you buy the most of your bulk food shopping? (please state **one answer** only)

_____

Appendix 6: Survey

Durham University
School of Medicine and Health

R-Weight Survey

Shaped by the past, creating the future

ID Number:

Please indicate your choices by ticking (✔) the box(es) in the table below
What commercial weight loss product(s) or/and service(s) have you used in the last twelve months?, how long did you use it/them for and, what was the approximate cost(s) of using this/these product(s) or services)?

	1 day	1 week	1 month	3 month	6 month	1 year	Approximate Cost(s)
Slimming World							
Weight Watchers							
Lighter Life							
Rosemary Connelly							
Diet Chef							
Tony Ferguson							
Alli							
Slim Fast							
Special K							
Lipobind							
Adios							
Weight Loss book(s)							
DVD(s)							
Magazine(s)							
Website(s)							
CD(s)							

Example: If you have only used Alli in the last twelve months for two weeks you would complete the survey as shown below:

	1 day	1 week	1 month	3 months	6 months	1 year	Cost
Slimming World		✔✔					£32.95

If you have used a commercial weight loss product or service that is not listed above, please complete the table below

What commercial weight loss product or service have you used in the last twelve months?	How long did you use the product or service for and, what was the approximate cost?

Appendix 6: Survey

If your GP has prescribed you with any commercial weight loss products or services in the last 12 months, please complete the table below

What commercial weight loss product or service was prescribed?	How long was the product or service prescribed for?

Appendix 7: Survey; information sheet

Durham University
School of Medicine and Health

R-Weight Shaped by the past, creating the future

Participant Information Sheet ID Number:

What is R-Weight, and why are we doing it?
R- Weight is a study that will find out how popular commercial weight loss products and services are in the Tees Valley area. The research team is conducting this study, as we do not know if commercial weight loss products and services are common, and if they are, has there been a preferred one in the last twelve months. This study is funded by Durham University, as part of a PhD researching commercial weight loss products and services.

Who can take part?
You can take part if you:

(i) Have used a commercial weight loss product or service in the last twelve months
And
(ii) Live in the Tees Valley area (TS1-TS18)
And
(iii) Are 16 years old or over

What are commercial weight loss products and services?
Commercial weight loss products and/or services involve a one-off or continuous payment/subscription to lose weight.

Examples include:

- Weight loss programmes or clubs (Slimming World, Weight Watchers, Lighter Life, Rosemary Connelly, Diet Chef, Tony Ferguson etc)
- Products (Alli, Slim Fast, Special K, Lipobind, Adios etc)
- Other (Weight loss books, DVDs, magazines, websites, CDs etc)

How do I take part?
To take part in this study the research team would like you to complete a survey about commercial weight loss products and services that you have used in the last twelve months, and a consent form. We will also ask you to supply additional information (sex, date of birth, ethnicity, marital status, highest level of education achievement, religion and where you buy the most of your bulk food shopping). Additional information will give more answers, helping us to understand if this information may affect the reasons for choosing commercial weight loss products and services. After you have completed the survey, consent form and additional information please return in the pre-paid envelope. The survey will take approximately 20 minutes to complete.

Do I have to take part?
No. It is entirely up to you if you want to take part in this study after reading this information sheet. You can withdraw up to the 28th February 2011; you will not have to explain why. If you do wish to withdraw, contact Alisha Crayton (full contact details listed below) with your unique identification number (displayed in the top right-hand box).

How do I consent?
Your written consent will be required to participate in this study (see the consent form for details). Please read the enclosed consent form carefully then tick the Yes or No boxes and initial all boxes. If you have ticked any of the No boxes to questions 1-7, your data will be securely destroyed when received. If you tick the No box to question 8, but tick the Yes boxes to questions 1-7 you will still be included in this survey.

Appendix 7: Survey; information sheet

What will happen to the findings of this study?
Findings from this study will be printed in scientific magazines and reports and will be presented at conferences both in the UK and abroad. Overall study results will be printed in the Evening Gazette. Information that you provide will not identify you. Results from this study will be submitted to Durham University for Alisha Crayton's PhD thesis. If you wish to be given a report of this study, contact Alisha Crayton after October 2012.

Will my data be kept confidential?
All personal information that you provide will be kept confidential and anonymised with a unique identification number linked to your name. Your data will be kept in locked filling cabinets and password protected files at Durham University inline with the Data Protection Act (1998); this will not be shared with anyone who is not part of the research team. After the study has finished, data will be saved securely until the 1st June 2015, after this date, all data will be destroyed. Any information that you provide will be confidential. Exceptional circumstances could require us to reveal this information in a court of law. The research team will follow ethical and legal practice, protecting your identity and information from this study.

How will this study benefit me?
Participation in this research may not benefit you personally, though the research team would be grateful if you could take 20 minutes of your time for us to find out if commercial weight loss products and services have been popular in the last twelve months in the Tees Valley.

Are there any risks to taking part?
Taking part in this study is unlikely to affect you. If you are concerned about weight loss, eating disorders, or any other health related issues, seek advice from your GP. General advice and support is enclosed on a separate 'useful contact details' sheet.

Who has reviewed the study?
This study was given a favourable ethical opinion by the School of Medicine and Health Ethics Committee at Durham University.

Who should I contact if I have any concerns or questions?
If you have any questions or concerns please contact Alisha Crayton (PhD student):

Telephone: 0191 3340820
Email: cwl.orbresearchgroup@durham.ac.uk
Postal address:
R- Weight
Obesity Related Behaviours Research Group
School of Medicine and Health
Durham University- Queens Campus
Wolfson Research Institute- E106
Stockton-on-Tees
TS17 6BH

Alternatively contact Professor Carolyn Summerbell (Supervisor):

Postal address: Obesity Related Behaviours Research Group
School of Medicine and Health
Durham University- Queens Campus
Wolfson Research Institute- E106
Stockton-on-Tees
TS17 6BH

Appendix 7: Survey; information sheet

If you wish to take part in the study, please keep a copy of the participant information, and useful contact details sheets for your personal use

Thank you for taking the time to read the participant information sheet

Appendix 8: Survey; covering letter

Shaped by the past, creating the future

Durham University
School of Medicine and Health

ID Number:

Alisha Crayton

Return before:

R- Weight
Obesity Related Behaviours Research Group (ORB)
School of Medicine and Health
Durham University-Queens Campus
Wolfson Research Institute- E106
TS17 6BH

Email: cwl.orbresearchgroup@durham.ac.uk
Telephone: 01913340820

Dear Sir/Madam,

Thank you for registering your interest in this study. For your convenience, a participant information sheet has been provided.

If you wish to participate after carefully reading the participant information sheet please complete the survey, consent form, and additional information sheet, and return to the researcher (Alisha Crayton) in the pre-paid envelope before the date stated in the top left-hand box. Documents returned after this date will be securely destroyed when received:

The study will take approximately 20 minutes of your time. This study is voluntary, it is your decision to decline or participate. All personal information that you provide will be kept confidential and anonymised with a unique identification number linked to your name. Your data will be kept in locked filling cabinets and password protected files at Durham University in accordance with the Data Protection Act (1998); which will not be shared with anyone who is not part of the research team. After the study has finished, data will be securely saved until the 1st June 2015, after this date, all data will be destroyed.

Thank you for taking the time to read this information.

Alisha Crayton (PhD Student)

Professor Carolyn Summerbell (Supervisor)

Appendix 9: Press release

1000 Tees Valley participants required for commercial weight loss survey

Volunteers in the North East are being invited to take part in a study about their experiences and use of commercial weight loss products and services in the past twelve months.

This study is being conducted by Alisha Crayton and Professor Carolyn Summerbell at Durham University, Queen's Campus. Research is important in providing more information that will help shape public health policy and practice.

Alisha explains that "the study is being conducted to provide additional information about the popularity of commercial weight loss methods in the region, and whether these options could be seen as a more cost effective treatment method for Primary Care Trust's than current provisions".

"Commercial weight loss products and/or services involve a one-off or continuous payment/subscription to lose weight. For example; Slimming World, Weight Watchers, Lighter Life, Rosemary Connelly, Diet Chef, Tony Ferguson, Alli, Slim Fast, Special K, Lipobind, Adios ,Weight loss books, DVDs, magazines, websites, CDs etc. This survey will require a similar amount of participants as the Get a Better Life Campaign, ideally 1000. Only one percent of people who read the Evening Gazette would reach this number. I am confident that people in the North East will provide much needed assistance to this research, as they did for the Get a Better Life Campaign." explains Alisha.

Alisha was one of the research team involved with the Get a Better Life Campaign, encouraging Teesside adults to make one dietary and one physical activity pledge, in partnership with Evening Gazette, Teesside University and NHS Middlesbrough. The Get a Better Life Campaign recruited over 1000 people to make healthy lifestyle changes.

This research will involve a survey about commercial weight loss products and services that have been used in the last twelve months, and a consent form. The researchers also ask for additional information (sex, date of birth, ethnicity, marital status, highest level of education achievement, religion and where the majority of food items are bought). Additional information will give more answers, helping the researchers to understand if this information may affect the reasons for choosing commercial weight loss products and services.

Participants who live in County Durham, Northumberland, Teesside, Tyne and Wear and parts of North Yorkshire, who have used a commercial weight loss product or service in the past 12 months and are over 16 can take part by providing a name, address, postcode and contact telephone number via calling 0191 3340820, emailing **cwl.orbresearchgroup@durham.ac.uk** or writing to R-Weight, ORB research group, Durham University, School of Medicine and Health, Queen's Campus, Wolfson Research Institute - E106, TS17 6BH.

Appendix 10: PCT; recruitment poster

Volunteers required for a regional commercial weight loss survey

Researchers at Durham University would like to know how popular commercial weight loss products and services are in County Durham, Northumberland, Tees Valley, and Tyne and Wear.

At least 1000 volunteers are required to complete a 20 minute postal survey about commercial weight loss products and services purchased within the last twelve months.

The research team at Durham University, Queen's Campus, are conducting this study, as it is not known if commercial weight loss products and services are common, which is the most popular, and the average cost spent. Researchers will feed the findings into public health policy, informing Primary Care Trusts about alternative cost effective methods of weight loss.

Who can take part?

You can take part if you:

(i) Have used a commercial weight loss product or service in the last twelve months **And** (ii) Live in County Durham, Northumberland, Tees Valley or Tyne and Wear **And** (iii) Are 16 years old or over

What are commercial weight loss products and services?

Commercial weight loss products and/or services involve a one-off or continuous payment/subscription to lose weight.

Examples include:

- Weight loss programmes or clubs (Slimming World, Weight Watchers, Lighter Life, Rosemary Connelly, Diet Chef, Tony Ferguson etc)
- Products (Alli, Slim Fast, Special K, Lipobind, Adios etc)
- Other (Weight loss books, DVDs, magazines, websites, CDs etc)

If you are interested in taking part in this study, please send your name and address, including your postcode, and contact telephone number*, either by emailing cwl.orbresearchgroup@durham.ac.uk, calling 0191-334- 0820 or by writing to R-Weight, Obesity Related Behaviours Research Group, School of Medicine and Health, Durham University, Queens Campus, Wolfson Research Institute, Stockton-on-Tees, TS17 6BH

*Details required are only needed to post the survey to you, these details will not be used for analysis. All personal information that you provide will be kept confidential and anonymised with a unique identification number linked to your name. Your data will be kept in locked filling cabinets and password protected files at Durham University in line with the Data Protection Act (1998); this will not be shared with anyone who is not part of the research team. After the study has finished, data will be saved securely until the 1st June 2015, after this date, all data will be destroyed.

Appendix 11: Interview schedule

- Consent forms, take information sheet

Hi everyone I'd firstly like to **thank you** for attending today. If we could all **introduce ourselves** would be great. I'm Alisha, Alisha Crayton. **The research that you are involved in is about commercial weight loss for my PhD thesis, you have all taken part in the survey**. I will be conducting other focus groups like this one over the next month with other survey participants, just to make sure that we are capturing as many viewpoints about the reasons for buying commercial weight loss products and services as possible.

Everyone who is here today has **used one or more methods** of commercial weight loss in the last twelve months, so everyone has a shared experience. By commercial weight loss I mean products and services that have been paid for to help you lose weight. Everything that is said here today is **confidentia**l, so if I could ask everyone to keep our **discussions** within these **four walls would be appreciated**.

As you might of gathered from the information sheets that have been sent to you previously, this research is **not affiliated** by commercial weight loss companies. So this is **not a test, there are no right or wrong answers**, as you would normally do, please **respect peoples opinions, and we will hear everyone's views today**.

Our **aim is to find out why you have chosen commercial weight loss products and services, and why you chose these over other commercial weight loss services and products**. Weight loss is an important health concern for the NHS, and **we'll inform them about what is said today, to help them develop better services for people who want to lose weight**.

Briefly, we will talk about **diet and exercise, weight loss and commercial weight loss.**

Just a couple of quick house keeping rules, the **toilets** are out of the door and to the right and the nearest **fire exit is** just opposite this door, whereby we would take the stairs, and at the bottom turn right if there is an evacuation.

Appendix 11: Interview schedule

Does anyone have any **questions so far**?. Ok, so without further adieu we will **begin**.

Questions

- Thinking back to before using a commercial weight loss products or service, what were your views on diet and physical activity?
- Has your opinion about diet and physical activity changed at all since using a commercial weight loss product or service?

- With regards to diet and exercise has anyone seen the NHS/Government guidelines about physical activity and diet?,
    - If **yes**, what was your opinions of them/, were they difficult or easy to understand?
    - If **No**, can anyone briefly talk about what they think is the amount of exercise required to stay fit and healthy on a weekly and/or daily basis?, and a quick summary about what is considered to be a healthy diet?.

We all know if we reduce the amount we eat and exercise a little more, we will lose weight.

- So, has anyone tried any other weight loss options before paying to lose weight through a commercial intervention?
    - If **yes**, can you share with the group the impact it had on you socially/emotionally/physically?.
    - If, **no**-Ok we'll move onto the subject at hand, commercial weight loss

Moving nicely on, we've talked about weight loss, but not the reasons for choosing commercial weight loss.

- Does anyone feel that they can share their commercial weight loss experiences with the group?
    - For example, why you chose a commercial weight loss method?, was there anything in particular that attracted you to it?
    - Did you have any reasons for choosing these commercial weight loss products and services over other commercial weight loss products and services?

There appears to be quite a few reasons why commercial weight loss has been chosen,

- Would anyone like to share their experiences of using a commercial weight loss method?
    - For example did it have any impact on you physically/emotionally/socially?
    - Positive and negative

Thinking about experiences

- Has anyone been to the doctor to talk about weight loss options?,
    - What experience did you have?
    - Was the doctor helpful/or not?

Linking on from the GP, to the NHS and the GP

- Hypothetically if commercial weight loss options were available for 8 or 12 weeks for free on the NHS, do you think you would have visited the GP to talk about weight loss?. If your GP were to offer you a commercial weight loss method, how do you think you would respond?

With commercial weight loss it appears that it can be done with others, or on your own.

- Support wise, did anyone feel able that they could tell their friends and family?
    - What was their initial reactions?

Appendix 11: Interview schedule

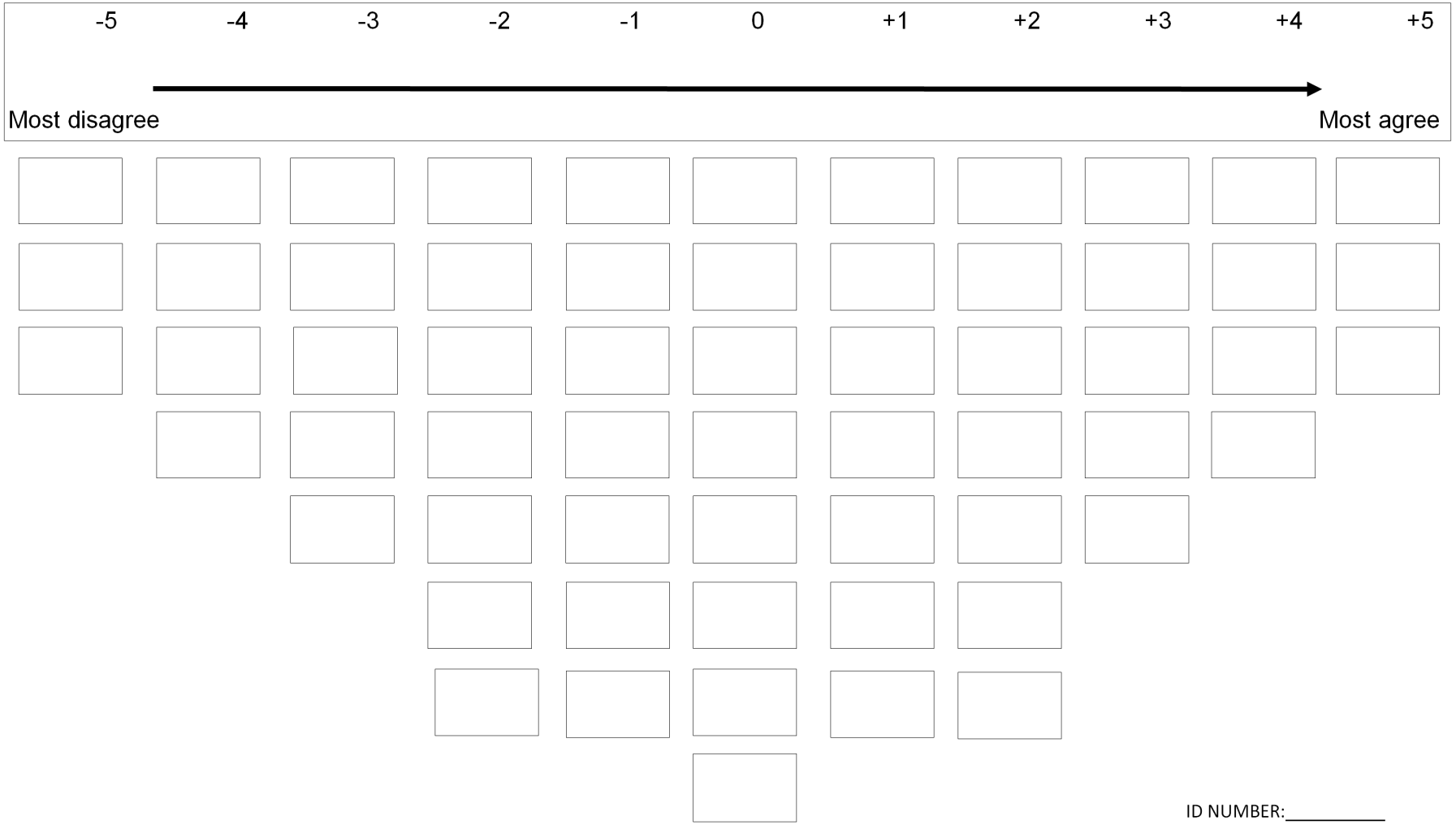
Stereotypes

- Just to round up, do you think that there is a stereotype of a typical person who would use commercial weight loss products and services?

Thank you all for attending, your input is greatly appreciated.

Appendix 12: Q-Sorting sheet

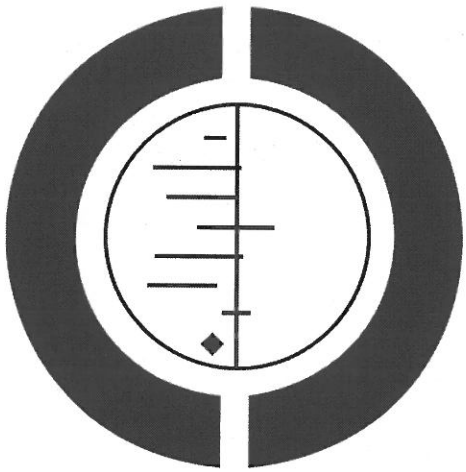
Sorting sheet



ID NUMBER:_____

Commercial weight loss products and services for obese and overweight adults (Protocol)

Crayton AM, Summerbell CD, Ells LJ, Sonnier TJ, Rutter H, Greenway FL



This is a reprint of a Cochrane protocol, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2013, Issue 12

http://www.thecochranelibrary.com

WILEY

Appendix 13: Cochrane protocol

TABLE OF CONTENTS

[Intervention Protocol]

Commercial weight loss products and services for obese and overweight adults

Alisha M Crayton[1], Carolyn D Summerbell[1], Louisa J Ells[2], Tance J Sonnier[3], Harry Rutter[4], Frank L Greenway[5]

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Contact address: Alisha M Crayton, School of Medicine and Health, Wolfson Research Institute, Queen's Campus, Durham University, University Boulevard, Thornaby, Stockton-on-Tees, TS17 6BH, UK. alisha.crayton@durham.ac.uk.

Editorial group: Cochrane Metabolic and Endocrine Disorders Group.
Publication status and date: New, published in Issue 12, 2013.

Citation: Crayton AM, Summerbell CD, Ells LJ, Sonnier TJ, Rutter H, Greenway FL. Commercial weight loss products and services for obese and overweight adults. *Cochrane Database of Systematic Reviews* 2013, Issue 12. Art. No.: CD010751. DOI: 10.1002/14651858.CD010751.

ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of commercial weight loss products and services for overweight or obese people.

BACKGROUND

There are a wide range of commercial weight loss options available to the general public, which vary in cost. It is not known which products and services offer the most effective and cost-effective results for weight loss and maintenance.

Description of the condition

Overweight and obesity are major preventable health burdens facing most middle and high income countries. Both overweight and obesity are defined as excessive fat accumulation that presents a risk to health (WHO 2013).

Trends indicate that a shift in energy balance, predominately excess energy intake exceeding energy expenditure rather than changes in our gene pool have led to the high levels of obesity and overweight we see in many countries (WHO 2013).

The body mass index (BMI) is the preferred method of body fat measurement in clinical settings, for practicality, and cost effectiveness to illustrate the health risks associated with a raised BMI (Gray 1991). However, BMI as a measurement method is only a proxy measure of body fatness. BMI is a measure of weight relative to height, calculated by dividing weight (kg) by height (m^2) (Foresight 2007). The World Health Organization (WHO) has identified particular cut-off points for the classification of underweight, ideal, overweight and obese adults (WHO 2006).

Underweight is defined as BMI < 18.5, normal weight is BMI 18.5 to 24.9, and overweight is BMI 25 to 29.9. Obesity is classified in three categories: class I obesity (BMI 30.0 to 34.9), class II obesity (BMI 35.0 to 39.9), and class III - morbid obesity (≥ 40.0).

BMI must be used with caution: This method of measurement assesses total body weight irrespective of muscle and fat mass. Certain populations (elderly and athletes) could fall into incorrect

categories in recognition of their BMI classification.

WHO has identified intermediate action points for Asian populations. However, these are not universal across all ethnicities. Studies that have included non-Caucasian populations should use BMI adjusted calculations for the participants involved.

Ideally, additional methods of assessment should be utilised to predict health risks associated with an increased fat mass (waist circumference and waist-to-hip ratio). However, caution should be used. Defined waist circumference protocols (minimal waist, umbilicus, immediately above the iliac crest, and midpoint point between the lowest rib and immediately above the iliac crest) correlate with different health related risk factor cut-off points.

The prevalence of obesity and overweight is not confined to Western populations. Deprived and developing countries have observed malnutrition equalling obesity (Lobstein 2004). Globally it is estimated that by 2015, approximately 700 million adults will be obese, and 2.3 billion will be overweight. If trends do not subside, 50% of the United Kingdom's population could be defined as obese by 2050 (Foresight 2007). There are indications from some countries that the rate of increase may have plateaued, for example in the US at about a third of the population (Flegal 2010). One in 10 five to seventeen year olds are classified as overweight, a total of 155 million, and 1 in 50 are classified as obese which accounts for 30 to 45 million of the presented figure (Lobstein 2004). The National Child Measurement Programme (NCMP) data set of four to five year olds and 10 to 11 year olds in England, 2009/2010 reported that in 23.1% of the younger children measured were either overweight or obese, one in three (33.4%) of the older children measured were either overweight or obese (Health and Social Care Information Centre 2010).

Obesity accounts for a plethora of physical, social and psychological consequences, and is associated with type 2 diabetes, hypertension, congestive heart failure, certain cancers, and non-alcoholic fatty liver disease. Obesity is also associated with early mortality (National Audit Office 2001).

Financial costs incurred to the individual and the state account for a considerable amount of state expenditure regardless of the country of origin. Indirect effects of obesity can be measured, calculating increased number of sick days, earlier retirement, decreased performance, loss of earnings, and loss of productivity and capability. Direct costs relate to the prevention, diagnosis and treatment of obesity.

At an individual level, increases in the consumption of whole grains, nuts, legumes, fruits, vegetables and physical activity is recommended, paralleled with the limitation of total fats, and reduced intake of sugars.

As a result of the rise in obesity prevalence, the search for cost-effective interventions is of paramount importance. Numerous treatment options are available via primary care providers, and available for purchase at an individual level, including bariatric surgery, pharmacological interventions, behaviour modification, and commercial alternatives.

Lowe 2001 report an increasing amount of overweight individuals who seek treatment in the commercial environment. However, insufficient evidence supports long-term effectiveness of commercial interventions (Ditschuneit 2001; Foster 2003; Heshka 2003). Research traditionally lies within short-term studies, reporting effectiveness of commercial alternatives (Heshka 2000).

Discontinuation of a commercial treatment option results in weight regain in 33% to 66% of individuals within the first year, and the majority of lost weight is regained within five years (Lowe 2001), warranting the requirement of effective long-term evaluation and research.

Some of the most recognisable commercial weight loss products and services have been established for only four decades. The last 10 years have seen the companies who produce and deliver these products and services strengthening their delivery, marketing strategies, and the sharing of results with the rest of the weight loss industry. It is uncertain whether commercial weight loss products and services are a cost effective method for weight loss maintenance (Gosselin 2001).

Within the United Kingdom, some primary care trusts have offered a referral option to commercial weight loss programmes, such as Weight Watchers (http://www.weightwatchers.com/) and Slimming World (http://www.slimmingworld.com/), but often for just a duration of12 weeks. Literature does not specifically illustrate why certain programmes have been favoured over others, other than their popularity in the public domain. As the value of the commercial sector which aims to help people lose weight continues to rise (it currently exceeds £2 billion (EURO2.3 billion) (Foresight 2007), it is of paramount importance to conduct research in relation to effectiveness of commercial weight loss products and services and translate this information to policy and practice so that they, and the public, can make better informed treatment choices.

Description of the intervention

Commercial weight loss products and services have increased in number, patterned with rising obesity and overweight prevalence (Hamilton 2004). Marketing of these products and services has been observed in various venues and advertising spaces, including online. There is a wealth of choice available to users in terms of types of products and services available for adults, including dietary supplements, own-brand groceries, meal replacement products, menu guides combined with food planning, and food calorie points systems. Numerous popular products and services focus on group support, led by an individual who has succeeded in the programme, and is maintaining their weight. Individuals who wish to lose weight through commercial weight loss products and services have a considerable amount of choices. Evidence to justify weight maintenance is overwhelmed by marketing strategies. Specifically for this systematic review, we will concentrate upon interventions that are commercial weight loss products and services which de-

liver advice via a number of settings and media (e.g. face to face group settings, online) where advice is restricted to diet and/or physical activity behaviour change, including meal replacements. The review will not include products and services which include weight loss drugs, hypnotherapy or hypnosis, incentives, or nutriceuticals.

Adverse effects of the intervention

Research has not specifically examined the adverse effects of commercial weight loss products and services, systematic assessment is required. Specifically, we will include information in relation to attrition and uptake of said interventions.

How the intervention might work

Increasing number of people turn to the commercial market for weight loss treatment (Lowe 2001). Research suggests that weight loss maintenance could be more effective for individuals who start a group-based behavioural treatment programme (Akers 2010). However, individual based programmes have also shown positive results (Rock 2010). Techniques taught by the programmes reviewed could be more successful in relapse prevention and problem solving. The format of the programme could also impact upon weight and BMI changes.

Why it is important to do this review

Advice on weight loss from primary care providers has been shown to be effective (Levy 1988). Individuals who wish to gain guidance and advice from a practitioner in relation to commercial weight loss products and services are often not able to do so, practitioners may feel ill equipped to confidently provide this information (Tsai 2005). In order to assist practitioners, and prior to selecting a commercial weight loss product or service, systematic synthesis of evidence is required. Commercial weight loss products and services are limited in number. However, short-term effectiveness has been demonstrated (Heshka 2000). Primarily, consumers and practitioners require information concerning cost-effectiveness, ascertaining how much a product or service costs for a prescribed and advised intervention period (12 weeks), and whether weight will be regained after the individual has discontinued with the product or service.

Commercial weight loss treatment options require evaluation to assess effectiveness, and to assist commissioners of service. This evidence is equally important for users in order to help them choose a method that is based upon evidence rather than marketing strategies.

Health inequalities could be tackled by marketing of commercial weight loss interventions targeting individuals with lower socio-economic status. Research suggests that socio-economic status is patterned with obesity and overweight prevalence (House of Commons Health Committee 2004). Specific areas of the United Kingdom with low socio-economic status, and increased deprivation could be widening the health inequalities gap via differential purchase of commercial weight loss treatment options.

OBJECTIVES

To assess the effects of commercial weight loss products and services for overweight or obese people.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and controlled clinical trials.

Types of participants

We will include males and/or females aged 18 years or older. Trials which focus on pregnant and lactating women will be excluded.

Types of interventions

We will include Interventions which have been conducted for a minimum of six months, one year, and beyond where data available.

Intervention

Commercial weight loss products and services which deliver advice via a number of settings and media (e.g. face to face group settings, online) where advice is restricted to diet and/or physical activity behaviour change, including meal replacements(interventions which include weight loss drugs, hypnotherapy or hypnosis, incentives, or nutriceuticals will not be included).

Control

- Placebo.
- Usual care.
- Another commercial weight loss product or service.

Appendix 13: Cochrane protocol

Types of outcome measures

Primary outcomes

- Weight change and change in BMI at one year.
- Health-related quality of life (measured by a validated instrument).
- Adverse effects.

Secondary outcomes

- Change data at six months, one year, and beyond where data are available for weight, BMI, percentage overweight and obese, waist-to-hip ratio, waist circumference, cholesterol (total cholesterol, high-density lipoprotein (HDL)-cholesterol, low-density lipoprotein (LDL)-cholesterol), and blood pressure (diastolic and systolic).
- Costs (delivery and cost effectiveness).
- All-cause mortality.
- Morbidity.
- Compliance with commercial weight loss product or service.
- Attrition.

Timing of outcome measurement

Outcomes measured at around six months, one year, and beyond where data are available will be included.

'Summary of findings' table

We will present a 'Summary of findings table' reporting the following outcomes listed according to priority.

1. Health-related quality of life.
2. Morbidity.
3. All-cause mortality.
4. Adverse effects.
5. Compliance.
6. Change in weight measure.
7. Costs.

Search methods for identification of studies

Electronic searches

We will search the following sources from inception to the present.

- *The Cochrane Library.*
- MEDLINE.
- EMBASE.
- CINAHL.
- PsycINFO.

We will also search databases of ongoing trials including ClinicalTrials.gov (http://clinicaltrials.gov/), *meta*Register of Controlled Trials (http://www.controlled-trials.com/mrct/), the EU Clinical Trials register (https://www.clinicaltrialsregister.eu/) and the WHO International Clinical Trials Registry Platform Search Portal (http://apps.who.int/trialsearch/).

For detailed search strategies see Appendix 1. We will continuously apply PubMed's 'My NCBI' (National Center for Biotechnology Information) email alert service to identify newly published studies using a basic search strategy (Appendix 1). Four weeks before we submit the final review draft to the Cochrane Metabolic and Endocrine Disorders Group for editorial approval, we will perform an updated search on all specified databases. If we identify new studies for inclusion we will evaluate these and incorporate findings in our review before submission of the final review draft. If we detect additional relevant key words during any of the electronic or other searches, we will modify the electronic search strategies to incorporate these terms and document the changes. We will place no restrictions on the language of publication when searching the electronic databases or reviewing reference lists in identified studies.

We will send results of electronic searches to the Cochrane Metabolic and Endocrine Disorders Group for databases which are not available at the editorial office.

Searching other resources

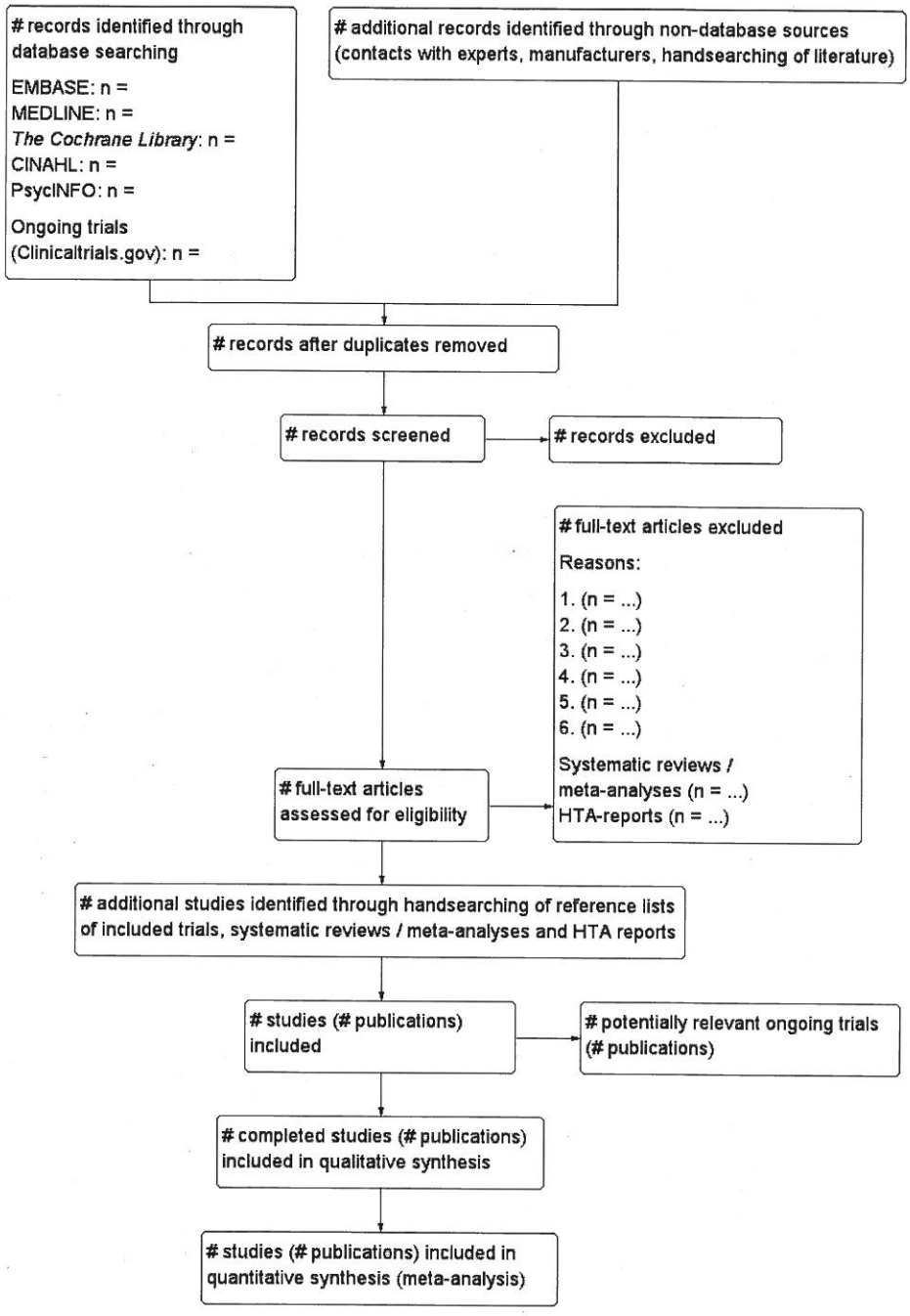
We will try to identify other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials, (systematic) reviews, meta-analyses and health technology assessment reports.

Data collection and analysis

Selection of studies

To determine the studies to be assessed further, two authors (AC, CS) will independently scan the abstract, title or both sections of every record retrieved. All potentially relevant articles will be investigated as full text. Where differences in opinion exist, they will be resolved by a third author (NN). If resolving disagreement is not possible, the article will be added to those 'awaiting assessment' and we will contact authors for clarification. We will present an adapted Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram of study selection (Figure 1) (Liberati 2009).

Figure 1. Study flow diagram.



Data extraction and management

For studies that fulfil inclusion criteria, two authors (AC, CS) will independently abstract relevant population and intervention characteristics using standard data extraction templates, with any disagreements to be resolved by discussion, or if required by a third author (Table 1; Appendix 2; Appendix 3; Appendix 4; Appendix 5; Appendix 6; Appendix 7; Appendix 8; Appendix 9; Appendix 10; Appendix 11; Appendix 12).

We will provide information including trial identifier about potentially-relevant ongoing studies in the 'Characteristics of ongoing studies' section and in the appendix 'Matrix of study endpoints (protocol/trial documents)'. We will try to find the protocol of each included study, either in databases of ongoing trials, in publications of study designs, or both, and specify data in the appendix 'Matrix of study endpoints (trial documents)'.

We will send an email to all study authors of included studies to enquire whether they are willing to answer questions regarding their trials. We will present the results of this survey in Appendix 13. Thereafter, we will seek relevant missing information on the trial from the primary author(s) of the article, if required.

Dealing with duplicate publications

In the event of duplicate publications, companion documents or multiple reports of a primary study, we will maximise yield of information by collating all available data. In case of doubt the publication reporting the longest follow-up associated with our primary or secondary outcomes will be given priority.

Assessment of risk of bias in included studies

Two authors (AC, CS) will assess each trial independently. Possible disagreements will be resolved by consensus. In cases of disagreement, the rest of the group will be consulted and a judgement will be made based on consensus.

We will assess risk of bias using the Cochrane Collaboration's tool for assessing risk of bias (Higgins 2011a; Higgins 2011b). We will use the following criteria.

- Random sequence generation (selection bias).
- Allocation concealment (selection bias).
- Blinding (performance bias and detection bias), separated for blinding of participants and personnel and blinding of outcome assessment.
- Incomplete outcome data (attrition bias).
- Selective reporting (reporting bias).
- Other bias.

We will assess outcome reporting bias by integrating the results of 'Examination of outcome reporting bias' (Appendix 7), 'Matrix of study endpoints (protocol/trial documents)' (Appendix 6) and section 'Outcomes (outcomes reported in abstract of publication)' of the 'Characteristics of included studies' section (Kirkham 2010). This analysis will form the basis for the judgement of selective reporting (reporting bias).

We will judge risk of bias criteria as 'low risk', 'high risk' or 'unclear risk' and evaluate individual bias items as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). We will present a 'Risk of bias' figure and a 'Risk of bias summary' figure.

We will assess the impact of individual bias domains on study results at endpoint and study levels.

For blinding of participants and personnel (performance bias), detection bias (blinding of outcome assessors) and attrition bias (incomplete outcome data) we intend to evaluate risk of bias separately for subjective and objective outcomes (Hróbjartsson 2013). We will consider the implications of missing outcome data from individual participants.

We define the following endpoints as subjective outcomes.

- Health-related quality of life.
- Adverse effects.
- Compliance with commercial weight loss product or service.

We define the following outcomes as objective outcomes.

- Weight change and change in BMI.
- Change data for percentage overweight and obese, waist-to-hip ratio, waist circumference, cholesterol (total cholesterol, HDL-cholesterol, LDL-cholesterol), and blood pressure (diastolic and systolic).
- Costs (delivery and cost effectiveness).
- All-cause mortality.
- Morbidity.
- Attrition.

Measures of treatment effect

We will express dichotomous data as odds ratios (ORs) or risk ratios (RRs) with 95% confidence intervals (CIs). We will express continuous data as mean differences (MD) with 95% CIs.

Unit of analysis issues

We will take into account the level at which randomisation occurred, such as cross-over trials, cluster-randomised trials and multiple observations for the same outcome.

Dealing with missing data

We will obtain relevant missing data from authors, if feasible and carefully perform evaluation of important numerical data such as screened, randomised patients as well as intention-to-treat (ITT), as-treated and per-protocol populations. We will investigate attrition rates, for example drop-outs, losses to follow up and withdrawals and critically appraise issues of missing data and imputation methods (for example last-observation-carried-forward (LOCF)).

Assessment of heterogeneity

In the event of substantial clinical, methodological or statistical heterogeneity, we will not report study results as meta-analytically pooled effect estimates.

We will identify heterogeneity by visual inspection of the forest plots and by using a standard Chi^2 test with a significance level of $\alpha = 0.1$, in view of the low power of this test. We will examine heterogeneity using the I^2 statistic, which quantifies inconsistency across studies to assess the impact of heterogeneity on the meta-analysis (Higgins 2002; Higgins 2003), where an I^2 statistic of 75% or more indicates a considerable level of inconsistency (Higgins 2011a).

When we find heterogeneity, we will attempt to determine potential reasons for it by examining individual study and subgroup characteristics.

We expect the following characteristics to introduce clinical heterogeneity.

- Co-morbidities such as diabetes mellitus, cancer, respiratory problems, and over- or under active thyroid could contribute to increases or decreases in weight or body mass index.
- Compliance to the weight loss product or service.
- Co-medications.
- Psychological issues.

Assessment of reporting biases

If we include 10 studies or more for a given outcome, we will use funnel plots to assess small study effects. Owing to several possible explanations for funnel plot asymmetry, we will interpret results carefully (Sterne 2011).

Data synthesis

Unless there is good evidence for homogeneous effects across studies, we will primarily summarise low risk of bias data by means of a random-effects model (Wood 2008). We will interpret random-effects meta-analyses with due consideration of the whole distribution of effects, ideally by presenting a prediction interval (Higgins 2009). A prediction interval specifies a predicted range for the true treatment effect in an individual study (Riley 2011). In addition, we will perform statistical analyses according to the statistical guidelines contained in the latest version of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a).

Subgroup analysis and investigation of heterogeneity

We will carry out the following subgroup analyses and plan to investigate interaction.

- Obesity and morbidly obese participants.
- Overweight and obese participants.
- Socio-economic status.
- Gender.
- Ethnicity.
- Age.

Sensitivity analysis

We will perform sensitivity analyses in order to explore the influence of the following factors (when applicable) on effect sizes.

- Restricting the analysis to published studies.
- Restricting the analysis taking into account risk of bias, as specified in the section Assessment of risk of bias in included studies.
- Restricting the analysis to very long or large studies to establish how much they dominate the results.
- Restricting the analysis to studies using the following filters: diagnostic criteria, language of publication, source of funding (industry versus other), country.

We will also test the robustness of the results by repeating the analysis using different measures of effect size (RR, OR etc.) and different statistical models (fixed-effect and random-effects models).

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* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. Overview of study populations

Characteristic	Intervention(s) and comparator(s)	Sample size[a]	[N] Screened/ eligible	[N] Randomised	[N] Safety	[N] ITT	[N] Finishing study	[%] Randomised finishing study	Follow-up [b]
(1) Study ID	Intervention 1								
	Intervention 2								
	Comparator 1								
	Comparator 2								
			total:						
Grand total	*All interventions*			...			...		
	All comparators			...			...		
	All interventions and comparators			...			...		

[a] According to power calculation in study publication or report
[b] Duration of intervention and/or follow-up under randomised conditions until end of study
"-" denotes not reported

ITT: intention-to-treat; N/A: not applicable

APPENDICES

Appendix 1. Search strategies

Search terms and databases
Unless otherwise stated, search terms are free text terms. Abbreviations: '$': stands for any character; '?': substitutes one or no character; adj: adjacent (i.e. number of words within range of search term); exp: exploded MeSH; MeSH: medical subject heading (MEDLINE medical index term); pt: publication type; sh: MeSH; tw: text word
The Cochrane Library
#1 MeSH descriptor Obesity explode all trees #2 MeSH descriptor Weight Gain explode all trees #3 MeSH descriptor Weight Loss explode all trees #4 MeSH descriptor Body Mass Index explode all trees #5 (overweight in All Text or (over in All Text and weight in All Text)) #6 (adipos* in All Text or (fat in All Text and overload in All Text and syndrom* in All Text)) #7 (overeat* in All Text or (over in All Text and eat* in All Text)) #8 (overfeed* in All Text or (over in All Text and feed* in All Text)) #9 (weight in All Text and (gain in All Text or chang* in All Text)) #10 (body in All Text and mass in All Text and ind* in All Text) #11 MeSH descriptor Waist circumference explode all trees #12 MeSH descriptor Waist-Hip Ratio explode all trees #13 MeSH descriptor Abdominal fat explode all trees #14 MeSH descriptor Body fat distribution explode all trees #15 MeSH descriptor Skinfold thickness explode all trees #16 MeSH descriptor Overweight explode all trees #17 ((weight in All Text near/6 cyc* in All Text) or (weight in All Text near/6 reduc* in All Text) or (weight in All Text near/6 los* in All Text) or (weight in All Text near/6 maint* in All Text) or (weight in All Text near/6 decreas* in All Text)) #18 ((weight in All Text near/6 watch* in All Text) or (weight in All Text near/6 control* in All Text) or (weight in All Text near/6 chang* in All Text) or (weight in All Text near/6 gain* in All Text)) #19 BMI in All Text #20 (waist-hip in All Text and ratio* in All Text) #21 (waist in All Text and circumferenc* in All Text) #22 (body in All Text and (fat in All Text near/6 distribution* in All Text)) #23 ((abominal in All Text and fat in All Text) or (skinfold in All Text and thickness in All Text)) #24 (obes* in All Text or adipos* in All Text) #25 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12) #26 (#13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24)

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(*Continued*)

#27 (#25 or #26)
#28 MeSH descriptor Diet explode all trees
#29 MeSH descriptor Dietary supplements explode all trees
#30 MeSH descriptor Caloric restriction explode all trees
#31 MeSH descriptor Directive counseling explode all trees
#32 (food in All Text near/3 formulated in All Text)
#33 (diet in All Text near/3 supplement* in All Text)
#34 (weight in All Text and (loss in All Text near/6 program* in All Text))
#35 (weight in All Text and (loss in All Text near/6 product* in All Text))
#36 (weight in All Text and (loss in All Text near/6 method* in All Text))
#37 (weight in All Text and (loss in All Text near/6 book* in All Text))
#38 (weight in All Text and (loss in All Text near/6 website* in All Text))
#39 (weight in All Text and (loss in All Text near/6 CD* in All Text))
#40 (weight in All Text and (loss in All Text near/6 service* in All Text))
#41 (weight in All Text and (reduction in All Text near/6 program* in All Text))
#42 (weight in All Text and (reduction in All Text near/6 method* in All Text))
#43 (weight in All Text and (reduction in All Text near/6 book* in All Text))
#44 (weight in All Text and (reduction in All Text near/6 website* in All Text))
#45 (weight in All Text and (reduction in All Text near/6 CD* in All Text))
#46 (weight in All Text and (reduction in All Text near/6 product* in All Text))
#47 (weight in All Text and (reduction in All Text near/6 service* in All Text))
#48 ((caloric in All Text and restriction* in All Text) or (directive in All Text and counsel* in All Text) or (food in All Text and formulated in All Text))
#49 ((food in All Text and plan* in All Text) or (slim in All Text and fast in All Text) or (slimming in All Text and world in All Text) or (weight in All Text and watchers in All Text) or Atkins in All Text)
#50 (#28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49)
#51 MeSH descriptor Commerce explode all trees
#52 commerc* in All Text
#53 (#51 or #52)
#54 (#27 and #50 and #53)

MEDLINE

1 exp Diet/
2 exp Dietary supplements/
3 exp Caloric restriction/
4 exp Directive counseling/
5 exp Food formulated/
6 diet supplement*.ti,ab.
7 ((weight-loss or weight reduction) adj6 (program* or product* or method* or book* or website* or magazine* or DVD* or CD* or service* or self-help)).ti,ab.
8 (caloric restriction* or hypocaloric or very low calorie* low calorie* or VLCD* or directive counsel* or food formulated or liquid-supplement* or meal replacement*).ti,ab.
9 (food plan* or slim fast or slimming world or weight watchers or Atkins).ti,ab.
10 exp Commerce/
11 (commerc* or proprietary).ti,ab.
12 or/1-11
13 exp Obesity/ or exp Obesity hypoventilation syndrome/ or exp Obesity, abdominal/ or exp Obesity, morbid/ or exp Prader-Willi Syndrome

Appendix 13: Cochrane protocol

(*Continued*)

14 exp Overweight
15 exp Adipose tissue/
16 exp Weight gain/ or exp Weight loss/
17 exp body fat distribution/ or exp body mass index/ or exp waist circumference/ or exp skinfold thickness/ or exp waist-hip ratio/
18 exp Body Composition/
19 (overweight$ or over weight$).ti,ab.
20 fat overload syndrom$.ti,ab.
21 (overeat$ or over eat$).ti,ab.
22 (overfeed$ or over feed$).ti,ab.
23 (adipos$ or obes$).ti,ab.
24 (weight adj3 (cyc$ or reduc$ or los$ or maint$ or decreas$ or watch$ or control$ or gain$ or chang$)).ti,ab.
25 (body mass ind$ or waist-hip ratio$).ti,ab.
26 skinfold thickness$.ti,ab.
27 abdominal fat$.ti,ab.
28 ((abdominal or subcutaneous or intra-abdominal or visceral or retroperitoneal or retro peritoneal) adj3 fat*).ti,ab.
29 or/13-28
30 (clinical control* or randomi?ed control* or control*).pt.
31 controlled clinical trial.pt.
32 randomi?ed.ab.
33 placebo.ab.
34 drug therapy.fs.
35 randomly.ab.
36 trial.ab.
37 groups.ab.
38 or/30-37
39 Meta-analysis.pt.
40 exp Technology Assessment, Biomedical/
41 exp Meta-analysis/
42 exp Meta-analysis as topic/
43 hta.ti,ab.
44 (health technology adj6 assessment$).ti,ab.
45 (meta analy$ or metaanaly$ or meta?analy$).ti,ab.
46 (search$ adj10 (literature$ or medical database$ or medline or pubmed or embase or cochrane or cinahl or psycinfo or psyclit or healthstar or biosis or current content$ or systemat$)).ti,ab.
47 or/39-46
48 38 or 47
49 (comment or editorial or historical-article).pt.
50 48 not 49
51 12 and 29 and 50
52 (animals not (animals and humans)).sh.
53 51 not 52

EMBASE

1 exp diet/
2 exp diet supplementation/
3 exp caloric restriction/
4 exp directive counseling/
5 exp elemental diet/
6 diet supplement*.tw,ot.

Appendix 13: Cochrane protocol

(*Continued*)

7 ((weight-loss or weight reduction) adj6 (program* or product* or method* or book* or website* or magazine* or DVD* or CD* or service* or self-help)).ti,ab.
8 (caloric restriction* VLCD or very low calorie* or low calorie* or directive counsel* or food formulated or meal replacement* or liquid supplement*).ti,ab.
9 (food plan* or slim fast or slimming world or weight watchers or Atkins).ti,ab.
10 or/1-9
11 exp Obesity/
12 exp weight change/ or exp weight control/ or exp weight gain/ or exp weight reduction/
13 exp body mass/ or exp waist circumference/ or exp waist hip ratio/
14 exp abdominal fat/ or exp body fat distribution/
15 exp skinfold thickness/
16 (obes$ or adipos* or overweight or over weight).ti,ab.
17 (overeat or over eat or overfeed or over feed or fat overload syndrom$).ti,ab.
18 (weight adj6 (cyc$ or reduc$ or los$ or maint$ or decreas$ or watch$ or control or chang$ or gain)).ti,ab.
19 (body mass ind$ or waist hip ratio or waist circumferenc$).ti,ab.
20 (body fat adj3 distribution*).ti,ab.
21 (abdominal fat or skinfold thickness).ti,ab.
22 or/11-21
23 exp commercial phenomena/
24 commerc*.tw,ot.
25 23 or 24
26 exp Randomized Controlled Trial/
27 exp Controlled Clinical Trial/
28 exp Clinical Trial/
29 exp Comparative Study/
30 exp Drug comparison/
31 exp Randomization/
32 exp Crossover procedure/
33 exp Double blind procedure/
34 exp Single blind procedure/
35 exp Placebo/
36 exp Prospective Study/
37 ((clinical or control$ or comparativ$ or placebo$ or prospectiv$ or randomi?ed) adj3 (trial$ or stud$)).ab,ti.
38 (random$ adj6 (allocat$ or assign$ or basis or order$)).ab,ti.
39 ((singl$ or doubl$ or trebl$ or tripl$) adj6 (blind$ or mask$)).ab,ti.
40 (cross over or crossover).ab,ti.
41 or/26-40
42 exp meta analysis/
43 (metaanaly$ or meta analy$ or meta?analy$).ab,ti,ot.
44 ((review$ or search$) adj10 (literature$ or medical database$ or medline or pubmed or embase or cochrane or cinahl or psycinfo or psyclit or healthstar or biosis or current content$ or systematic$)).ab,ti,ot.
45 exp Literature/
46 exp Biomedical Technology Assessment/
47 hta.tw,ot.
48 (health technology adj6 assessment$).tw,ot.
49 or/42-48
50 41 or 49
51 (comment or editorial or historical-article).pt.
52 50 not 51

(*Continued*)

53 10 and 22 and 25 and 52
54 limit 53 to human

PsycINFO

1. (MM "Diet*")
2. (MM "Dietary Supplements") OR (MM "Dietary Supplementation") OR "liquid supplement*" OR "meal replacement*" OR "hypocaloric" OR "very low calorie" OR "VLCD" or "low calorie"
3. (MM "Food")
4. TX diet supplement*
5. TX (weight-loss or weight reduction) n6 (program* or product* or method* or book* or website* or magazine* or DVD* or CD* or service*)
6. TX caloric restriction* or directive counsel* or food formulated
7. TX food plan* or slim fast or slimming world or weight watchers or Atkins or ("self-help")
8. commerc* or ("proprietary")
9. S1 or S2 or S3 or S4 or S5 or S6 or S7 OR S8
10. (MM "Obesity")
11. (MM "Adipose Tissue")
12. (MM "Body Weight Changes")
13. (MM "Weight Control")
14. (MM "Body Mass Index")
15. MM ("Waist Circumference") OR (MM "Waist-Hip Ratio")
16. (MM "Skinfold Thickness")
17. (MM "Abdominal Fat")
18. (MM "Body Composition")
19. TX overeat or "over eat" or overfeed or "over feed" or "fat overload syndrom*"
20. TX adipos* or obes*
21. TX overweight* or "over weight*"
22. TX weight n6 cyc* or reduc* or los* or maint* or decreas* or watch* or control or chang* or gain
23. TX "body mass ind*" or "waist-hip ratio*" or "waist circumference"
24. TX "abdominal fat*" or "skinfold thickness*"
25. TX "body fat" n3 distribution*
26. S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or s25
27. (MM "Clinical Trials")
28. (MM "Comparative Studies") OR (MM "Prospective Studies")
29. (MM "Crossover Design")
30. (MM "Crossover Design") Search modes - SmartText Searching
31. (MM "Placebo")
32. TX (clinical or control* or comparativ* or placebo* or prospectiv* or randomi*) n3 (trial* or stud*)
33. TX random* n6 (allocat* or assign* or basis or order*)
34. TX (singl* or doubl* or trebl* or tripl*) n6 (blind* or mask*)
35. TX crossover or "cross over"
36. S27 or S28 or S29 or S30 or S31 or S32 or S33 or S34 or s35
37. (MM "Meta Analysis")
38. "metaanaly*" or "meta analy*" or "meta?analy*"
39. TX (review* or search*) n10 (literature* or "medical database*" or medline or pubmed or embase or cochrane or cinahl or psycinfo or psyclit or healthstar or biosis or "current content*" or systematic*)
40. (MM "Literature Searching")
41. "health technology" n6 assessment*

Appendix 13: Cochrane protocol

(*Continued*)

42. TX hta
43. S37 or S38 or S39 or S40 or S41 or S42
44. PT comment or editorial or historical-article
45. (S36 OR S43) NOT S44
46. S9 and S26 and S45
47. Limiters - Population Group: Human

CINAHL

1. (MH "Diet+")
2. (MH "Dietary Supplements+") OR (MH "Dietary Supplementation") OR "liquid supplement*" OR "meal replacement*" OR "very low calorie" or VLCD" or low calorie" or "hypocaloric"
3. (MH "Food, Formulated+")
4. TX diet supplement*
5. TX (weight-loss or weight reduction) n6 (program* or product* or method* or book* or website* or magazine* or DVD* or CD* or service*)
6. TX caloric restriction* or directive counsel* or food formulated
7. TX food plan* or slim fast or slimming world or weight watchers or Atkins or ("self-help")
8. TX commerc* or ("proprietary")
9. S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8
10. (MH "Obesity+")
11. (MH "Adipose Tissue+")
12. (MH "Body Weight Changes+")
13. (MH "Weight Control")
14. (MH "Body Mass Index")
15. MH ("Waist Circumference") OR (MH "Waist-Hip Ratio")
16. (MH "Skinfold Thickness")
17. (MH "Abdominal Fat")
18. (MH "Body Composition")
19. TX overeat or "over eat" or overfeed or "over feed" or "fat overload syndrom*"
20. TX adipos* or obes*
21. TX overweight* or "over weight*"
22. TX weight n6 cyc* or reduc* or los* or maint* or decreas* or watch* or control or chang* or gain
23. TX "body mass ind*" or "waist-hip ratio*" or "waist circumference"
24. TX "abdominal fat*" or "skinfold thickness*"
25. TX "body fat" n3 distribution*
26. S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 OR S25
27. (MH "Clinical Trials+")
28. (MH "Comparative Studies") OR (MH "Prospective Studies+")
29. (MH "Crossover Design")
30. (MH "Placebos")
31. TX (clinical or control* or comparativ* or placebo* or prospectiv* or randomi*) n3 (trial* or stud*)
32. TX random* n6 (allocat* or assign* or basis or order*)
33. TX (singl* or doubl* or trebl* or tripl*) n6 (blind* or mask*)
34. TX crossover or "cross over"
35. S27 or S28 or S29 or S30 or S31 or S32 or S33 or S34
36. (MH "Meta Analysis")
37. TX "metaanaly*" or "meta analy*" or "meta?analy*"
38. TX (review* or search*) n10 (literature* or "medical database*" or medline or pubmed or embase or cochrane or cinahl or

(*Continued*)

psycinfo or psyclit or healthstar or biosis or "current content*" or systematic*) 39. (MH "Literature Searching+") 40. TX "health technology" n6 assessment* 41. TX hta 42. S36 or S37 or S38 or S39 or S40 or S41 43. PT comment or editorial or historical-article 44. (S35 OR S42) NOT S43 45. S9 AND S26 AND S26 AND S44 46. Limiters Human
'My NCBI' alert service
commercial[All Fields] AND ("weight reduction programs"[MeSH Terms] OR ("weight"[All Fields] AND "reduction"[All Fields] AND "programs"[All Fields]) OR "weight reduction programs"[All Fields] OR ("weight"[All Fields] AND "loss"[All Fields] AND "programs"[All Fields]) OR "weight loss programs"[All Fields])

Appendix 2. Description of interventions

Characteristic Study ID	Intervention(s) [route, frequency, total dose/day]	Comparator(s) [route, frequency, total dose/day]
Study 1	Intervention 1	Comparator 1
	Intervention 2	Comparator 2
Footnotes "-" denotes not reported		

Appendix 3. Baseline characteristics (I)

Characteristic	Intervention(s) and comparator(s)	Duration of intervention (duration of follow-up)	Participating population	Study period [year to year]	Country	Setting	Ethnic groups [%]	Duration of condition [mean/range years (SD), or as reported]
Study 1	Intervention 1							
	Intervention 2							

(*Continued*)

	Comparator 1						
	Comparator 2						
					all:		

Footnotes
"-" denotes not reported
SD: standard deviation

Appendix 4. Baseline characteristics (II)

Characteristic	Intervention(s) and comparator (s)	Sex [female %]	Age [mean/ range years (SD) , or as reported]	BMI [mean kg/ m^2 (SD)]	Co-medications / Co-interventions	Co-morbidities
Study 1	Intervention 1					
	Intervention 2					
	Comparator 1					
	Comparator 2					
	all:					

Footnotes
"-" denotes not reported
BMI: body mass index; SD: standard deviation

Appendix 5. Matrix of study endpoints (publications)

Characteristic		Endpoint reported in publication	Endpoint not reported in publication	Time of measurement[a]
Example	**Review's primary outcomes**			
	Adverse effects		x	0, 12 mo

Appendix 13: Cochrane protocol

(*Continued*)

Health-related quality of life	x		0, 6, 12 mo
Weight change and change in body mass index (BMI)	x		0, 12 mo
Review's secondary outcomes			
Attrition	x		0, 12 mo
Change data for percentage overweight and obese, waist-to-hip ratio, waist circumference, cholesterol (total cholesterol, HDL-cholesterol, LDL-cholesterol), blood pressure (diastolic and systolic)	x		0, 6, 12 mo
Compliance with commercial weight loss product or service		x	N/A
Morbidity		x	N/A
Mortality, all-cause		x	N/A
Other than review's primary/secondary outcomes reported in publication (classification: P/S/O)[b]			
Insulin resistance (P), patient satisfaction (S), safety parameters (O), socioeconomic outcomes (O)			
Subgroups reported in publication			
Age < 65 years vs. ≥ 65 years, obesity vs overweight			

Footnotes

[a]Underlined data denote times of measurement for primary and secondary review outcomes, if measured and reported in the results section of the publication (other times represent planned but not reported points in time)

[b](P) Primary or (S) secondary endpoint(s) refer to verbatim statements in the publication, (O) other endpoints relate to outcomes which were not specified as 'primary' or 'secondary' outcomes in the publication

BMI: body mass index; HDL: high-density lipoprotein; LDL: low-density lipoprotein; mo: months; N/A: not acknowledged

Appendix 6. Matrix of study endpoints (trial documents)

Characteristic / Study ID (trial identifier)	Endpoint[a]	Review's primary outcome	Review's secondary outcome	Time of measurement	Source (FDA document / EMA document / manufacturer's website / design paper / trial protocol document)
Example	Cardiovascular mortality (P)		x	12 mo	
	Health-related quality of life (O)	x		24 mo	
	Myocardial infarction (S)		x	6, 12 mo	

Footnotes
"-" denotes not reported
[a](P) Primary or (S) secondary endpoint(s) refer to verbatim statements in the publication, (O) other endpoints relate to outcomes which were not specified as 'primary' or 'secondary' outcomes in the report
mo: months; N/A: not acknowledged

Appendix 7. Examination of outcome reporting bias

Characteristic	Clear that outcome was measured and analysed[a] [trial report states that outcome was analysed but only reports that result was not significant]	Clear that outcome was measured and analysed[b] [trial report states that outcome was analysed but no results reported]	Clear that outcome was measured[c] [clear that outcome was measured but not necessarily analysed (judgement says likely to have been analysed but not reported because of non-significant results)]	Unclear whether the outcome was measured[d] [not mentioned but clinical judgement says likely to have been measured and analysed but not reported on the basis of non-significant results]
Study 1				

Footnotes
'High risk of bias' categories for outcome reporting bias according to the Outcome Reporting Bias In Trials (ORBIT) study classification system for missing or incomplete outcome reporting in reports of randomised trials (Kirkham 2010).
[a]Classification 'A' (table 2, Kirkham 2010)
[b]Classification 'D' (table 2, Kirkham 2010)
[c]Classification 'E' (table 2, Kirkham 2010)
[d]Classification 'G' (table 2, Kirkham 2010)

Appendix 8. Definition of endpoint measurement (I)

Characteristic Study ID	Health-related quality of life	Attrition	Overweight	Obesity	Waist-to-hip ratio	Waist circumference
Study 1						

Footnotes
ND: not defined; N/I: not investigated

Appendix 9. Definition of endpoint measurement (II)

Characteristic Study ID	Costs	Compliance	Morbidity	Severe / serious adverse events
Study 1				

Footnotes
ND: not defined; N/I: not investigated

Appendix 10. Adverse events (I)

Character-istic Study ID	Interven-tion(s) and comparator (s)	Ran-domised / Safety [N]	Deaths [N]	Deaths [%]	All adverse events [N]	All adverse events [%]	Severe/ serious adverse events [N]	Severe/ serious adverse events [%]
Study 1	Intervention 1							
	Intervention 2							
	Comparator 1							
	Comparator 2							
	all:							

(*Continued*)

Footnotes "-" denotes not reported

Appendix 11. Adverse events (II)

Characteristic Study ID	Intervention(s) and comparator (s)	Randomised / Safety [N]	Left study due to adverse events [N]	Left study due to adverse events [%]	Hospitalisation [N]	Hospitalisation [%]	Out-patient treatment [N]	Out-patient treatment [%]
Study 1	Intervention 1							
	Intervention 2							
	Comparator 1							
	Comparator 2							
	all:							
Footnotes "-" denotes not reported								

Appendix 12. Adverse events (III)

Characteristic Study ID	Intervention(s) and comparator(s)	Randomised / Safety [N]	Specific adverse events [description]	Specific adverse events [N]	Specific adverse events [%]
Study 1	Intervention 1				
	Intervention 2				
	Comparator 1				
	Comparator 2				
	all:				

(*Continued*)

Footnotes "-" denotes not reported

Appendix 13. Survey of authors providing information on included trials

Characteristic Study ID	Study author contacted	Study author replied	Study author asked for additional information	Study author provided data
Study 1	Y			

Footnotes
N: no; Y: yes

CONTRIBUTIONS OF AUTHORS

Alisha M Crayton (AC): protocol draft, search strategy development, acquirement of trial copies, trial selection, data extraction, data analysis, data interpretation, review draft and future review updates.

Carolyn D Summerbell (CS): protocol draft, search strategy development, acquirement of trial copies, trial selection, data extraction, data analysis, data interpretation, review draft and future review updates.

Tance J Sonnier (TS) : protocol draft, search strategy development, review draft and future review updates.

Louisa J Ells (LE): protocol draft, search strategy development, review draft and future review updates.

Harry R Rutter (HR): protocol draft, search strategy development, review draft and future review updates.

Frank K Greenway (FG): protocol draft, search strategy development, review draft and future review updates.

DECLARATIONS OF INTEREST

Alisha M Crayton: none known.

Carolyn D Summerbell: none known.

Tance J Sonnier: none known.

Louisa J Ells: none known.

Harry R Rutter: none known.

Frank K Greenway: I consult for a number of companies involved in the obesity space. I hold several patents in the obesity space. I am a member of several advisory boards in the obesity space including the head of the Medical Advisory Board for Jenny Craig which is a commercial weight loss program. I hold stock in four companies in the obesity space.

Note from the Metabolic and Endocrine Disorders Group: according to the 'Cochrane organisational, editorial and publishing policies' (http://www.cochrane.org/about-us/our-policies/cochrane-policies) authors with a direct financial interest in a particular intervention will not be involved in a Cochrane Review of that intervention.

SOURCES OF SUPPORT

Internal sources

- Durham University, UK.

This review is one element of study is funded by Durham University, as part of a PhD researching commercial weight loss products and services.

External sources

- No sources of support supplied

Appendix 14: Q- Methodology focus group/interview consent form

Durham University
School of Medicine and Health

Shaped by the past, creating the future

Consent Form

ID Number:

Please read the following consent form carefully then tick the **Yes** or **No** boxes and **initial** all boxes. If you have ticked any of the **No** boxes to questions 1-7, your data will be securely destroyed.

	Yes	No	Initial
1. I confirm that I have read and understood the participant information sheet for this study (version 4.0) and am aware of what it will involve.	☐	☐	☐
2. I have had the opportunity to ask questions and have been provided with sufficient answers.	☐	☐	☐
3. I understand that my participation is voluntary and that I can withdraw from the research at any point before 15th October 2011 when data analysis will be complete. I am aware that if I choose to withdraw I will not be required to give a reason.	☐	☐	☐
4. I am 16 years of age or older	☐	☐	☐
5. I am aware that my participation in the group discussion will be audio-recorded for data analysis purposes.	☐	☐	☐
6. I understand that the information that I provide will be kept confidential and anonymised with an identification number linked to my name, kept in locked filing cabinets and password protected files on computers at Durham University in accordance with the Data Protection Act (1998). My anonymous information will not be shared with anyone who is not part of the research team. After the Q-Weight study has finished, data will be securely saved until the 1st June 2015, after this date, all data will be destroyed.	☐	☐	☐
7. I agree to take part in this study.	☐	☐	☐
8. I agree to be contacted to discuss my willingness to participate in the next stages of the overall study.	☐	☐	☐
9. I wish to be sent a copy of the final results in the post after October 2012.	☐	☐	☐

---	---	---
Name of Participant (please print)	Date	Signature
---	---	---
Name of Researcher (please print)	Date	Signature
---	---	---

Appendix 15: Q-Methodology focus group/interview registration form

Durham University
School of Medicine and Health

Q-Weight Shaped by the past, creating the future

Registration of interest form

Name: …….

Contact telephone number: ……..

If you are interested in taking part in the Q-Weight study, please complete the information below and return in the pre-paid envelope.

Suitable day/s and time/s available (please ✔)

Monday **7-8pm**	**Wednesday** **2-3pm**	**Friday** **10-11am**

If the above days and times are not suitable, please specify a suitable date/day and time that is suitable

……
……..

Suitable location/s (please ✔)

Durham University- Queens Campus; Stockton	**Durham University Durham**	**Teesside University**

If the above location's are not suitable, please specify a suitable location

……
……..

Please complete the registration of interest form, and return in the pre-paid envelope before the 15th October 2011

Appendix 16: Q-Methodology focus group/interview information sheet

Durham University
School of Medicine and Health

Q-Weight

Shaped by the past, creating the future

ID Number:

Participant Information Sheet

What is Q-Weight study, are why are we doing it?
Q-Weight is a study that will find out what are the reasons of 16 year olds and over in County Durham, Northumberland, Tees Valley or Tyne and Wear for choosing commercial weight loss products or services within the last twelve months. This study is funded by Durham University, as part of a PhD researching commercial weight loss products and services. This is one stage of the full Q-Weight study; stage two involves a focus group discussion and stage three will involve a ranking exercise of statements related to commercial weight loss. All stages will take approximately 30 minutes.

Who can take part?
You can take part if you:

(i) Have used a commercial weight loss product or service in the last twelve months

And

(ii) Live in County Durham, Northumberland, Tees Valley or Tyne and Wear

And

(iii) Are 16 years old or over

What are commercial weight loss products and services?
Commercial weight loss products and/or services involve a one-off or continuous payment/subscription to lose weight.

Examples include:

- Weight loss programmes or clubs (Slimming World, Weight Watchers, Lighter Life, Rosemary Connelly, Diet Chef, Tony Ferguson etc)
- Products (Alli, Slim Fast, Special K, Lipobind, Adios etc)
- Other (Weight loss books, DVDs, magazines, websites, CDs etc)

How do I take part?
You have been invited to take part in a group discussion with other people who have also used commercial weight loss products and/or services within the last twelve months. The group discussion will take place at a convenient time for all participants in the group at various suitable locations. The group will consist of 6-10 participants, taking approximately 30 minutes. You will be asked informal questions about your experiences of commercial weight loss methods, weight loss and issues surrounding obesity. Group discussions will be recorded on an audio device (Dictaphone). ***If you wish to take part, please complete the registration of interest slip, and in the pre-paid envelope.***

Do I have to take part?
No. It is entirely up to you if you want to take part in this study after reading this information sheet. You can withdraw up to the 15th October 2011; you will not have to explain why. If you do wish to withdraw, contact Alisha Crayton (full contact details listed below) with your unique identification number (displayed in the top right-hand box).

Appendix 16: Q-Methodology focus group/interview information sheet

How do I consent?
Your written consent will be required before the group discussion starts; you will have the opportunity to ask the researcher about any concerns or questions that you have about the study and your participation.

What will happen to the data?
The group discussion will be transcribed (excluding identifiable details), creating statements from key quotes about the different reasons of choice for choosing commercial weight loss products and/or services. These anonymous statements will not identify you; they will be used at the later stages of the Q-Weight study. Findings from this study will be printed in scientific magazines and reports and will be presented at conferences both in the UK and abroad. Overall study results will be printed in the Evening Gazette. Information that you provide will not identify you. Results from this study will be submitted to Durham University for Alisha Crayton's PhD thesis.

Will my data be kept confidential?
All personal information that you provide will be kept confidential and anonymised with a unique identification number linked to your name. Your data will be kept in locked filling cabinets and password protected files at Durham University inline with the Data Protection Act (1998); this will not be shared with anyone who is not part of the research team. After the study has finished, data will be saved securely until the 1st June 2015, after this date, all data will be destroyed. Any information that you provide will be confidential. Exceptional circumstances could require us to reveal this information in a court of law. The research team will follow ethical and legal practice, protecting your identity and information from this study.

How will this study benefit me?
Participation in this research may not benefit you personally; the group discussion will inform the next stages of the Q- Weight Study.

Are there any risks to taking part?
Taking part in this study is unlikely to affect you. If you are concerned about weight loss, eating disorders, or any other health related issues, seek advice from your GP. General advice and support is enclosed on a separate 'useful contact details' sheet.

Who has reviewed the study?
This study was given a favourable ethical opinion by the School of Medicine and Health Ethics Committee at Durham University.

Who should I contact if I have any concerns or questions?
If you have any questions or concerns please contact Alisha Crayton (PhD student):

Telephone: 0191 3340820
Email: cwl.orbresearchgroup@durham.ac.uk
Postal address:
Q- Weight
School of Medicine and Health
Durham University-Queens Campus
Holliday Building-A100
TS17 6BH

Alternatively contact Professor Carolyn Summerbell (Supervisor):

Postal address: Obesity Related Behaviours Research Group
School of Medicine and Health
Durham University- Queens Campus

Appendix 16: Q-Methodology focus group/interview information sheet

Wolfson Research Institute- E106
Stockton-on-Tees
TS17 6BH

If you wish to take part in the study, please keep a copy of the participant information sheet for your personal use

Thank you for taking the time to read the participant information sheet

Appendix 17: Q-Methodology pilot study consent form

Durham University
School of Medicine and Health

Shaped by the past, creating the future

Consent Form

ID Number:

Please read the following consent form carefully then tick the **Yes** or **No** boxes and **initial** all boxes. If you have ticked any of the **No** boxes to questions 1-7, your data will be securely destroyed.

	Yes	No	Initial
1. I confirm that I have read and understood the participant information sheet for this study (version 4.0) and am aware of what it will involve.	☐	☐	☐
2. I have had the opportunity to ask questions and have been provided with sufficient answers.	☐	☐	☐
3. I understand that my participation is voluntary and that I can withdraw from the research at any point before 11 March 2012 when data analysis will be complete. I am aware that if I choose to withdraw I will <u>not</u> be required to give a reason.	☐	☐	☐
4. I am 16 years of age or older	☐	☐	☐
5. I am aware that my participation in the group discussion will be audio-recorded for data analysis purposes.	☐	☐	☐
6. I understand that the information that I provide will be kept confidential and anonymised with an identification number linked to my name, kept in locked filing cabinets and password protected files on computers at Durham University in accordance with the Data Protection Act (1998). My anonymous information will not be shared with anyone who is not part of the research team. After the Q-Weight study has finished, data will be securely saved until the 1st June 2015, after this date, all data will be destroyed.	☐	☐	☐
7. I agree to take part in this study.	☐	☐	☐
8. I agree to be contacted to discuss my willingness to participate in the next stages of the overall study.	☐	☐	☐
9. I wish to be sent a copy of the final results in the post after October 2012.	☐	☐	☐

| --- | --- | --- |
Name of Participant (please print)	Date	Signature
Name of Researcher (please print)	Date	Signature

Appendix 18: Q-Methodology pilot study information sheet

Durham University
School of Medicine and Health

Shaped by the past, creating the future

Q-Weight

ID Number:

Participant Information Sheet

What is the Q-Weight study, and why are we doing it?
Q-Weight is a study that will find out what are the reasons of 16 year olds and over in the Tees Valley choosing commercial weight loss products or services within the last twelve months. This study is funded by Durham University, as part of a PhD researching commercial weight loss products and services. This is one stage of the full Q-Weight study; your participation will only be required for this stage.

Who can take part?
You can take part if you:

(i) Have used a commercial weight loss product or service in the last twelve months

And

(ii) Live in the Tees Valley area (TS1-TS18)

And

(iii) Are 16 years old or over

What are commercial weight loss products and services?
Commercial weight loss products and/or services involve a one-off or continuous payment/subscription to lose weight.

Examples include:

- Weight loss programmes or clubs (Slimming World, Weight Watchers, Lighter Life, Rosemary Connelly, Diet Chef, Tony Ferguson etc)
- Products (Alli, Slim Fast, Special K, Lipobind, Adios etc)
- Other (Weight loss books, DVDs, magazines, websites, CDs etc)

How do I take part?
You have been invited to take part in a group discussion with other people who have also used commercial weight loss products and/or services within the last twelve months. The group discussion will take place at a convenient time and location for all people in the group (4-6 participants); this will take approximately 30 minutes. Each member of the group will be given a set of statements about the reasons for choosing commercial weight loss products and/or services, each statement will be printed on 9x5cm cards. You will be asked to look through the statements, roughly sorting them into agree, disagree and neutral/not relevant piles. The group will be asked if the statements are easy to understand, and if they feel that there are any missing statements about the reasons for choosing commercial weight loss products and services. Group discussions will be recorded on an audio device (Dictaphone). ***If you wish to take part, please complete the registration of interest form and return in the pre-paid envelope.***

Do I have to take part?
No. It is entirely up to you if you want to take part in this study after reading this information sheet. You can withdraw up to the 1st May 2011; you will not have to explain why. If you do wish to withdraw, contact Alisha Crayton (full contact details listed below) with your unique identification number (displayed in the top right-hand box).

Appendix 18: Q-Methodology pilot study information sheet

How do I consent?

Your written consent will be required before the group discussion starts; you will have the opportunity to ask the researcher about any concerns or questions that you have about the study and your participation. You will carefully then tick the Yes or No boxes and, initial all boxes on the consent form. If you have ticked any of the No boxes to questions 1-7, your data will be securely destroyed.

What will happen to the data?

The research team will make any suggested changes about the statements before the fifth stage of the Q-Weight study. Your participation is only required for this stage. Findings from this study will be printed in scientific magazines and reports and will be presented at conferences both in the UK and abroad. Overall study results will be printed in the Evening Gazette. Information that you provide will not identify you. Results from this study will be submitted to Durham University for Alisha Crayton's PhD thesis. If you wish to be given a report of this study, contact Alisha Crayton after October 2012.

Will taking part be kept confidential?

All personal information that you provide will be kept confidential and anonymised with a unique identification number linked to your name. Your data will be kept in locked filling cabinets and password protected files at Durham University inline with the Data Protection Act (1998); this will not be shared with anyone who is not part of the research team. After the study has finished, data will be saved securely until the 1st June 2015, after this date, all data will be destroyed. Any information that you provide will be confidential. Exceptional circumstances could require us to reveal this information in a court of law. The research team will follow ethical and legal practice, protecting your identity and information from this study.

How will this study benefit me?

Participation in this research may not benefit you personally; the group discussion will inform the next stage of the Q- Weight Study. Your participation is only required for this stage.

Are there any risks to taking part?

Taking part in this study is unlikely to affect you. If you are concerned about weight loss, eating disorders, or any other health related issues, seek advice from your GP. General advice and support is enclosed on a separate 'useful contact details' sheet.

Who has reviewed the study?

This study was given a favourable ethical opinion by the School of Medicine and Health Ethics Committee at Durham University.

Who should I contact if I have any concerns or questions?

If you have any questions or concerns please contact Alisha Crayton (PhD student):

Telephone: 0191 3340820
Email: cwl.orbresearchgroup@durham.ac.uk
Postal address:
Q- Weight
Obesity Related Behaviours Research Group
School of Medicine and Health
Durham University- Queens Campus
Wolfson Research Institute- E106
Stockton-on-Tees
TS17 6BH

Alternatively contact Professor Carolyn Summerbell (Supervisor):

Appendix 18: Q-Methodology pilot study information sheet

Postal address: Obesity Related Behaviours Research Group
School of Medicine and Health
Durham University- Queens Campus
Wolfson Research Institute- E106
Stockton-on-Tees
TS17 6BH

If you wish to take part in the study, please keep a copy of the participant information sheet for your personal use

Thank you for taking the time to read the participant information sheet

Appendix 19: Q-Methodology pilot study registration form

Durham University
School of Medicine and Health

Shaped by the past, creating the future

ID Number:

Return before:

……

Q-Weight

Registration of interest form

Name:
……

Contact telephone number:
……..

If you are interested in taking part in the Q-Weight study, please complete the information below and return in the pre-paid envelope.

Suitable day/s and time/s available (please ✔)

	Monday	Tuesday	Wednesday	Thursday	Friday
9am					
10am					
11am					
12pm					
1pm					
2pm					
3pm					
4pm					
5pm					
6pm					
7pm					

Please complete the registration of interest form, and return in the pre-paid envelope before the date stated in the top left-hand box of the form

Appendix 20: Q-Methodology q-sort information sheet

Durham University
School of Medicine and Health

Shaped by the past, creating the future

Q-Weight

ID Number:

Participant Information Sheet

What is the Q-Weight study, and why are we doing it?
Q-Weight is a study that will find out what are the reasons of 16 year olds and over in County Durham, Northumberland, Tees Valley or Tyne and Wear for choosing commercial weight loss products or services within the last twelve months. This study is funded by Durham University, as part of a PhD researching commercial weight loss products and services. This is the final stage of the Q-Weight study.

Who can take part?
You can take part if you:

(i) Have used a commercial weight loss product or service in the last twelve months

And

(ii) Live in County Durham, Northumberland, Tees Valley or Tyne and Wear

And

(iii) Are 16 years old or over

What are commercial weight loss products and services?
Commercial weight loss products and/or services involve a one-off or continuous payment/subscription to lose weight.

Examples include:

- Weight loss programmes or clubs (Slimming World, Weight Watchers, Lighter Life, Rosemary Connelly, Diet Chef, Tony Ferguson etc)
- Products (Alli, Slim Fast, Special K, Lipobind, Adios etc)
- Other (Weight loss books, DVDs, magazines, websites, CDs etc)

How do I take part?
You have been invited to take part in an exercise where you will be given a set of cards (9x5cm) which contain statements about the reasons for choosing commercial weight loss products and/or services. You will be asked to look through the statements, then sort them into three piles: agree, disagree and neutral/not relevant. You will be asked to take the statements in your agree pile and place them onto a sorting sheet (see figure 1) which shows how strongly you agree with each of the statements. You will then be asked to do the same for your disagree pile, placing them on the sorting sheet to show how strongly you disagree with each of the statements. Statements that were placed in the neutral/not-relevant pile will be placed in the remaining boxes on the sorting sheet. Please be aware that the exercise will be audio-recorded (sound only) and your participation will involve the researcher conducting an informal interview with you to explain your placement of the statements at opposite ends. The exercise will be conducted at a convenient time and location for you and will take approximately 30 minutes. ***If you wish to take part, please complete the registration of interest slip, and return in the pre-paid envelope.***

Do I have to take part?
No. It is entirely up to you if you want to take part in this study after reading this information sheet. You can withdraw up to the 1st December 2011; you will not have to explain why. If you do wish to withdraw, contact Alisha Crayton (full contact details listed below) with your unique identification number (displayed in the top right-hand box).

Appendix 20: Q-Methodology q-sort information sheet

Will my travel costs be reimbursed?
Yes. Second class rail fare, standard bus fare or mileage costs.

How do I consent?
Your written consent will be required before the group discussion starts; you will have the opportunity to ask the researcher about any concerns or questions that you have about the study and your participation..

What will happen to the data?
Findings from this study will be printed in scientific magazines and reports and will be presented at conferences both in the UK and abroad. Overall study results will be printed in the Evening Gazette. Information that you provide will not identify you. Results from this study will be submitted to Durham University for Alisha Crayton's PhD thesis.

Will taking part be kept confidential?
All personal information that you provide will be kept confidential and anonymised with a unique identification number linked to your name. Your data will be kept in locked filling cabinets and password protected files at Durham University inline with the Data Protection Act (1998); this will not be shared with anyone who is not part of the research team. After the study has finished, data will be saved securely until the 1st June 2015, after this date, all data will be destroyed. Any information that you provide will be confidential. Exceptional circumstances could require us to reveal this information in a court of law. The research team will follow ethical and legal practice, protecting your identity and information from this study.

How will this study benefit me?
Participation in this research may not benefit you personally; your participation will give a better understanding about the reasons why commercial weight loss products and services might be chosen.

Are there any risks to taking part?
Taking part in this study is unlikely to affect you. If you are concerned about weight loss, eating disorders, or any other health related issues, seek advice from your GP. General advice and support is enclosed on a separate 'useful contact details' sheet.

Who has reviewed the study?
This study was given a favourable ethical opinion by the School of Medicine and Health Ethics Committee at Durham University.

Who should I contact if I have any concerns or questions?
If you have any questions or concerns please contact Alisha Crayton (PhD student):

Telephone: 0191 3340820
Email: cwl.orbresearchgroup@durham.ac.uk
Postal address:
Q-Weight
School of Medicine and Health
Durham University-Queens Campus
Holliday Building-A100
TS17 6BH

Alternatively contact Professor Carolyn Summerbell (Supervisor):

Appendix 20: Q-Methodology q-sort information sheet

Postal address: Obesity Related Behaviours Research Group
School of Medicine and Health
Durham University- Queens Campus
Wolfson Research Institute- E106
Stockton-on-Tees
TS17 6BH

If you wish to take part in the study, please keep a copy of the participant information sheet for your personal use

Thank you for taking the time to read the participant information sheet

Appendix 21: Q-Methodology q-sort registration form

Durham University
School of Medicine and Health

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Q-Weight

ID Number:

Registration of interest form

Name: …….

Contact telephone number: ……..

If you are interested in taking part in the Q-Weight study, please complete the information below and return in the pre-paid envelope.

Suitable day/s and time/s available (please ✔)

Monday **7-8pm**	**Wednesday** **2-3pm**	**Friday** **10-11am**

If the above days and times are not suitable, please specify a suitable date/day and time that is suitable

……
……..

Suitable location/s (please ✔)

Durham University- Queens Campus; Stockton	**Durham University Durham**	**Teesside University**

If the above location's are not suitable, please specify a suitable location

……
……..

Please complete the registration of interest form, and return in the pre-paid envelope before the 12th February 2012

Appendix 22: Q-Methodology q-sort consent form

Durham University
School of Medicine and Health

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Consent Form

ID Number:

Please read the following consent form carefully then tick the **Yes** or **No** boxes and **initial** all boxes. If you have ticked any of the **No** boxes to questions 1-7, your data will be securely destroyed.

	Yes	No	Initial
1. I confirm that I have read and understood the participant information sheet for this study (version 4.0) and am aware of what it will involve.	☐	☐	☐
2. I have had the opportunity to ask questions and have been provided with sufficient answers.	☐	☐	☐
3. I understand that my participation is voluntary and that I can withdraw from the research at any point before 1st May 2012 when data analysis will be complete. I am aware that if I choose to withdraw I will <u>not</u> be required to give a reason.	☐	☐	☐
4. I am 16 years of age or older			
5. I am aware that my participation will be audio-recorded for data analysis purposes.	☐	☐	☐
6. I understand that the information that I provide will be kept confidential and anonymised with an identification number linked to my name, kept in locked filing cabinets and password protected files on computers at Durham University in accordance with the Data Protection Act (1998). My anonymous information will not be shared with anyone who is not part of the research team. After the Q-Weight study has finished, data will be securely saved until the 1st June 2015, after this date, all data will be destroyed.	☐	☐	☐
7. I agree to take part in this study.	☐	☐	☐
8. I wish to be sent a copy of the final results in the post after October 2012.	☐	☐	☐

----------	----------	----------
Name of Participant (please print)	Date	Signature
----------	----------	----------
Name of Researcher (please print)	Date	Signature

Appendix 23: Q-Methodology statements

1.

I chose this CWLPS, as I wanted a better choice of clothes that I would be able to buy, in losing weight from this particular CWLPS.

2.

I chose this CWLPS, as I wanted to have fun during the process of losing weight.

3.

I chose this CWLPS as I wanted something where there was a consistent guide to weight loss that did not change, which I could get from this CWLPS.

4.

I chose this CWLPS, as I did not want to get to the stage whereby I would be needing weight-loss surgery.

5.

I chose this CWLPS, as it would allow me to go out for meals, which was important for me as I like the social side of eating.

6.

I chose this CWLPS, as I knew it would give me the support that I needed in assisting me to lose weight.

7.

I chose this CWLPS as it was of a case of all or nothing.

8.

I chose this particular CWLPS, as I wanted to know how many calories are in different foods, which was particularly important for me to understand.

9.

I chose this CWLPS, as I wanted it to show me how to understand the health value in different foods.

10.

I chose this CWLPS, as it was particularly important for me to be with others in a group setting, which I could get from this CWLPS.

11.

I chose this CWLPS, as I wanted to be able to buy the products associated with this CWLPS (scales, books).

12.

I chose this CWLPS, as I wanted to buy the meals, and snacks provided by the commercial weight loss company that produces this CWLPS.

13.

I chose this CWLPS, as I was aware that it would provide me with the element of competition about weight-loss between others who were also using the same CWLPS as me.

14.

I chose this CWLPS, as I wanted to be able to compare my progress with others who were also using the same CWLPS as me.

15.

I chose this CWLPS based upon the endorsement from celebrities who had successfully tried it themselves.

16.

I did not chose this CWLPS based upon the endorsement from other people (group leaders and case studies of 'real life' people) who had successfully tried it themselves.

17.

I chose to use this particular CWLPS because I could see celebrities who had been through the process themselves and could understand what I was going through.

18. I chose to use this particular CWLPS because I could see other people (group leaders and case studies of 'real life' people) who had been through the process themselves, and could understand what I was going through.

19.

I chose this particular CWLPS, as I knew it would allow me to share hints, tips and experiences with others who were also using the same CWLPS as me.

20.

I chose this particular CWLPS as I thought it would encourage me to do new activities to help me lose weight (Great North Run, joining a gym).

21.

I chose this CWLPS as I wanted to be healthier - improving my appearance was not the main reason for choosing this particular CWLPS.

22.

I chose this CWLPS, as I was aware that it would not be a massive lifestyle change in following it.

23.

I chose this CWLPS as I had confidence in its results, because the CWLPS shows people who have lost three stone.

24.

I did not chose this CWLPS because of seeing advertisements which showed lots of people who have succeeded from this CWLPS.

Appendix 23: Q-Methodology statements

25. I did not chose this CWLPS because of the cost.	**26.** I chose this particular CWLPS, as I knew I would be able to identify with people in a similar position to me.
27. I chose this CWLPS, as my GP was not helpful in providing any weight loss advice.	**28.** I chose to pay for this CWLPS, as I knew that paying for it would motivate me into losing weight.
29. I chose this CWLPS as I thought it would be more socially accepted amongst my peers.	**30.** I chose this CWLPS as it was the last resort for me.
31. I chose this CWLPS to educate me about what sorts of foods I was supposed to eat.	**32.** I chose this CWLPS to support a friend or family member to lose weight.

33.

I chose this CWLPS as I knew it would allow me to view weight-loss as being a challenge, something that I wanted to conquer.

34.

I chose this CWLPS as losing weight was beneficial for my job.

35.

I chose this CWLPS, as I wanted the 'pat on the back' from someone telling me that I had lost weight.

36.

I chose this CWLPS, as I knew it would allow me to meet new people, and make new friends; which I wanted to do.

37.

I chose this CWLPS to educate me about what exercise I was supposed to do.

38.

I chose to pay for this CWLPS because it is my responsibility to lose weight. If I do mess up, I fail.

39.

I chose this CWLPS as someone suggested that I could do with losing some weight.

40.

I chose this CWLPS to lose weight for an event (wedding, holiday etc).

Appendix 23: Q-Methodology statements

41.

I chose this CWLPS because I saw it advertised (online, TV, newspaper, radio).

42.

I chose this CWLPS as I thought it would help me to give my family a healthier diet too.

43.

I chose this CWLPS as I could set my own realistic weight loss target to aim for.

44.

I chose this CWLPS as I wanted advice from people (group leaders and case studies of 'real life' people) to help me make better choices.

45.

I chose this CWLPS, as I wanted advice from celebrities to help me make better choices.

46.

I chose this CWLPS, as I wanted to understand why I overeat so that I could change my relationship with food.

47.

I chose this CWLPS as it would help me to maintain my weight loss.

48.

I chose this CWLPS based upon convenience.

Appendix 23: Q-Methodology statements

49. I chose this CWLPS, as I did not want to try and lose weight with other people; I wanted to do it alone.	**50.** I chose this CWLPS as it was gender specific (men only or women only).
51. I chose this CWLPS, as I wanted to lose weight quickly.	**52.** I chose this CWLPS, as I wanted the 'coping/rebound' advice after I came off the CWLPS.
53. I chose this particular CWLPS because I hoped the counselling would help me get to the root cause of why I overeat.	**54.** I chose this CWLPS, as I did not want to talk about food at all.
55. I chose this CWLPS because of the short duration of the CWLPS.	**56.** I chose this CWLPS, as it looked easy to follow.

57.

I chose this CWLPS, as I wanted regular weigh-ins.

58.

I chose this CWLPS, as I wanted the meal replacements provided by this CWLPS (food packs, shakes etc).

59.

I chose this CWLPS, as I wanted the camaraderie from others who were also following the same CWLPS as me.

60.

I chose this CWLPS based upon the endorsement from friends who had successfully tried it themselves.

-1

7 statements below

-2

7 statements below

-3

5 statements below

+4

4 statements below

+1 **7 statements below**	**+2** **7 statements below**
+3 **5 statements below**	**0** **8 statements below**
+5 **3 statements below**	**-4** **4 statements below**
-5 **3 statements below**	

Appendix 24: Q-methodology factor 3; factor arrays

PQMethod2.20 cwlps
PAGE 24
Path and Project Name: c:/Program Files/pqm220win/pqmethod/cwlps
May 21 12

Factor Q-Sort Values for Statements sorted by Consensus vs. Disagreement (Variance across Factor Z-Scores)

			Factor Arrays		
No.	Statement	No.	1	2	3
36	i chose this cs as i knew it would allow me to meet new peop	36	-4	-4	-3
39	i chose this cs as someone suggested that i could do with lo	39	-2	-2	-2
47	i chose this cs as it would help me to maintain my weight lo	47	3	4	4
24	i did not chose this cs bse of seeing advertisements which s	24	0	1	0
3	i chose this cs as i wnted something where there was a cnst	3	4	4	3
15	i chose this cs based upon the endorsement from celebrities	15	-4	-5	-5
23	i chose this cs as i had confidence in its results because t	23	2	1	2
37	i chose this cs to educate me about what exercise i was supp	37	-3	-3	-1
25	i did not chose this cs bse of the cost	25	1	0	0
38	i chose to pay for this cs because it is my responsibility t	38	4	2	3
28	i chose to pay for this cs as i knew that paying for it woul	28	3	3	1
19	i chose the ptr cs as i knew it would allow me to share hint	19	1	1	2
32	i chose this cs to support a friend or family member to lose	32	-1	-3	-3
2	i chose this cs as i wanted to have fun during the process o	2	0	-2	0
26	i chose this ptr cs as i knew i would be able to identify wi	26	1	1	2
50	i chose this cs as it was gender specific (men only or women	50	-1	-4	-2
45	i chose this cs as i wanted advice from celebrities to help	45	-5	-3	-5
17	i chose to use this ptr cs because i cld see cts who had bee	17	-3	-4	-5
4	i chose this cs as i did not want to get to the stage whereb	4	-3	-1	-4
48	i chose this cs based upon convenience	48	4	2	4
20	i chose this ptr cs as i thought it wld encourage me to do n	20	2	0	0
16	i did not chose this cs based upon the edt from other ple (g	16	0	-2	-2
14	i chose this cs as i wntd to be able to compare my pgs with	14	-1	-1	1

Appendix 24: Q-methodology factor 3; factor arrays

34	i chose this cs as losing weight was beneficial for my job	34	0	-2	-4
13	i chose this cs as i was awe that it wld pve me with the emt	13	-2	-5	-2
56	i chose this cs as it looked easy to follow	56	5	2	4
9	i chose this cs as i wntd it to show me how to understand th	9	-1	1	1
44	i chose this cs as i wanted advice from people (grp leaders	44	0	0	2
42	i chose this cs as i thought it would help me to give my fam	42	0	-3	-1
18	i chose this ptr cs bse i cld see other ple (grp lds & cs of	18	1	0	3
8	i chose this ptcr cs as i wntd to know how many cals are in	8	-1	-2	1
6	i chose this cs as i knew it would give me the support that	6	2	3	5
11	i chose this cs as i wntd to be able to buy the products ass	11	0	-1	-3
59	i chose this cs as i wanted the camaraderie from others who	59	-3	0	0
35	i chose this cs as i wanted the pat on the back from someone	35	0	-2	1
43	i chose this cs as i could set my own realistic weight loss	43	5	2	2
60	i chose this cs based upon the endorsement from friends who	60	4	3	0
1	i chose this cs as i wanted a better choice of clothes that	1	1	1	5
33	i chose this cs as i knew it would allow me to view wl as be	33	2	0	4
49	i chose this cs as i did not want to try and lose weight wit	49	1	-3	-2
41	i chose this cs because i saw it advertised (onlne,tv,newspa	41	2	-1	-3
40	i chose this cs to lose weight for an event (wedding,holiday	40	3	0	-1
29	i chose this cs as i thought it would be more socially accep	29	-2	-5	-1
54	i chose this cs as i did not want to talk about food at all	54	-3	1	-4

Appendix 25: Data extraction sheet; Anderson 1994b

Bibliographic Details	
Study ID	Anderson 1994b
Author (first)	Anderson JW, Brinkman-Kaplan, VL, Lee H, Wood CL.
Journal	American College of Nutrition
Year	1994b
Volume	3
Pages	256-261
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	James W. Anderson, MD, VA Medical Center, Cooper Drive Division (111C), Lexington, KY 40511

Character of included studies	
Methods	Controlled before and after
Participants	Exclusion criteria Authors do not report this Inclusion criteria BMI 40+
Interventions	Number of study centres: Authors do not report this Country/location: US Setting: Authors do not report this Treatment before study Authors do not report this Titration period: Authors do not report this
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Authors do not state what the primary and secondary outcomes are. Outcome measures for weight, lipids and BP are listed. Primary outcome(s) Secondary outcome (s) Other outcome (s)
Study details	Run-in period: Authors do not report this Study terminated before regular end: Authors do not report this
Publication details	Language of publication: English

Appendix 25: Data extraction sheet; Anderson 1994b

	Commercial funding: Authors do not report this Non-commercial funding: Authors do not report this Publication status (peer review journal): yes Publication status (journal supplement): Authors do not report this Publication status (abstract): Authors do not report this
Stated aim for study	Quote "this study critically examined the relationships between weight loss and changes in serum lipid and blood pressure levels"
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	High risk No randomisation
Allocation concealment (selection bias)	High risk Authors do not report this
Blinding (performance & detection bias)	High risk Authors do not report this
Blinding of participants and personnel (performance bias)	High risk Authors do not report this
Blinding of outcome assessment (detection bias)	High risk Authors do not report this
Incomplete outcome data (attrition bias)	Low risk 10 dropped out in-between 6 and 12 months, 2 additional participants dropped out at 18, and five additional participants dropped out at 24 months
Selective reporting (reporting bias)	Authors do not report this
Other bias	
Comments	

Overview of study populations	Anderson 1994b
Number invited	80 participants in total
Number screened	Authors do not report this
Number randomised	Authors do not report this
Number ITT	Authors do not report this
Number finishing the study	63
(%) of randomised patients finishing study	This was not an RCT

Appendix 25: Data extraction sheet; Anderson 1994b

Description of interventions	Anderson 1994b
Intervention(s) [route, frequency, total dose/day] Control(s) [route, frequency, total dose/day]	Participants were instructed to consume at least five packages of supplement, abstain from food, and drink 2L of non-alcoholic drinks per day. Two vitamin tablets were also taken.

Baseline characteristics	Anderson 1994b
Number of intervention participants Number of control participants	80 patients in total, not randomised
Participating population	80 patients with a BMI above 40
Sex [female %]	68.75% female
Age [mean years (SD)]	42±1.5 females 44±2.0
HbA1c [mean % (SD)]	Authors do not report this
BMI [mean kg/m2 (SD)]	45.5±0.6
Ethnic groups [%]	Authors do not report this
Duration of intervention [mean ... (SD)]	14 week core curriculum
Duration of follow-up [mean ... (SD)]	follow up data for 12, 18 and 24 months
Co-medications	Authors do not report this
Co-interventions	Authors do not report this
Co-morbidities	Authors do not report this

Matrix of study endpoints	Anderson 1994b
Intervention(s)	Not an RCT. Authors do not report this
Control (s)	Not an RCT. Authors do not report this
Primary endpoint(s)	Authors do not specifically report what the primary and secondary endpoints are, though BP and lipids are factored in the aim Weight 93.9±2.4* BMI 33.1±0.7* Cholesterol mmol/L

Appendix 25: Data extraction sheet; Anderson 1994b

	4.76±1.09 Mg/dl 184±4.2* LDL Cholesterol mmol/L 3.15±0.098 Mg/dl 122±3.8* HDL Cholesterol mmol/L 1.04±0.028 Mg/dl 40.2±1.1* LDL:HDL Cholesterol ratio 3.21±0.13* Triglycerides mmol/L 1.35±0.078 Mg/dl 120±6.9* Systolic bp (mmHg) 124±1.7* Diastolic bp (mmHg) 81.4±0.8*
Secondary endpoint(s)	Authors do not report this
Other endpoint(s)	Authors do not report this
Effect size	35.3kg was lost at 25.6 weeks. 19.7 kg were maintained of their weigh loss at 2 year follow up. Cholesterol (15.1%), LDL cholesterol (17.0%), triglycerides (14.2%), systolic BP (8.8%) and diastolic BP (10.2%) decreased significantly. lipids and BP were significantly correlated with baselines values and change in BMI after adjustment for baselines values.

Adverse events	Anderson 1994b

Appendix 25: Data extraction sheet; Anderson 1994b

All adverse events	Authors do not report this

Appendix 26: Data extraction sheet; Truby 2006

Bibliographic Details	
Study ID	Truby 2006
Author (first)	Truby H, Baic S, deLooy A, Fox KR, Livingstone MBE, Logan CM, Macdonald, IA, Morgan, LM, Taylor, MA, Millward, DJ.
Journal	BMJ
Year	2008
Volume	Authors do not report this
Pages	1-6
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper See Morgan et al (2008)
Corresponding author and contact details	Authors do not report this. Email the author listed in the Morgan paper

Character of included studies	
Methods	Multicentre randomised unblended controlled trial.
Participants	Exclusion criteria Coronary heart disease; type 1 or type 2 diabetes; renal, liver, or respiratory failure; gout; obesity with known cause (Cushing's disease, hypothyroidism); previous gastric or weight loss surgery; clinical depression; eating disorders; drug or alcohol misuse; any malabsorptive state (including lactose intolerance); taking lipid lowering or anti-hypertensive drugs; taking any drugs (including orlistat and sibutramine) for weight loss; being treated for cancer; and being pregnant or breastfeeding. Inclusion criteria Participants were chosen from people who lived within 30 miles of a test centre, were aged between 18 and 65, and had a self reported body mass index between 27 and 40.
Interventions	Number of study centres: five Country/location: UK Setting: community based

Appendix 26: Data extraction sheet; Truby 2006

	Treatment before study: Authors do not report this Titration period: Authors do not report this
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Main weight and body fat changes over six months Primary outcome(s) Authors do not report this. They state the main outcome measures were body fat and weight changes over six months Secondary outcome (s) Authors do not report this Other outcome (s) Authors do not report this
Study details	Run-in period: Authors do not report this Study terminated before regular end: Authors do not report this
Publication details	Language of publication: English Commercial funding: BBC Non-commercial funding: Authors do not report this Publication status (peer review journal): Yes Publication status (journal supplement): Authors do not report this Publication status (abstract): Authors do not report this
Stated aim for study	Quote “To compare the effectiveness of four commercial weight loss diets available to adults in the United Kingdom.”
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	Low At each test centre, they stratified participants by sex and allocated them to a group using random number generation.
Allocation concealment (selection bias)	High risk Authors do not report this
Blinding (performance & detection bias)	High risk Participants and staff were not blind, this is stated in the paper
Blinding of participants and personnel (performance bias)	High risk Authors do not report this
Blinding of outcome assessment (detection bias)	High risk Authors do not report this

Appendix 26: Data extraction sheet; Truby 2006

Incomplete outcome data (attrition bias)	Low 83 dropped out
Selective reporting (reporting bias)	Authors do not report this
Other bias	
Comments	

Overview of study populations	Truby 2006
Number invited	300 participants were contacted
(number screened	300, 7 were excluded
Number randomised	293
Number ITT	292 (one was excluded due to pregnancy) The primary analysis was on an intention to treat basis, with baseline values carried forward to replace missing values (one participant was not used in this analysis as she withdrew because of pregnancy).
(n) finishing study Intervention Control Total	210 158 at 12 months with return data
(%) of randomised patients finishing study	71.7% including control

Description of interventions	Truby 2006
Intervention(s) [route, frequency, total dose/day]	For the group based programmes (weight Watchers and Rosemary Conley), participants attended the most convenient class and they reimbursed the costs of joining and attending one class each week. Both parent companies signed a contract committing to the provision of standard care. For Slim-Fast, they reimbursed the cost of up to two meal replacements each day and provided a copy of the Slim-Fast support pack. They gave participants in the Atkins group a copy of Dr Atkins' New Diet Revolution.
Control(s) [route, frequency, total dose/day]	They asked the members of the control group to maintain their current diet and exercise pattern and offered them any

	of the diets for six months at the end of study (free of charge). It doesn't state if all participants or just those receiving a commercial programme (see below) Participants completed a seven day diet and activity diary at baseline, eight week, and 24 week. They gave no dietary or exercise advice so as not to compromise the study. When they analysed the food diaries at two months they found that some of the participants on the Atkins diet were not taking supplements of micronutrients as advised in the book. Therefore, from week 10 they offered free daily supplements of multivitamins. All participants who withdrew completed a short exit questionnaire. At 12 months, they recorded the weight and dieting behaviour from six to 12 months of all participants still willing to attend test centres.

Baseline characteristics	Truby 2006
Number of intervention participants Number of control participants	232 61
Participating population	Participants who lived within 30 miles of a test centre, aged between 18 and 65, and had a self-reported body mass index between 27 and 40.
Sex [female %]	73.7% Atkins 72.4%weight watchers 71.2% slim fast 72.4% rosemary Connelly 75.4% control
Age [mean years (SD)]	40.9 (9.7) Atkins 39.9 (10.9) weight watchers 38.9 (10.7) slim fast 40.6 (10.3) rosemary Connelly 40.8 (9.6) control
HbA1c [mean % (SD)]	Authors do not report this
BMI [mean kg/m2 (SD)]	31.9 (2.2) Atkins 31.2 (2.7)weight watchers 32.2 (3.0) slim fast 31.6 (2.6) rosemary Connelly 31.5 (2.9) control
Ethnic groups [%]	Authors do not report this
Duration of intervention [mean ... (SD)]	24 weeks
Duration of follow-up [mean ... (SD)]	Authors do not report this
Co-medications	Authors do not report this
Co-interventions	Authors do not report this

Appendix 26: Data extraction sheet; Truby 2006

Co-morbidities	Authors do not report this

Matrix of study endpoints	Truby 2006
Intervention(s)	SD in brackets Atkins weight watchers slim fast rosemary Connelly control 0-2 months Weight kg 5.2 (4.4) 4.7 (3.2) 3.7 (3.5) 4.0 (3.3) 0.4 (1.8) Weight loss % 5.5 (4.2) 5.1(3.5) 3.8 (3.4) 4.5 (3.6) 0.4 (2.2) Fat loss 3.5† (3.0) 3.1 (2.4) 2.3† (2.3) 2.5 (2.1) 0.2 (1.3) Fat loss % 1.9† (1.9) 1.6 (1.9) 1.0† (1.4) 1.5 (1.5) 0.1 (1.4) Reduction in waist circumference 6.7 (6.1) 5.5 (5.1) 4.8 (4.6) 4.5 (5.3) 1.0 (4.0) 2-6 month Weight kg 1.3 (3.1) 2.2 (3.0) 1.4 (2.8) 2.4 (3.4) −0.9 (1.6) Weight loss % 1.3 (3.1) 2.4 (3.4) 1.3 (2.9) 2.7 (3.7) −1.2 (1.9) Fat loss 1.2 (2.3) 2.0 (2.3) 1.2 (2.6) 2.1 (2.5) −0.5 (1.2) Fat loss % 1.3 (1.9) 2.0 (2.0) 1.2 (2.4) 2.1 (2.4) −0.0 (1.0) Reduction in waist circumference 2.4 (4.0) 3.0 (3.5) 2.1 (3.4) 3.0 (4.2) −0.3 (2.4) 0-6 months Weight loss 6.0 (6.4) 6.6 (5.4) 4.8 (5.6) 6.3 (6.1) −0.6 (2.2) Weight loss %

	6.2 (6.2) 7.3 (6.1) 4.9 (5.5) 7.0 (6.6) −0.6 (2.7) Fat loss kg 4.6 (4.8) 5.0 (4.3) 3.4 (4.3) 4.5 (4.3) −0.3 (4.4) Fat loss % 3.1 (3.3) 3.6 (3.3) 2.1 (2.9) 3.4 (3.5) 0.1 (1.6) Reduction in waist circumference 8.1 (7.4) 8.3 (7.0) 6.4 (6.3) 7.2 (7.2) 0.8 (3.8) For all variables reported, the control group was significantly different from all other groups (P<0.001). *Not measured in all participants: 57 for Weight Watchers, 56 for Rosemary Conley, 60 for controls. †Pairwise comparison of group means with post hoc Tukey's HSD (honestly significantly different) test found a significant difference between the Atkins and Slim-Fast groups 0-2 months Fall in blood pressure systolic 5.7* (12.7) 3.5 (9.6) 0.5* (11.4) 2.4 (11.2) 3.3 (11.0) Diastole 3.6 (8.4) 4.1 (6.8) 3.1 (7.8) 2.8 (7.1) 2.0 (7.0) 0.61 Fall in total glucose 0.04 (0.4) 0.14 (0.5) 0.13 (0.5) 0.15 (0.5) 0.02 (0.4) 0.44 Fall in cholesterol 0.08 (0.7) 0.44* (0.6) 0.26* (0.6) 0.35* (0.8) 0.08 (0.5) 0.001 2-6 months Fall in systolic blood pressure 1.3 (9.8) 0.9 (10.3) 2.9 (12.4) 2.1 (9.2) −0.9 (8.3) 0.23 Fall in diastolic blood pressure 1.1 (6.3) 0.8 (6.7) −0.3 (8.6) 1.0 (5.5) −0.4 (5.7) 0.51 Fall in total glucose 0.13 (0.5) 0.29 (0.6) 0.12 (0.5) 0.17 (0.5) 0.13 (0.4) 0.34 Fall in cholesterol 0.19 (0.5) 0.11 (0.5) 0.07 (0.5) 0.08 (0.6) 0.24 (0.24) 0.24 0-6 months

Appendix 26: Data extraction sheet; Truby 2006

	Systolic 7.2 (11.6) 4.1 (11.7) 2.7 (10.7) 4.5 (9.8) 2.8 (11.8) 0.19 Diastolic 4.9 (8.1) 4.4 (8.6) 2.5 (8.6) 3.6 (6.0) 1.6 (7.4) 0.13 Fall in total glucose 0.19 (0.5) 0.46* (0.6) 0.19 (0.6) 0.27 (0.5) 0.14* (0.5) 0.013 Fall in cholesterol 0.29 (0.8) 0.55* (0.7) 0.35 (0.6) 0.5 (0.5) 0.5* (0.18) 0.013
Control (s)	See above for control data.
Primary endpoint(s)	
Secondary endpoint(s)	
Other endpoint(s)	
Effect size	All diets resulted in significant loss of body fat and weight over six months. Groups did not differ significantly but loss of body fat and weight was greater in all groups compared with the control group. In an intention to treat analysis, average weight loss was 5.9 kg and average fat loss was 4.4 kg over six months. The Atkins diet resulted in significantly higher weight loss during the first four weeks, but by the end was no more or less effective than the other diets.

Adverse events	Truby 2006
All adverse events	Authors do not report this

Appendix 27: Data extraction sheet; Anderson 1991

Bibliographic Details	
Study ID	Anderson 1991
Author (first)	Anderson JW, Hamilton, CC, Crown-Weber E, Riddlemoser M, Gustafson NJ.
Journal	American Dietetic Association
Year	1991
Volume	1582(3)
Pages	Authors do not report this six pages in total
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	J.W. Anderson (corresponding author) is chief of the Metabolic and Endocrinology, Section VA Medical Center, Lexington, KY 40511.

Character of included studies	
Methods	Before and after study
Participants	Exclusion criteria Body weight less than 120% of desirable, recent surgery or myocardial infarction (< 6 weeks), unstable heart disease, pregnancy, lactation, severe psychological disturbance, alcohol abuse, or drug abuse. Inclusion criteria Authors do not report this
Interventions	Number of study centres: No study centre, Slim Fast or something similar was used, and does not require attending specific locations. Country/location: US Setting: No study centre, Slim Fast or something similar was used, and does not require attending specific locations.

Appendix 27: Data extraction sheet; Anderson 1991

	Treatment before study: Authors do not report this Titration period: Authors do not report this
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Does not state the specific outcome measures. At the beginning of the weight loss phase, a complete blood chemistry, lipid profile, complete blood cell count, differential blood cell count, urinalysis, and 12-lead electrocardiogram (ECG) were obtained. Thereafter, a blood chemistry panel was obtained every 2 weeks, a complete blood cell count and serum high-density-lipoprotein (HDL) cholesterol value every 4 weeks, and a differential blood cell count every 8 weeks. Primary outcome(s): Authors do not report this Secondary outcome (s): Authors do not report this Other outcome (s): Authors do not report this
Study details	Run-in period None reported Study terminated before regular end None reported
Publication details	Language of publication: English Commercial funding: Authors do not report this Non-commercial funding: Authors do not report this Publication status (peer review journal): yes

Appendix 27: Data extraction sheet; Anderson 1991

	Publication status (journal supplement): Authors do not report this Publication status (abstract): Authors do not report this
Stated aim for study	Quote “ “ No specific aim stated. This study examined the safety and effectiveness of a VLCD regimen being followed by 100 subjects.
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	High Authors do not report this, all participants received the same product
Allocation concealment (selection bias)	High Authors do not report this. A trained physician and nurse monitored weight, blood pressure, and changes in medical status weekly.
Blinding (performance & detection bias)	High None reported
Blinding of participants and personnel (performance bias)	High None reported
Blinding of outcome assessment (detection bias)	High None reported
Incomplete outcome data (attrition bias)	High None reported
Selective reporting (reporting bias)	High None reported
Other bias	None reported

Appendix 27: Data extraction sheet; Anderson 1991

Comments	All received the same liquid supplement. However, participants were not told how much activity to do. Certain participants could have done more activity than others and could have altered the results. Participants were told not to eat anything else, however, as this was not monitored, they could have consumed additional food.

Overview of study populations	Anderson 1991
Number invited	Only one group After completing an initial medical and laboratory evaluation, individuals attended the first group session and entered the weight loss program. Patients were monitored weekly by trained physicians and nurses. Patients also attended 90-minute group classes conducted by trained behavioural health educators.
Number screened	Authors do not state this
Number randomised	100 subjects
(n) ITT Intervention Control Total	Authors do not state this
Number finishing study	49
(%) of randomised patients finishing study Intervention Control Total	49%

Description of interventions	Anderson 1991
Intervention(s) [route, frequency, total dose/day] Control(s) [route, frequency, total dose/day]	Five chocolate or vanilla liquid supplements plus two vitamin-mineral tablets daily. There was no comparison group

Baseline characteristics	Anderson 1991
Number of intervention participants Number of control participants	100 in total, no comparison group

Appendix 27: Data extraction sheet; Anderson 1991

Participating population	Authors do not report this. The report only states the exclusion criteria, not the participant characteristics
Sex [female %]	Authors do not report this
Age [mean years (SD)]	Authors do not report this
HbA1c [mean % (SD)]	Authors do not report this
BMI [mean kg/m2 (SD)]	Authors do not report this
Duration of disease [mean years (SD)]	Authors do not report this
Ethnic groups [%]	Authors do not report this
Duration of intervention [mean ... (SD)]	Authors do not report this
Duration of follow-up [mean ... (SD)]	Authors do not report this
Co-medications	Authors do not report this
Co-interventions	Authors do not report this
Co-morbidities	When they entered the program, many patients had obesity-related diseases such as hypertension (n = 68), hypercholesterolemia (n = 28), degenerative joint disease (n = 21), hypertriglyceridemia (n = 15), and type II diabetes (n = 10).

Matrix of study endpoints	Anderson 1991
Intervention(s)	At the end of the weight loss period (when desired eight was achieved), female lost a mean of 19.2 kg, or 20%, of initial body weight in 17 weeks (range=1 to 39 week). Males lost a mean of 18.6 kg, or 16%, of initial body weight in 12 weeks (range=1 to 22 weeks). 62 % of females and 69% of males had a non-obese body mass index (kg[m.sup.2]<30) by the end of the VLCD weight loss phase. Total serum cholesterol decreased a mean of 14% (P<.001) for both females and males during the weight loss phase. Final mean cholesterol values for females. Mean HDL-cholesterol levels decreased 17% (P<.001) for females and did not significantly change for males. Mean triglyceride values decreased 8% for females and 24% for males (P<.05). Fasting serum glucose values decreased a mean of 12% (P<.001) for females and 16% (P<.05) for males during the weight loss phase. Of the 10 patients (6 females, 4 males) with type II diabetes, 5 patients had serum glucose decreases of 32% or more and 4 patients had decreases of 44% or more.

Appendix 27: Data extraction sheet; Anderson 1991

	Mean systolic blood pressure decreased 12.5% (P<.001) for females and 11% (P<.001) for males during weight loss. Mean diastolic blood pressure decreased 9% (P<.001) for both females and males. Fifty-six patients who were initially taking antihypertensive/diuretic medications were able to discontinue them during the VLCD phase.
Control (s)	Authors do not report this. There is no comparison group.
Primary endpoint(s)	
Secondary endpoint(s)	
Other endpoint(s)	
Effect size	Of the 100 subjects, 49 stayed on the diet until reaching their desired weight. The average weight loss was 19.2 kg for females and 18.6 kg for males. At the end of the study period, 62 % of the females and 69 % of the males had body masses outside the obese range. At follow-up, females had maintained 36 % of the weight loss and males had maintained 39 % of the weight loss.

Adverse events	Anderson 1991
	Two patients required antigout medication, and 27 patients were started on iron supplements during the weight loss phase. Patients reported the following side effects at least once during the weight loss phase: fatigue (n-47), orthostatic dizziness (n=41), constipation (n=35), headaches (n=25), palpitations (n=7), hair loss (n=5), cold intolerance (n=5), irregular menses (n=4), and dry skin (n=1).

Appendix 28: Data extraction sheet; Anderson 1994a

Bibliographic Details	
Study ID	Anderson 1994a
Author (first)	Anderson JW, Brinkman-Kaplan V, Hamilton CC, Logan JE, Collins RW, Gustafson NJ.
Journal	Diabetes Care
Year	1994a
Volume	17 (6)
Pages	602-604
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Short report
Corresponding author and contact details	James W. Anderson, MD, VA Medical Center, Cooper Drive Division (111C), Lexington, KY 40511.

Character of included studies	
Methods	Randomised controlled clinical trial (RCT)
Participants	Exclusion criteria If participants do not have the expressed inclusion criteria Inclusion criteria non-insulin-dependent diabetes mellitus of > 1-year duration, 40-70 years of age, BMI 30-40 kg/m2, serum creatinine levels ^176 /xM, serum cholesterol levels ^7.8 mM, serum triglycerides <22.6 mM, and no recent cardiovascular events. Diagnostic criteria
Interventions	Number of study centres: Authors do not report this. No particular study centre, this study researched Slim Fast (or something similar), which can be consumed anywhere Country/location: US Setting: Authors do not report this No particular study centre, this study researched Slim Fast (or something similar), which can be consumed anywhere Treatment before study: Authors do not report this Titration period: Authors do not report this
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) This study was designed to determine if food-containing hypocaloric diets are as effective as liquid-supplement diets in

Appendix 28: Data extraction sheet; Anderson 1994a

	promoting weight loss for obese individuals with non-insulin-dependent diabetes mellitus (NIDDM). Primary outcome(s) Authors do not report this Outcome measures are weight, BP, Serum glucose (mM) ,Glycosylated hemoglobin (%), Serum cholesterol (mM), Serum LDL cholesterol (mM), Serum HDL cholesterol (mM), Serum triglycerides (mM) Secondary outcome (s) Other outcome (s)
Study details	Run-in period: Authors do not report this Study terminated before regular end : Authors do not report this
Publication details	Language of publication English Commercial funding: Authors do not report this Non-commercial funding: Supported in part by Health Management Resources and the HCF Nutrition Research Foundation in Lexington, Kentucky. Publication status (peer review journal): Yes Publication status (journal supplement): Authors do not report this Publication status (abstract)
Stated aim for study	Quote “This study was designed to determine if food-containing hypocaloric diets are as effective as liquid-supplement diets in promoting weight loss for obese individuals with non-insulin-dependent diabetes mellitus (NIDDM).”
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	Low Forty subjects (19 women and 21 men) entered the study and were assigned to one of two diets using a stratified randomization based on gender, body mass index (BMI), and insulin use.

Appendix 28: Data extraction sheet; Anderson 1994a

Allocation concealment (selection bias)	High Authors do not report this. Twenty subjects (10 women and 10 men) were assigned to liquid supplement, and 20 subjects (9 women and 11 men) were assigned to liquid supplement plus food.
Blinding (performance & detection bias)	High Authors do not report this
Blinding of participants and personnel (performance bias)	Low 90-min group classes conducted by a trained behavioral health educator. Both groups received an intensive behavioural programme. It does not state is the groups were mixed, which could have meant that participants were telling one another about what they were doing, and could have contaminated the results (participants could have decided to swap the programme that they were assigned too, to the other programme that another participant had told them about). This would not have been blind to personnel either, which could have meant that the sessions picked out specific people and ensured that they received better behavioural messages (i.e. group a). Nurses and physicians were not blind to who had received what. Participants could have discussed what they were doing during consultations. This would not affect the results massively as it would only be a person's weight that could be tampered with, other outcome measures related to bloods, and BP which could not be tampered with.
Blinding of outcome assessment (detection bias)	Low Nurses and physicians were not blind to who had received what. Participants could have discussed what they were doing during consultations. This would not affect the results massively as it would only be a person's weight that could be tampered with, other outcome measures related to bloods, and BP, which could not be tampered with.
Incomplete outcome data (attrition bias)	Low Three subjects data were not available for 1 year follow up
Selective reporting (reporting bias)	High Authors do not report this.
Other bias	
Comments	

Appendix 28: Data extraction sheet; Anderson 1994a

Overview of study populations	Anderson 1994a
Number invited	Low Forty subjects (19 women and 21 men) entered the study and were assigned to one of two diets using a stratified randomization based on gender, body mass index (BMI), and insulin use. Twenty subjects (10 women and 10 men) were assigned to liquid supplement, and 20 subjects (9 women and 11 men) were assigned to liquid supplement plus food.
Number screened	Low Authors do not report this. Interested subjects attended an orientation session and underwent careful medical and laboratory screening.
Number randomised	Low Forty subjects (19 women and 21 men) entered the study and were assigned to one of two diets using a stratified randomization based on gender, body mass index (BMI), and insulin use.
(n) ITT Intervention Control Total	Authors do not report this.
Number finishing study	37 were available for follow up. Does not state which group the dropouts were from
(%) of randomised patients finishing study	92.5%

Description of interventions	Anderson 1994a

Appendix 28: Data extraction sheet; Anderson 1994a

Intervention(s) [route, frequency, total dose/day]	For the weight-loss diet program, group A subjects were instructed to consume at least five liquid supplements a day, which provide 800 kcal and 80 g of high-quality protein, and take two vitamin/mineral tablets.
Control(s) [route, frequency, total dose/day]	Group B subjects were instructed to consume at least three liquid supplements a day, which provide 320 kcal and 32 g of high-quality protein, take one vitamin/mineral supplement, and consume a recommended evening meal containing ~500 kcal and 50 g of high-quality protein.

Baseline characteristics	Anderson 1994a
Number of intervention participants Number of control participants	40
Participating population	NIDDM subjects with body mass indexes (BMIs) of 30-40 kg/m2
Sex [female %]	50% and 45%
Age [mean years (SD)]	Authors do not report this. They state 40-70 years of age
HbA1c [mean % (SD)]	8.2 ± 0.5 8.6 ± 0.5
BMI [mean kg/m2 (SD)]	Authors do not report this.
Duration of disease [mean years (SD)]	Authors do not report this.
Ethnic groups [%]	Authors do not report this.
Duration of intervention [mean ... (SD)]	12 weeks intervention
Duration of follow-up [mean ... (SD)]	Follow up after one year
Co-medications	Initial treatment regimens included insulin, 5 subjects; insulin and oral hypoglycemic agents, 3 subjects; oral hypoglycemic agents, 24 subjects; and diet alone, 7 subjects.
Co-interventions	Authors do not report this.
Co-morbidities	Authors do not report this.

Matrix of study endpoints	Anderson 1994a
Intervention(s)	Body weight (kg) 88.6 ± 2.8 Systolic blood pressure (mmHg) 124.2 ± 3.6 Diastolic blood pressure (mmHg) 76.3 ± 1.8

Appendix 28: Data extraction sheet; Anderson 1994a

	Serum glucose (mM) 7.6 ± 0.5 Glycosylated hemoglobin (%)6.2 ± 0.2 Serum cholesterol (mM) 4.6 ± 0.2 Serum LDL cholesterol (mM) 2.8 ± 0.2 Serum HDL cholesterol (mM) 1.0 ±0.1 Serum triglycerides (mM) 1.7 ± 0.2
Control (s)	Body weight (kg) 89.4 ± 2.7 Systolic blood pressure (mmHg) 123.8 ± 3.9 Diastolic blood pressure (mmHg) 75.3 ± 2.2 Serum glucose (mM) 8.9 ± 0.8 Glycosylated hemoglobin (%)6.8 ± 0.3 Serum cholesterol (mM) 4.7 ± 0.2 Serum LDL cholesterol (mM) 2.7 ± 0.2 Serum HDL cholesterol (mM) 1.1 ±0.0 Serum triglycerides (mM) 2.0 ± 0.2
Primary endpoint(s)	Authors do not report this.
Secondary endpoint(s)	Authors do not report this.
Other endpoint(s)	
Effect size	Both groups lost significant amounts of weight, and weight losses did not differ significantly between groups. Weight loss averaged 15.7 kg for the entire group.

Adverse events	Anderson 1994a

Appendix 28: Data extraction sheet; Anderson 1994a

All adverse events	The authors do not state which group suffered the events below Frequently reported side effects during the weight-loss phase included constipation (56% of subjects), diarrhea (31%), dizziness (31%), fatigue (31%), flu/sore throat (13%), headache (10%), vomiting (10%), blurred vision (10%), muscle cramps (8%), and syncope (5%). One woman in group B discontinued the study because of coronary bypass surgery for pre-existing coronary heart disease.

Appendix 29: Data extraction sheet; Ditschuneit 1999

Bibliographic Details	
Study ID	Ditschuneit 1999
Author (first)	Ditschuneit HH, Flechtner-Mors M, Johnson TD, Adler G
Journal	American Journal of Clinical Nutrition
Year	1999
Volume	69
Pages	198-204
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	HH Ditschuneit, University Hospital, Department of Medicine, University Ulm, Robert-Koch-Strasse 8, D-89081 Ulm, Germany. E-mail: herwig.ditschuneit@medizin.uni-ulm.de.

Character of included studies	
Methods	Prospective, randomized, parallel intervention study
Participants	Exclusion criteria Individuals with a history or presence of significant disease, endocrine disorders, psychiatric diseases, alcohol or drug abuse, or abnormal laboratory test results of clinical significance were excluded. In addition, women were excluded if they were lactating, pregnant, or wished to become pregnant. Inclusion criteria Patients were men and women aged >18 y whose body mass indexes were > 25.0 and 40.0 and who gave their informed consent to participate. Patients indicated their willingness to be randomly assigned to study groups and to follow the program protocol, which included monthly hospital visits for physical examinations and review of diet records. One hundred patients met the inclusion criteria, agreed to be randomly assigned to study groups, and adhered to the study protocol.

Appendix 29: Data extraction sheet; Ditschuneit 1999

Interventions	Number of study centres: Authors do not report this Country/location: US Setting: Authors do not report this No particular setting, slim fast allows participants to consume the shake wherever they wish to. Treatment before study: Authors do not report this Titration period: Authors do not report this
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Authors do not report this. The authors do not specifically state what the primary outcomes were, but tables state weight (kg), weight loss(%),SBP (mm Hg), DBP (mm Hg), Triacylglycerol (mmol/L), Cholesterol (mmol/L), HDL cholesterol (mmol/L), Glucose (mmol/L), Insulin (pmol/L) Primary outcome(s) Authors do not report this Secondary outcome (s) Authors do not report this Other outcome (s)
Study details	Run-in period: Authors do not report this Study terminated before regular end: Authors do not report this
Publication details	Language of publication: English Commercial funding: Slim fast Non-commercial funding: Authors do not report this Publication status (peer review journal): yes Publication status (journal supplement): Authors do not report this Publication status (abstract): Authors do not report this
Stated aim for study	Quote “We assessed the long-term effects of an energy restricted diet combined with 1 or 2 daily meal replacements on body weight and biomarkers of disease risk in 100 obese patients.”
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	Low Computer-generated identification number.
Allocation concealment (selection bias)	High Participants would have known what they were receiving, the dietician would not have been blind as they were to prescribe diet plans according to the participant and what they were receiving

Appendix 29: Data extraction sheet; Ditschuneit 1999

Blinding (performance & detection bias)	High Authors do not report this
Blinding of participants and personnel (performance bias)	High Authors do not report this
Blinding of outcome assessment (detection bias)	High Authors do not report this. It does not state whether many participants had their anthropometrics done at the same time. If they were, this could have had an impact on the results, especially if the answers were read out (element of completion)
Incomplete outcome data (attrition bias)	Low All patients completed the first three months (phase 1) During the next 24 mo (phase 2), patient attrition occurred and at the end of this phase 37 patients had dropped out (n=63)
Selective reporting (reporting bias)	Authors do not report this
Other bias	
Comments	It is not stated whether the dietician also assisting in data collection. The dietician could have pulled the waist measure tighter for slim fast participants it does not state whether inter and intra reliability was done for the waist measurements. If various researchers did these they could be quite a large margin of error

Overview of study populations	Ditschuneit 1999
Number invited	Low Authors do not report this 50 participants were randomly assigned to group A (control group) and 50 patients to group B (meal-replacement group). The study patients were referred to the Obesity Center at the University Hospital of Ulm for obesity management. All patients had been treated by the referring practitioner with energy restricted diets for ³3 mo. Dissatisfaction with the degree of weight loss was the primary reason for transfer to the University Center

Appendix 29: Data extraction sheet; Ditschuneit 1999

Number screened	Low Screening was initially carried out by the Obesity Center at the University Hospital of Ulm for obesity management. Patients were referred.
Number randomised	Low 50 and 50
(n) ITT Intervention Control Total	High Authors do not report this
Number finishing study	Low All finished the study, however at 24 months dropouts started to occur.
(%) of randomised patients finishing study	62% finished the study control 64% finished the study intervention

Description of interventions	Ditschuneit 1999
Intervention(s) [route, frequency, total dose/day]	Group B was prescribed similar self-selected diets, except that 2 of the 3 main meals (breakfast, lunch, or dinner) were replaced with meal-replacement shakes, soups, or hot chocolate (Slim•Fast). Each meal replacement contained 0.84–1.05 MJ energy, 14.0–17.0 g protein, 27.0–33.5g carbohydrate, 5.0–6.6 g fat, and 4.5–6.5 g fiber and was supplemented with essential vitamins and minerals. In place of snacks, patients were provided with 2 nutrition snack bars (Slim•Fast) per day containing 0.38–0.46 MJ energy, 1.4–1.7 g protein, 16.1–18.1 g carbohydrate, 2.4–3.9 g fat, and 1.1 g fiber. In phase 2, all patients were seen monthly and continued to receive the same instructions while following their food plans. The energy content of the prescribed diet was the same in both groups, and all patients were instructed to replace one meal and one snack with the energy-controlled, nutrient-dense meal and snack replacements.

Appendix 29: Data extraction sheet; Ditschuneit 1999

Control(s) [route, frequency, total dose/day]	The dietary intervention during phase 1 was structured such that a staff nutritionist explained the diet plan in detail and counselled participants by using personalized sample menus and recipes and instruction in maintenance of a food diary. Throughout the study, patients were prescribed a balanced diet providing 5.2–6.3 MJ/d (1200–1500 kcal/d) and 19–21% of energy as protein, 48–54% of energy as carbohydrate, and 25–34% of energy as fat. Three meals (breakfast, lunch, and dinner) and 2 snacks (1 between breakfast and lunch and 1 between lunch and dinner) were recommended. The nutritionist provided monthly, personalized instructions by using food exchange lists and food diaries to equalize the prescribed energy intakes between groups A and B. Individual preferences for various food items were integrated into the diet plan. During phase 1, the 3-mo weight-loss period, group A was prescribed a diet in which all meals and snacks were prepared from self-selected, conventional foods. In phase 2, all patients were seen monthly and continued to receive the same instructions while following their food plans. The energy content of the prescribed diet was the same in both groups, and all patients were instructed to replace one meal and one snack with the energy-controlled, nutrient-dense meal and snack replacements.

Baseline characteristics	Ditschuneit 1999
Number of intervention participants Number of control participants	50 50
Participating population	Patients were men and women 18+ years, between 25-40 BMI
Sex [female %]	82% control 76% intervention
Age [mean years (SD)]	Control Age (y) women 46.8 ±11.2 men 45.5 ±12.0 Intervention Women 44.3 ±9.8 men 46.5 ±9.5
HbA1c [mean % (SD)]	Authors do not report this
BMI [mean kg/m2 (SD)]	Control Women 33.9 ±3.0 men 33.1 ±4.1 Intervention Women 33.1 ±4.1 men 33.0 ±3.7

Appendix 29: Data extraction sheet; Ditschuneit 1999

Duration of disease [mean years (SD)]	Authors do not report this
Ethnic groups [%]	Authors do not report this
Duration of intervention [mean ... (SD)]	3 months
Duration of follow-up [mean ... (SD)]	24 month follow up
Co-medications	Authors do not report this
Co-interventions	Authors do not report this
Co-morbidities	Authors do not report this

Matrix of study endpoints	Ditschuneit 1999
Intervention(s)	Weight 89.1 ±12.1 women;baseline 82.3 ±12.0 women;3 months 104.1 ±13.1 men;baseline 95.2 ±13.1 men;three months Waist:hip ratio 0.86 ±0.15 women;baseline 0.84 ±0.13 women;3 months 0.95 ±0.09 men;baseline 0.93 ±0.11 men;3 months Systolic blood pressure 139 ±18 women;baseline 130 ±14 women;3months 142 ±15 men;baseline 132 ±10 women;3 months Diastolic blood pressure 82 □8 women;baseline 80 □5 women;3 months 83 □7 men;baseline 82 ±3 men;3 months Triglycerol 2.00 ±1.07 women;baseline 1.57 ±0.74 women;3 months 2.94 ±1.48 men;baseline 2.29 ±1.70 men;3 months Chloestrol 5.75 ±1.02 women;baseline 5.70 ±0.94 women;3months 6.07±0.97 men;baseline 6.09 ±0.66 men;3 months HDL 1.40 ±0.41 women;baseline 1.34 ±0.46 women;3 months 1.04 ±0.28 men;baseline 1.15 ±0.33 men;3 months Blood glucose 4.96 ±0.28 women;baseline 4.55 ±0.69 women;3 months 5.11 ±1.02 men;baseline 4.74 ±0.99 men;3 months Insulin 128.5 ±51.7 women;baseline 78.9 ±23.4 women;3 months 143.5 ±53.6 men;baseline 100.8 ±34.9 men;3 months

Appendix 29: Data extraction sheet; Ditschuneit 1999

	Phase 1 Body weight (kg) Group B 92.6 ±13.7 baseline 85.5 ±13.4 3 months Waist-to-hip ratio Group B 0.89 ±0.12 baseline 0.86 ±0.18 3months SBP (mm Hg) Group B 139 ±15 baseline 130 ±13 3months DBP (mm Hg) Group B 82 □6 baseline 80 □5 3months Triacylglycerol (mmol/L) Group B 2.23 ±1.24 baseline 1.75 ±1.09 3months Cholesterol (mmol/L) Group B 5.83 ±1.01 baseline 5.79 ±0.89 3 months HDL cholesterol (mmol/L) Group B 1.31 ±0.41 baseline 1.30 ±0.44 3 months Glucose (mmol/L) Group B 4.97 ±0.87 baseline 4.58 ±0.74 3 months Insulin (pmol/L) Group B 132.0 ±53.1 baseline 84.9 ±30.4 3months Phase 2 Body weight (kg) Group B 84.3 ±13.8 15months 82.2 ±13.4 27 months Waist-to-hip ratio Group B 0.85 ±0.20 15 months 0.85 ±0.19 27 months SBP (mm Hg) Group B 123 ±11 15months 124 ±12 27months DBP (mm Hg) Group B 76 □5 15months 78 ±5 27months

	Triacylglycerol (mmol/L) Group B 1.58 ±0.41 15months 1.40 ±0.49 27months Cholesterol (mmol/L) Group B 5.51 ±0.53 15months 5.35 ±0.95 27months HDL cholesterol (mmol/L) Group B 1.24 ±0.30 15months 1.39 ±0.77 27months Glucose (mmol/L) Group B 4.75 ±0.63 15months 4.40 ±0.39 27months Insulin (pmol/L) Group B 96.2 ±48.0 15months 81.8 ±30.2 27months
Control (s)	Weight 90.6 ±9.4 women;baseline 89.4 ±10.4 women;3months 101.7 ±12.3 men;baseline 100.5 ±13.0 men;3 months Waist hip ratio 0.86 ±0.15 women;baseline 0.84 ±0.13 women;3 months 0.95 ±0.09 men;baseline 0.93 ±0.11 men;3 months Systolic BP 141 ±16 women;baseline 142 ±16 women;3 months 136 ±15 men;baseline 134 ±14 men;3 months Diastolic BP 84 □8 women;baseline 82 □6 women;3 months 82 □8 men;baseline 80 ±4 men;3 months Triacylglycerol 1.96 ±1.10 women;baseline 1.93 ±1.10 women;3 months 2.92 ±2.03 men;baseline 3.16 ±2.50 men;3 months Chloestrol 5.97 ±1.00 women;baseline 5.78 ±1.01 women;3 months 6.17 ±0.61 men;baseline 6.12 ±0.97men;3 months HDL 1.33 ±0.34 women;baseline 1.30 ±0.30 women;3 months 1.02 ±0.15 men;baseline 0.96 ±0.16 men;3 months Blood glucose 5.05 ±0.78 women;baseline 5.08 ±0.77 women;3 months 5.01 ±1.05 men;baseline 5.06 ±0.88 men;3 months Insulin 129.5 ±45.8 women;baseline 128.6 ±59.7 women;3 months 172.3 ±60.3 men;baseline 171.6

	±65.9 men;3 months Phase 1 Body weight (kg) Group A 92.7 ±10.8 baseline 91.4 ±11.6 3months Waist-to-hip ratio Group A 0.90 ±0.10 baseline 0.86 ±0.21 3months SBP (mm Hg) Group A 140 ±14 baseline 141 ±16 3months DBP (mm Hg) Group A 83 □6 baseline 82 □5 3months Triacylglycerol (mmol/L) Group A 2.13 ±1.34 baseline 2.15 ±1.50 3months Cholesterol (mmol/L) Group A 6.01 ±0.94 baseline 5.84 ±1.00 3months HDL cholesterol (mmol/L) Group A 1.27 ±0.33 baseline 1.24 ±0.31 3 months Glucose (mmol/L) Group A 5.05 ±0.85 baseline 5.07 ±0.79 3 months Insulin (pmol/L) Group A 134.6 ±50.4 baseline 139.1 ±63.2 3months Phase 2 Body weight (kg) Group A 87.5 ±12.1 15months 85.0 ±11.8 27months Waist-to-hip ratio Group A 0.85 ±0.24 15 months 0.84 ±0.18 27months SBP (mm Hg) Group A 135 ±12 15months 138 ±13 27months DBP (mm Hg)

Appendix 29: Data extraction sheet; Ditschuneit 1999

	Group A 78 □5 15months 80 ±6 27months Triacylglycerol (mmol/L) Group A 1.65 ±0.53 15months 1.77 ±0.62 27months Cholesterol (mmol/L) Group A 5.45 ±0.93 15months 5.69 ±0.60 27months HDL cholesterol (mmol/L) Group A 1.24 ±0.26 15months 1.18 ±0.17 27months Glucose (mmol/L) Group A 4.55 ±0.40 15months 4.52 ±0.42 27months Insulin (pmol/L) Group A 93.1 ±28.4 15months 98.8 ±30.0 27months
Primary endpoint(s)	Authors do not report this
Secondary endpoint(s)	Authors do not report this
Other endpoint(s)	
Effect size	The study favoured group B (meal replacement). Group B lost 11.3 ± 6.8% vs 5.9 ± 5.0% (as a percentage of initial body weight, (P < 0.0001). During phase 1, mean weight loss in group B (n = 50) was 7.1 ± 3.5 kg, with significant reductions in plasma triacylglycerol, glucose, and insulin concentrations (P < 0.0001). Group A patients (n = 50) lost an average of 1.3 ± 2.2 kg with no significant improvements in these biomarkers. During phase 2, both groups lost on average an additional 0.07% of their initial body weight every month (P < 0.01). During the 27-mo study, both groups experienced significant reductions in systolic blood pressure and plasma concentrations of triacylglycerol, glucose, and insulin (P < 0.01).

Adverse events	Ditschuneit 1999

Appendix 29: Data extraction sheet; Ditschuneit 1999

All adverse events	Patient complaints included headache (n = 10), loss of hair (n = 4), abdominal discomfort (diarrhoea, gas, and constipation; n = 7), back pain (n = 3), depressed mood (n = 2), cold intolerance (n = 2), and influenza syndrome (n = 32). The paper states that these were not due to the intervention; headache and abdominal discomfort might be due to using slim fast in my opinion.

Appendix 30: Data extraction sheet; Djuric 2002

Bibliographic Details	
Study ID	Djuric 2002
Author (first)	Djuric Z, DiLaura NM, Jenkins I, Darga L, Jen CK, Mood D, Bradley E, Hryniuk WM.
Journal	Obesity Research
Year	2002
Volume	10
Pages	657-655
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	Zora Djuric djuricz@karmanos.org

Character of included studies	
Methods	Randomised pilot study
Participants	Exclusion criteria Opposite of the below Inclusion criteria Eligible subjects were ages 18 to 70 years. They had stage I or II breast cancer that was diagnosed within the past 4 years and were free of any recurrence as confirmed by a physician. Chemotherapy or radiation therapy was to have been completed at least 3 months previously with the exception of tamoxifen. Recruitment sources were direct mail to "Race for the Cure" participants, press releases, and brochures at breast clinics.
Interventions	Number of study centres: Authors do not report this. 4 different arms, does not specifically state where the interventions were held Country/location: US Setting: Authors do not report this. 4 different arms, does not specifically state where the interventions were held Treatment before study: Authors do not report this. Titration period: Authors do not report this.
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Authors do not report what these are. However, data at 12 month follow up is available for Numbers of women achieving 10% weight loss, Energy intake (kcal/d)*, Fat intake (% of energy). Primary outcome(s) Authors do not report this.

Appendix 30: Data extraction sheet; Djuric 2002

	Secondary outcome (s) Authors do not report this. Other outcome (s)
Study details	Run-in period: Authors do not report this. Study terminated before regular end: Authors do not report this.
Publication details	Language of publication: English Commercial funding: This study was supported in part by grant RO3 CA89761 from NIH, The Weight Watchers Group, Inc, Farmington Hills, Michigan, and the Ford Motor Company Fund. Non-commercial funding: Authors do not report this. Publication status (peer review journal): yes Publication status (journal supplement): Authors do not report this. Publication status (abstract): Authors do not report this.
Stated aim for study	Quote “The objective was to develop effective weight loss methods for women who have had breast cancer, because obesity may result in an adverse prognosis”
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	High Authors do not report how they were randomised to each of the four arms
Allocation concealment (selection bias)	High Authors do not report this.
Blinding (performance & detection bias)	High Authors do not report this.
Blinding of participants and personnel (performance bias)	High Authors do not report this.
Blinding of outcome assessment (detection bias)	High Authors do not report this.
Incomplete outcome data (attrition bias)	High Nine of the 48 women did not complete 12 months of participation. Two were dropped for noncompliance after 3 and 6 months, respectively. Seven women withdrew from the study, and all but two did so before 3 months. After 12 months,

Appendix 30: Data extraction sheet; Djuric 2002

	subjects assigned to any intervention arm were given the option of continuing with the program.
Selective reporting (reporting bias)	Authors do not report this.
Other bias	
Comments	It does not state whether the participants in the weight watchers arm and the comprehensive arm mixes (e.g. did they both attend the weight watchers meetings at the same time). There could be contamination of data, if these two arms met at the same time and the comprehensive arm discussed what they were doing with the weight watchers only arm.

Overview of study populations	Djuric 2002
Number invited	Authors do not report this.
Number screened	Authors do not report this. 48 women too part, there was no screening, just to meet the criteria set out.
Number randomised	Authors do not report this, or how many were randomised to each arm, it can only be assumed that 12 were randomised to each arm, given equal distribution.
(n) ITT Intervention Control Total	None reported
Number finishing study	Nine of the 48 women did not complete 12 months of participation. Two were dropped for noncompliance after 3 and 6 months, respectively. Seven women withdrew from the study, and all but two did so before 3 months. Reasons for withdrawal were medical problems (n = 1), too busy (n = 2), emotional distress (n= 3), and lost interest (n =1).
(%) of randomised patients finishing study	81.25%

Description of interventions	Djuric 2002
Intervention(s) [route, frequency, total dose/day]	Weight watchers arm For the WW arm, women were encouraged to attend WW meetings but received no other dietary or exercise

	instruction. These meetings were conveniently available throughout the Detroit area at various times during the day. Coupons for weekly attendance were provided free of charge. The “weigh-in” data card from the WW meetings was faxed or mailed to the dietician as proof of attendance, and this also provided additional data to assess weight-loss patterns and attendance. The WW program is designed for weekly attendance. Individualized Arm Contacts by the dietician were scheduled to be weekly for the first 3 months, biweekly for months 3 to 6, and monthly thereafter. Women were accommodated if they needed a greater or lesser frequency of contacts at any given time. They were also free to call the dietician, and some women enjoyed sharing their successes as they occurred. Apart from the quarterly data collection visits, all of the individual contacts were by telephone appointment. A monthly group meeting was held during the lunch hour, and women were encouraged, but not required, to attend. A monthly packet of written information was prepared on various weight-loss topics (environmental control, serving-size control, exercise, motivation, goal setting, holiday, eating, seasonal foods) and either presented to the women at the monthly meeting or mailed to their homes. One-on-one counselling was provided regarding diet and exercise by a registered dietician. Comprehensive Arm For the comprehensive arm, subjects received the individualized counselling described above and were asked to attend weekly WW meetings using free coupons. Because the subjects had group meetings with WW, and it was felt that adding the dietician-led monthly group might be an overly burdensome time commitment, the monthly meeting was omitted. The WW program has dietary guidelines that coincide well with cancer-prevention guidelines and with the dietary-exchange goals that were presented to the participants and this was explained in detail. The women learned how the “points” system of WW, which takes into account energy, fat, and fibre contents of foods, coincides well with the food-group exchanges that were assigned for each individualized diet plan. It was requested that exercise and dietary logs be kept daily.

Appendix 30: Data extraction sheet; Djuric 2002

Control(s) [route, frequency, total dose/day]	Subjects randomized to the control arm received the National Cancer Institute's "Action Guide to Healthy Eating" and the "Food Guide Pyramid" pamphlets, but they received no other dietary or exercise instructions or help. They met with the dietician at baseline, 3, 6, and 12 months for the required assessments. Controls were allowed to follow a weight-reduction diet on their own if desired.

Baseline characteristics	Djuric 2002
Number of intervention participants Number of control participants	Authors do not report this. all reported as one
Participating population	All females aged 18 to 70 years. They had stage I or II breast cancer that was diagnosed within the past 4 years and were free of any recurrence as confirmed by a physician. Chemotherapy or radiation therapy was to have been completed at least 3 months previously with the exception of tamoxifen
Sex [female %]	100
Age [mean years (SD)]	51.7 ± 8.4 (range, 36 to 70)
HbA1c [mean % (SD)]	Authors do not report this.
BMI [mean kg/m2 (SD)]	35.5 ± 3.9
Duration of disease [mean years (SD)]	Authors do not report this.
Ethnic groups [%]	12 (25%) 35 (73%) One study subject was Native American.
Duration of intervention [mean ... (SD)]	3 months
Duration of follow-up [mean ... (SD)]	6 months, 9 months, 12 months
Co-medications	Three women were taking estrogen replacement therapy, and of those, one was taking both tamoxifen and hormone replacement therapy.

Appendix 30: Data extraction sheet; Djuric 2002

	Three were taking diabetes medication (6%)
Co-interventions	
Co-morbidities	They had stage I or II breast cancer that was diagnosed within the past 4 years and were free of any recurrence as confirmed by a physician. Chemotherapy or radiation therapy was to have been completed at least 3 months previously with the exception of tamoxifen. 4 were smokers (8%) 19 had arthritis (40%)

Matrix of study endpoints	Djuric 2002
Intervention(s)	Weight change after 12 months -2.6 ± 5.9 kg in the Weight Watchers group, -8.0 ±5.5 kg in the individualized group, and -9.4 ± 8.6 kg in the comprehensive group that used both individualized counselling and Weight Watchers Comprehensive arm Weight loss was most rapid in the comprehensive arm, with mean weight losses of 7.4, 9.3, and 9.4 kg at 3, 6, and 12 months, respectively individualized counselling group All women in this arm exhibited weight loss at 6 months, ranging from 1.4 to 17.7 kg. After 6 months, six of nine women continued to lose weight, whereas three women regained 30% to 39% of their lost weight. At 12 months, the range of weight loss from baseline was 3.2 to 20.9 kg, indicating a loss in every woman who completed 12 months on

	the individualized arm. Weight watchers only Weight change at 6 months ranged from a loss of 14.5 kg to a gain of 10 kg, and six of nine women lost %1 kg. The weight change from baseline to 12 months ranged from a loss of 11.4 kg to a gain of 4.8 kg, and five of eight women lost %1 kg, indicating that some women can benefit from a WW-only approach. 12 Months Numbers of women achieving 10% weight loss Control 0% Weight Watchers 25% Individualized 22% Comprehensive 60%
Control (s)	Weight change after 12 months 0.85 ± 6.0 kg in the control group 12 months, mean body weight increased by 0.85 kg 12 Months Numbers of women achieving 10% weight loss Control 0%
Primary endpoint(s)	Authors do not report this. Does not specifically state what the primary end point was, though it does state The main goal of the interventions tested in this study was weight loss
Secondary endpoint(s)	Authors do not report this.
Other endpoint(s)	
Effect size	Data indicated that the most successful (at 12 months of intervention) was weight watchers combined with counselling -9.4 ±8.6 kg the individualised group -8.0 ± 5.5kg. Weight loss relative to control was statistically significant in the comprehensive group 3, 6, and 12 months after randomization, whereas weight loss in the individualized group was significant only at 12 months. Weight loss of 10% or more of initial body weight was observed

Appendix 30: Data extraction sheet; Djuric 2002

	in 6 of 10 women in the comprehensive group at 12 months.

Adverse events	Djuric 2002
All adverse events	Authors do not report this

Appendix 31: Data extraction sheet; Gold 2007

Bibliographic Details	
Study ID	Gold 2007
Author (first)	Gold BC, Burke S, Pintauro S, Buzzell P, Harvey-Berino J.
Journal	Obesity
Year	2007
Volume	15(1)
Pages	155-164
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	Jean Harvey-Berino, Department of Nutrition and Food Sciences, University of Vermont, 250 Carrigan Wing, 109 Carrigan Drive, Burlington, VT 05405. E-mail: jharvey@uvm.edu

Character of included studies	
Methods	Randomised controlled clinical trial (RCT)
Participants	Exclusion criteria Opposite of the below Inclusion criteria 18 years+ BMI >25 and≤ 39.9 kg/m2 Regular access to a computer (not more than 3 years old with CD-ROM drive, Internet connection, at least 64 Megabytes of RAM, 350 MHz processor speed, and Windows 98 or higher as a computer operating system) Ineligible if they planned to move from the area or get pregnant within the next 12 months, had a history of major medical or psychiatric problems, smoked or had been a non-smoker for less than 1 year, took medications known to affect weight, were unable to participate in a mild to moderate exercise program, or were unable to regularly attend

Appendix 31: Data extraction sheet; Gold 2007

	weekly meetings.
Interventions	Number of study centres: Authors do not report this. This was an online study. Country/location: US Setting; Authors do not report this. This was an online study. Treatment before study: Authors do not report this. Titration period n/a
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Primary outcome(s) The primary purpose of this study was to compare weight losses achieved through a behavioral on-line intervention vs. a commercial self-help website. A second aim was to evaluate the use of web components and their relationship to weight loss between groups and within groups to identify which web components correlated with weight loss. Secondary outcome (s) Other outcome (s)
Study details	Run-in period: Authors do not report this. Study terminated before regular end: Authors do not report this.
Publication details	Language of publication: English Commercial funding: Authors do not report this. Non-commercial funding; This study was supported by U.S. Department of Agriculture Hatch Act Funds (Grant VT-NS-00,904) Publication status (peer review journal): yes Publication status (journal supplement): Authors do not report this. Publication status (abstract): Authors do not report this.
Stated aim for study	Quote “This study aimed to investigate the effectiveness of a structured behavioural weight loss website (VTrim) vs. a commercial weight loss website (eDiets.com).”
Notes	

Appendix 31: Data extraction sheet; Gold 2007

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	High Authors do not report this.
Allocation concealment (selection bias)	High Authors do not report this.
Blinding (performance & detection bias)	High Authors do not report this.
Blinding of participants and personnel (performance bias)	High Authors do not report this. Staff would have known which website the participant was to be directed too
Blinding of outcome assessment (detection bias)	High Authors do not report this. It does not state if the same researchers who told participants what website they were to use, were the same for carrying out the measures. This could have impacted on the results
Incomplete outcome data (attrition bias)	Low 14 were lost from ediets (n=62-14) 22 were lost from v trim (n=62-22) 48 included in completers analysis e diets 40 included in completers analysis vtrim
Selective reporting (reporting bias)	Authors do not report this.
Other bias	
Comments	

Overview of study populations	Gold 2007
Number invited	595
(n) screened Intervention Control Total	595
(n) randomised Intervention Control Total	185 62 62 61 allocated to an arm not related to the study

Appendix 31: Data extraction sheet; Gold 2007

(n) ITT Intervention Control Total	An intention-to-treat analysis examined weight change using baseline carried forward.
Number finishing study	48 e diets 40 v trim
(%) of randomised patients finishing study	77.4% e diets 64.5% v trim

Description of interventions	Gold 2007
Intervention(s) [route, frequency, total dose/day]	The eDiets.com program provided a calorie-controlled meal plan tailored to individual preferences. Participants were encouraged to follow their meal plan ("my diet"); recipe instructions and menu-specific grocery lists were offered as aids. The program encouraged exercise ("my fitness"). Participants tailored their program on the basis of their exercise abilities and their likes and dislikes. An on-line exercise journal was provided to track weekly progress. There were check-in points interactively but no direct accountability to a therapist. Although the website did not include a structured behavioural curriculum (lessons, activities), fundamental behavioural weight loss concepts were present. "Support central," monitored by experts and peers, offered opportunities for social support.
Control(s) [route, frequency, total dose/day]	Subjects randomized to VTrim participated in a 6-month on-line therapist-led weight loss program and a subsequent 6-month on-line weight maintenance program. A unique username and password were established for each subject so that web use could be tracked throughout the study. 6-month Weight Loss Phase. The weight loss phase focused on the modification of eating and exercise habits through the use of behavioural strategies and self-management skills. The program layout was similar to a workbook in that specific behaviour modification lessons, such as "Eating in Social Situations," were featured each week, and the leader focused on the topic during the weekly on-line meeting. The instruction and support were delivered solely online. Participants self-reported their weight each week online, and they participated in hour-long weekly on-line chats, led by a trained therapist.

Baseline characteristics	Gold 2007
Number of intervention participants Number of control participants	62 62
Participating population	Participants aged 18 years +, BMI >25 and≤ 39.9 kg/m2, and with access to a pc less than 3 years of age.

Appendix 31: Data extraction sheet; Gold 2007

Sex [female %]	48 (77) v trim 53 (86) e diets
Age [mean years (SD)]	46.5 (10.7) v trim 48.9 (9.9) e diets
HbA1c [mean % (SD)]	Authors do not report this.
BMI [mean kg/m2 (SD)]	32.3 (3.9) vtrim 32.5 (4.2) ediets
Duration of disease [mean years (SD)]	Authors do not report this.
Ethnic groups [%]	61 (98) vtrim 61 (98) ediets
Duration of intervention [mean ... (SD)]	0-6 months
Duration of follow-up [mean ... (SD)]	6-12 months
Co-medications	Authors do not report this.
Co-interventions	Authors do not report this.
Co-morbidities	Authors do not report this.

Matrix of study endpoints	Gold 2007
Intervention(s)	4.1 ±6.2 kg e diet 6 months weight loss 3.4 ±5.8 e diets weight maintained at 12 months
Control (s)	7.8 ±7.5 v trim weight maintained at 12 months 8.3 ± 7.9 kg v trim 6 month weight loss
Primary endpoint(s)	8.3 ± 7.9 kg v trim 6 month weight loss 4.1 ±6.2 kg e diet 6 months weight loss 7.8 ±7.5 v trim weight maintained at 12 months 3.4 ±5.8 e diets weight maintained at 12 months 65% of participants in the VTrim group lost 5% or more of initial body weight, compared with 37.5% of participants in the eDiets.com group at 12 months
Secondary endpoint(s)	
Other endpoint(s)	
Effect size	VTrim group lost significantly more weight than the eDiets.com group at 6 months (8.3 ± 7.9 kg vs. 4.1±6.2 kg) and maintained a greater loss at 12 months (7.8 ±7.5 kg vs. 3.4 ±5.8 kg). More participants in the VTrim group maintained a 5% weight loss goal 65% vs. 37.5% at 12 months

Appendix 31: Data extraction sheet; Gold 2007

Adverse events	Gold 2007
All adverse events	Authors do not report this.

Appendix 32: Data extraction sheet; Gosselin 2001

Bibliographic Details	
Study ID	Gosselin 2001
Author (first)	Gosselin C, Cote G.
Journal	Women's Health (biomed central)
Year	2001
Volume	1:2
Pages	Not stated, 7 pages in total
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	Caroline Gosselin* - gosselin.cabanac@sympatico.ca

Character of included studies	
Methods	Controlled before and after study
Participants	Exclusion criteria Pregnant women at the time of interview and individuals who had followed the program for less than a month were excluded from the analysis. Inclusion criteria Participants had to of entered the Mincavi program at least two years prior to the study
Interventions	Number of study centres: Authors do not report this. Country/location: Quebec Setting: The study was done via the telephone (weight maintenance, and weights were adjusted according to previous studies on self-reporting) Treatment before study: Authors do not report this. Titration period: Authors do not report this.
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Does not state the exact primary or secondary outcomes, however, data was collected in relation too BMI, weight and % weight loss Primary outcome(s) Authors do not report this.

Appendix 32: Data extraction sheet; Gosselin 2001

	Secondary outcome (s) Authors do not report this. Other outcome (s)
Study details	Run-in period: Authors do not report this. Study terminated before regular end; Authors do not report this.
Publication details	Language of publication: English Commercial funding: Authors do not report this. Non-commercial funding: Authors do not report this. Does not state who the funders were, but data was obtained from the commercial weight loss company. Publication status (peer review journal); yes Publication status (journal supplement): Authors do not report this. Publication status (abstract): Authors do not report this.
Stated aim for study	Quote Authors do not report this.. However, the study reports weight maintenance in women 2 to 11 years after their participation in a popular commercial program in the province of Quebec, Canada.
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	High Authors do not report this.. It states that clients were randomly picked from the programs client list.
Allocation concealment (selection bias)	High Authors do not report this. Participants had already used the programme and were in the maintenance phase. All participants should have been the same, though some could have lost 5% of their body weight at baseline to programme end, and some could have lost 10% at baseline to the end of the programme. It does not state that any form of clustering of participants was used i.e. 5% weight loss vs 10% weight loss
Blinding (performance & detection bias)	High Data had already been collected at the various time points. However, there was only data available for 11% of the subjects. The other participants had to have their weight adjusted with a 2.9% increase, as their was self-reported over the telephone
Blinding of participants and personnel (performance bias)	High Personnel were not blind at all. Specific participants could have been picked to participant in the study. even though it states it was randomly done, there was no science behind this (i.e. participants were not inputted into a computer

Appendix 32: Data extraction sheet; Gosselin 2001

	programme and the first 291 selected were those to be contacted).
Blinding of outcome assessment (detection bias)	High Start date data was available for all participants, though only 31 participants had complete records. It does not state why data was only available for these participants. There are no statistical tests to show the data available participants vs the adjusted weight data for the other participants.
Incomplete outcome data (attrition bias)	High Attrition not as such. Participants had already completed the programme, the study was a follow up to assess weight maintenance. However, data was only available for 31 participants, the rest (260) had to have their weight adjusted (+2.9%) as it was self-reported via the telephone.
Selective reporting (reporting bias)	Authors do not report this.
Other bias	
Comments	The programme that the participants were involved in had a penalty of $7 if weight was gained when attaining the sessions; this could have had quite an impact of the results overall, and for weight maintenance. Participants could have subconsciously thought that every time they weighed themselves at home, that they would be penalised, and therefore were more strict with the diet that other commercial programmes. Within the group sessions, the numbers were very large (50-100), and would group leaders would not be able to answer all client questions. This could have impacted on weight loss, or it could have meant that weight loss should be the same with all participants as they all received the same treatment . Though others could have responded better than others in a large group case scenario, other clients could have assisted other clients to reach their weight loss goals.

Overview of study populations	Gosselin 2001
Number invited	323 were originally contacted if 90% took part in the present study. it does not state why they did not want to take part.
Number screened	291 participants participated in the present study. 323 were originally contacted if 90% took part in the present study. it does not state why they did not want to take part.
Number randomised	Authors do not report this. This was a CBA study. No randomisation
(n) ITT Intervention Control Total	Authors do not report this.
Number finishing study	291 All participants had originally took part in the Mincavi programme
(%) of randomised patients finishing study	Authors do not report this. This is a CBA.

Appendix 32: Data extraction sheet; Gosselin 2001

Description of interventions	Gosselin 2001
Intervention(s) [route, frequency, total dose/day] Control(s) [route, frequency, total dose/day]	Initially a recipe book was given ,stating the importance of three meals a day using the specific food groups. Recipes are given in the book that are cheap, readily available and focus on the specific food groups. The participant decided on how much they want to lose (it does not state if they are ever advised that they have set an unrealistic goal). Meals at 1400kcal (for women) 1800kcal (for men) are encouraged in the weight loss phase, and in the weight maintenance phase participants are to increase their intake by 50kcal. Large groups of women (50-100) attend their session every week with their food diary for feedback (it does not state what percentage of diaries are looked at each week). Topics of specific subjects are addressed each week 30-45mins, and recipe sampling takes place. Additional support from a dietician and a psychologist is available through a toll-free phone line and internet. Participating in the program involves a one-time fee of 25$ (Canadian dollars), and a 7$ fee per week during the weight loss phase. Once a participant has reached her goal weight, she is given free access to weekly sessions for as long as she maintains her goal weight. A fee of 7$ will be charged on weighing sessions if she is found to have gained weight.

Baseline characteristics	Gosselin 2001
Number of intervention participants Number of control participants	Authors do not report this. This was a CBA
Participating population	Participants had to of entered the Mincavi program at least two years prior to the study
Sex [female %]	100%
Age [mean years (SD)]	43,0 ±12,8 (all 2-11 years)
HbA1c [mean % (SD)]	Authors do not report this.
BMI [mean kg/m2 (SD)]	29,8 ±4,7 (all 2-11 years)
Duration of disease [mean years (SD)]	Authors do not report this.
Ethnic groups [%]	Authors do not report this.
Duration of intervention [mean ... (SD)]	The intervention had already taken place.
Duration of follow-up [mean ... (SD)]	11 years
Co-medications	Authors do not report this.
Co-interventions	Authors do not report this.
Co-morbidities	Authors do not report this.

Matrix of study endpoints	Gosselin 2001

Appendix 32: Data extraction sheet; Gosselin 2001

Intervention(s)	25 ±45 bmi after program (all 2-11 years) 29.5 ±5.4 bmi at follow up (all 2-11 years) 4.5 ±6.6 weight loss maintained (all 2-11 years)
Control (s)	Authors do not report this. There was not a control. It was a CBA.
Primary endpoint(s)	Authors do not report this.
Secondary endpoint(s)	Authors do not report this.
Other endpoint(s)	
Effect size	Five to eleven years after they had participated in the program 29.1% of all women maintained a weight loss of at least 5%, while 14.3% maintained a loss of at least 10%. Percentage of women who maintained at least 5% of their initial weight loss are as following; 2 years = 43.6% (n = 55), 3 years = 33.3% (n = 42), 4 years = 23.8% (n = 42), 5–6 years = 38.2% (n = 55), 7–8 years = 29.4% (n = 51), and 9–11 years; 19.6% (n= 46).

Adverse events	Gosselin 2001
All adverse events	Authors do not report this.

Appendix 33: Data extraction sheet; Heshka 2000

Bibliographic Details	
Study ID	Heshka 2000
Author (first)	Heshka S, Greenway F, Anderson JW, Atkinson RL, Hill JO, Phinney SD, Miller-Kovach K, Pi-Sunyer FX.
Journal	The American Journal of Medicine
Year	2000
Volume	109
Pages	282-287
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	Stanley Heshka, PhD, New York Obesity Research Center, St. Luke's/Roosevelt Hospital Center, 1090 Amsterdam Avenue, 14C, New York, New York 10025.

Character of included studies	
Methods	Randomised controlled clinical trial (RCT)
Participants	Exclusion criteria Those with a fasting glucose level greater than 140 mg/dL, a triglyceride level greater than 1,000 mg/dL, a serum aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, lactate dehydrogenase, gamma glutamyltransferase, or bilirubin level that was more than twice the upper limit of normal, or a serum creatinine level greater than 1.4 mg/dL were excluded, as were those using systemic or inhaled corticosteroids or lithium. We excluded persons with a history of alcohol abuse within the past year or any significant psychiatric disorder or other condition that, in the investigator's judgment, would interfere with participation in the trial. Candidates who initiated a new drug therapy within 30 days of randomization, who were in a weight-loss program, or who took prescription weight-loss or investigational medications within 90 days of randomization were also excluded. Inclusion criteria Men and women with a body mass index of 27 to 40 kg/m2, age 18 to 65 years, including those who had health problems for which weight reduction is a medically accepted therapy, were eligible. Diagnostic criteria
Interventions	Number of study centres: six

Appendix 33: Data extraction sheet; Heshka 2000

	Country/location: US Setting: Clinical research centres Treatment before study: Authors do not report this. Titration period: Authors do not report this.
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Outcome measures were changes in body weight, body mass index, waist circumference, and body fat. Changes in serum homocysteine levels were measured in a subsample of participants during the first 12 weeks. Primary outcome(s) Authors do not report this. Secondary outcome (s) Authors do not report this. Other outcome (s)
Study details	Run-in period: Authors do not report this. Study terminated before regular end: Authors do not report this.
Publication details	Language of publication: English Commercial funding: Supported by a grant from the Weight Watchers Foundation. Non-commercial funding: Authors do not report this. Publication status (peer review journal): yes Publication status (journal supplement): Authors do not report this. Publication status (abstract): Authors do not report this.
Stated aim for study	Quote “The principal objective of this 2-year trial is to compare weight loss and health benefits achieved and maintained by moderately overweight and obese men and women in a structured commercial weight-loss program with that achieved through self-help, which includes the use of books, manuals, and brief consultations with a dietitian.”
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	Low A randomization envelope prepared by the data-coordinating center was opened, and the candidate was assigned to

Appendix 33: Data extraction sheet; Heshka 2000

	the self-help or the commercial program. A blocked randomization scheme was used, such that within the overall randomization of 70 subjects per site, assignment was constrained to an equal number of self-help and commercial assignments within blocks of size 2 to 10. Block size, and assignment within each block, was determined by a random number table. A different randomization sequence was prepared for each site.
Allocation concealment (selection bias)	High Participants would have know which arm they were assigned too, based on the methods used (self-help vs commercial)
Blinding (performance & detection bias)	Low Subjects in the commercial arm were instructed not to mention their participation in a research study to other group participants or staff at the program site. However, participants were given vouchers, so the group leaders could have realised that they were not ordinary clients. It does not state whether the dietician in the self-help group knew that their new clients were involved in a research project. The dietician could have given additional advice during the 20 minute consultation
Blinding of participants and personnel (performance bias)	Low Subjects in the commercial arm were instructed not to mention their participation in a research study to other group participants or staff at the program site. However, participants were given vouchers, so the group leaders could have realised that they were not ordinary clients. It does not state whether the dietician in the self-help group knew that their new clients were involved in a research project. The dietician could have given additional advice during the 20 minute consultation
Blinding of outcome assessment (detection bias)	High Authors do not report this.
Incomplete outcome data (attrition bias)	Low Three hundred eighty-one subjects (90%) attended the week 12 visit and 347 (82%) attended the week 26 visit to the clinical research centers. The numbers of dropouts were similar in the two groups (commercial 37, self-help 40), and dropouts were not different from subjects who continued to participate, except for a small difference in age (41.5 6 1.2 years for dropouts vs 45.5 6 0.5 years for participants).
Selective reporting (reporting bias)	High Authors do not report this.
Other bias	
Comments	

Appendix 33: Data extraction sheet; Heshka 2000

Overview of study populations	Heshka 2000
Number invited	484 went through screening. Authors do not report this.
Number screened	Of the 484 candidates who went through screening, 423 (87%) were enrolled in the trial (358 women, 65 men).
Number randomised	Randomization of 70 subjects per site, assignment was constrained to an equal number of self-help and commercial assignments within blocks of size 2 to 10. Block size, and assignment within each block, was determined by a random number table. A different randomization sequence was prepared for each site. 67 to 73 subjects at each of six clinical research centres. Of the 484 candidates who went through screening, 423 (87%) were enrolled in the trial (358 women, 65 men). 211commercial 212 self-help
(n) ITT Intervention Control Total	An intention-to-treat analysis, with missing data replaced by last observation carried forward, was applied to measures of body weight and body mass index. Data were also analysed on an available-cases basis [i.e., using subjects who provided data at both week 12 and week 26, because intention-to-treat analyses may underestimate the effect of the actually administered treatment (14)]. Analysis of variance or covariance models were used to test the hypotheses of greater changes in the commercially treated subjects than in the self-help subjects. Statistical significance was set at 0.05 (two sided). The chi-squared test was used to compare proportions; if overall differences were observed, binomial tests were used within categories to compare the commercially treated and self-help groups. Unless otherwise specified, continuous results are presented as mean 6 SD. Analyses were conducted using SAS version 6.12 (SAS Institute, Inc., Cary, North Carolina) and SPSS version 8.0 (SPSS, Inc., Chicago, Illinois) statistical software.
Number finishing study	174 commercial 172 self-help
(%) of randomised patients finishing study	82.46% commercial 81.13% self help

Description of interventions	Heshka 2000
Intervention(s) [route, frequency, total dose/day]	Subjects assigned to the commercial program were given vouchers entitling them to attend Weight Watchers sessions, and the locations of publicly available Weight Watchers sites were reviewed with them. They were then left

Appendix 33: Data extraction sheet; Heshka 2000

Control(s) [route, frequency, total dose/day]	to make their own choice of meeting location and time. Subjects assigned to self-help had 20-minute consultations with a dietician at the week 0 (randomization) and week 12 visits and were given publicly available printed material orienting them to dietary principles and exercise guidelines for weight loss (10,11). Other resources, such as public library materials, web sites on the Internet, and telephone numbers of health promotion organizations offering free weight-control information, were drawn to their attention.

Baseline characteristics	Heshka 2000
Number of intervention participants Number of control participants	211 212
Participating population	Men and women with a body mass index of 27 to 40 kg/m2, age 18 to 65 years, including those who had health problems for which weight reduction is a medically accepted therapy, were eligible.
Sex [female %]	Does not state the split between groups. 84.6% were women overall
Age [mean years (SD)]	45 ±10 commercial 44 ± 10 self-help
HbA1c [mean % (SD)]	Authors do not report this.
BMI [mean kg/m2 (SD)]	33.8 ± 3.4 commercial 33.6 ± 3.7 self-help
Duration of disease [mean years (SD)]	Authors do not report this.
Ethnic groups [%]	74% white, 13% African-American, 8% Hispanic, 1% Asian, and 4% other.
Duration of intervention [mean ... (SD)]	26 weeks
Duration of follow-up [mean ... (SD)]	Authors do not report this. See other heshka study
Co-medications	Authors do not report this.
Co-interventions	Smokers 21 (10) commercial Smokers 19 (9) self-help
Co-morbidities	Authors do not report this.

Matrix of study endpoints	Heshka 2000
Intervention(s)	Commercial Weight loss

Appendix 33: Data extraction sheet; Heshka 2000

	-4.8 ± 5.6kg Bmi -1.7±1.9 Waist -4.3 ± 10.5 Fat mass -3.8 ± 7.0 serum homocysteine -0.5 ± 1.3
Control (s)	Weight loss -1.4±4.7 kg Bmi -0.5±1.6 Waist -0.7 ± 12.7 Fat mass -1.5 ± 7.6 kg, serum homocysteine 0.9 6 1.8 mM,
Primary endpoint(s)	Authors do not report this.
Secondary endpoint(s)	Authors do not report this.
Other endpoint(s)	
Effect size	After 26 weeks, subjects in the commercial program, as compared with those in the self-help program, had greater decreases in body weight [mean (± SD) 24.8 6 5.6 vs 21.464.7 kg] and body mass index (21.761.9 vs20.561.6 kg/m2, both P ,0.001) in intention-to-treat analyses.

Adverse events	Heshka 2000

Appendix 33: Data extraction sheet; Heshka 2000

All adverse events	Authors do not report this.

Appendix 34: Data extraction sheet; Heshka 2003

Bibliographic Details	
Study ID	Heshka 2003
Author (first)	Heshka S, Anderson JW, Atkinson RL, Greenway FL, Hill JO, Phinney SD, Kolotkin RL, Miller-Kovach K, Pi-Sunyer FX.
Journal	JAMA
Year	2003
Volume	289
Pages	1792-1798
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	Stanley Heshka sh311@columbia.edu

Character of included studies	
Methods	Randomised controlled clinical trial (RCT)
Participants	Exclusion criteria Fasting glucose higher than 140 mg/dL (7.8 mmol/L), triglycerides higher than 1000 mg/dL (11.3 mmol/L), liver function test results (aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, lactate dehydrogenase, -glutamyltransferase, and bilirubin) more than 2 times the upper normal limit, and serum creatinine higher than 1.4 mg/dL (124 µmol/L). Also excluded were potential participants using systemic or inhaled corticosteroids or lithium, having a history of alcohol abuse within the past year, or having a history or presence of a significant psychiatric disorder or any condition that, in the investigator's judgment, would interfere with participation in the trial. Potential participants who initiated a new drug therapy within 30 days of randomization, who were already participating in a weight loss program, or who took prescription weight loss or investigational medications within 90 days of randomization were also excluded. Inclusion criteria

Appendix 34: Data extraction sheet; Heshka 2003

	Men and women with a BMI of 27 to 40, aged 18 to 65 years, including persons with health problems for which weight reduction is a medically accepted therapy, were eligible for the study. Diagnostic criteria
Interventions	Number of study centres: 6 US clinical centers Country/location :US Setting: Authors do not report this. Research centres (doesn't specifically state where the self-help or commercial interventions were held, i.e. community centre etc) Treatment before study: Authors do not report this. Titration period: Authors do not report this.
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Primary outcome(s) Weight change Secondary outcome (s) Waist circumference, body mass index, blood pressure, serum lipids, glucose, and insulin levels. Other outcome (s)
Study details	Run-in period: Authors do not report this. Study terminated before regular end: Authors do not report this.
Publication details	Language of publication: English Commercial funding: This study was supported by a grant from Weight Watchers International (Woodbury, NY) to the New York Obesity Research Center at St Luke's/ Roosevelt Hospital. Non-commercial funding: Authors do not report this. Publication status (peer review journal): Yes Publication status (journal supplement): Authors do not report this. Publication status (abstract): Authors do not report this.
Stated aim for study	Quote "To compare weight loss and health benefits achieved and maintained through self-help weight loss vs with a structured commercial program."
Notes	

Risk of bias	unclear / low / high risk

Appendix 34: Data extraction sheet; Heshka 2003

Random sequence generation (selection bias)	Low randomization envelope prepared by the data coordinating center was opened and the participant was assigned to self-help or the commercial program
Allocation concealment (selection bias)	High Authors do not report this.
Blinding (performance & detection bias)	Low Participants and investigators at each site were blind to the assignment condition until the envelope was opened.
Blinding of participants and personnel (performance bias)	Low Participants and investigators at each site were blind to the assignment condition until the envelope was opened.
Blinding of outcome assessment (detection bias)	High Authors do not report this.
Incomplete outcome data (attrition bias)	High Authors do not report this.
Selective reporting (reporting bias)	High Authors do not report this.
Other bias	
Comments	

Overview of study populations	Heshka 2003
Number invited	Authors do not report how many were invited, only that 484 assessed for eligibility
Number screened	484 assessed for eligibility
Number randomised	423 randomised 211 intervention group (commercial) 212 (self-help)
(n) ITT Intervention Control Total	Three analyses were performed on weight change and related outcome variables: an intent-to-treat (ITT) analysis including all randomized participants (missing values were imputed by last-observation-carried-forward or linear interpolation and participants who made no follow-up visits were assumed to remain at baseline value); a modified ITT analysis including all participants who made at least 1 clinic visit after randomization; and a completers analysis using

Appendix 34: Data extraction sheet; Heshka 2003

	only participants who completed the study.
Number finishing study	Commercial Follow-up Measurement Visits 198 at Week 12 175 at Week 26 176 at Week 52 154 at Week 78 Self-help 183 at Week 12 172 at Week 26 170 at Week 52 156 at Week 78 Commercial 61 Lost to Follow-up or Withdrew Consent Self-help 53 Lost to Follow-up or Withdrew Consent Commercial 150 Completed Week 104 Self-help 159 Completed Week 104 Commercial 211 Included in Intent-to- Treat Analysis 198 Included in Modified Intent-to-Treat Analysis 148 Included in Completers Analysis 2 Excluded From Completers Analysis (Lymphoma) Self-help 212 Included in Intent to- Treat Analysis 188 Included in Modified Intent-to-Treat Analysis 159 Included in Completers Analysis

Appendix 34: Data extraction sheet; Heshka 2003

(%) of randomised patients finishing study	After two years 71% of commercial participants had completed the study, and 75% of self-help participants had completed the study

Description of interventions	Heshka 2003
Intervention(s) [route, frequency, total dose/day]	Participants assigned to the commercial program were given vouchers entitling them to attendance at sessions of Weight Watchers, and the locations of available sites of this commercial program were reviewed with them. The vouchers enabled participants to attend sessions at no cost and, during the study period. Weekly group meetings of approximately an hour's duration are led by successful program graduates who act as role models and provide written educational materials, a weekly weigh-in, and social support.
Control(s) [route, frequency, total dose/day]	Participants assigned to the self-help group received 20-minute consultations with a dietitian at the week 0 (baseline) and week 12 visits and were given publicly available printed material orienting them to dietary principles and exercise guidelines for safe weight loss.16,17 Other resources such as public library materials, Web sites, and telephone numbers of health promotion organizations offering free weight control information were drawn to their attention.

Baseline characteristics	Heshka 2003
Number of intervention participants Number of control participants	211 212
Participating population	Overweight and obese men (n=65) and women (n=358) (body mass index, 27-40) aged 18 to 65 years.
Sex [female %]	82% commercial 87% self-help
Age [mean years (SD)]	46 (10) commercial 44(10) self-help
HbA1c [mean % (SD)]	Authors do not report this
BMI [mean kg/m2 (SD)]	33.8 (3.4) commercial 33.6 (3.7) self-help
Duration of disease [mean years (SD)]	Authors do not report this

Appendix 34: Data extraction sheet; Heshka 2003

Ethnic groups [%]	Authors do not report this
Duration of intervention [mean ... (SD)]	26 weeks
Duration of follow-up [mean ... (SD)]	52, 78, and 104 weeks follow up
Co-medications	Authors do not report this
Co-interventions	Authors do not report this
Co-morbidities	Authors do not report this

Matrix of study endpoints	Heshka 2003
Intervention(s)	See below
Control (s)	See below
Primary endpoint(s)	Commercial 1year weight change (–4.3 [6.1] kg, 2 year weight change (–2.9 [6.5] kg Self-help 1 year weight change –1.3 [6.1] kg 2 year weight change –0.2 [6.5] kg
Secondary endpoint(s)	Commercial Waist change year 1 –4.1 (0.6) Self-help Waist change year 1 –1.6 (0.6) Commercial Waist change year 2 –2.4 (0.6) Self help Waist change year 2 –0.6 (0.6) Commercial 1year Blood pressure, mm Hg Systolic –0.6 (0.9) Self-help 1 year Blood pressure, mm Hg Systolic 0.2 (0.8) Commercial systolic year 2 –2.2 (1.1)*

Appendix 34: Data extraction sheet; Heshka 2003

	Self-help systolic year 2 –2.4 (1.0)* Commercial 1 year Diastolic –0.4 (0.6) Self-help 1 year diastolic 1.4 (0.6)* Commercial diastolic year 2 –0.6 (0.7) Self-help diastolic year 2 0 (0.6) Commercial year 1 Glucose, mg/dL 3.5 (0.6)* Self year year 1 Glucose, mg/dL 3.6 (0.6)* Commercial year 2 Glucose, mg/dL 5.2 (0.7)* Self-help year 2 Glucose, mg/dL 4.6 (0.7)* Commercial Insulin, IU/L year 1 –2.0 (0.5)* Self help Insulin, IU/L year 1 –0.3 (0.5) Commercial Insulin, IU/L year 2 0.6 (0.6) Self-help Commercial Insulin, IU/L year 2 2.3 (0.6)* Cholesterol, mg/dL Total year 1commercial l –8.7 (1.7)* Cholesterol, mg/dL Total year 1self-help –9.5 (1.7)* Cholesterol, mg/dL Total year 2commercial –10.4 (2.0)* Cholesterol, mg/dL Total year 2 self-help –11.3 (1.9)* HDL commercial year 1 2.0 (0.7)*

Appendix 34: Data extraction sheet; Heshka 2003

	HDL self-help year 1 0.8 (0.7) HDL commercial year 2 0.5 (0.8) HDL self-help year 2 0.6 (0.8) HDL/total cholesterol ratio commercial year 1 0.02 (0.003)*self-help year 1 HDL/total cholesterol ratio 0.020 (0.003)* HDL/total cholesterol ratio commercial year 2 0.02 (0.003)* HDL/total cholesterol ratio self-help year 2 0.02 (0.003)* Triglycerides, mg/dL commercial year 1 –7.8 (3.7)* Triglycerides, mg/dL self-help year 1 1.5 (3.8) Triglycerides, mg/dL commercial year 2 –0.3 (4.0) Triglycerides, mg/dL self-help year 2 –0.1 (3.9)
Other endpoint(s)	
Effect size	In ITT analysis, mean(SD) weight loss of participants in the commercial group was greater than in the self-help group at 1 year (–4.3 [6.1] kg vs –1.3 [6.1] kg) and at 2 years (–2.9 [6.5] kg vs –0.2 [6.5] kg). Body mass index also decreased more in the commercial group –1.6 (0.2) vs –0.5 (0.2) self-help

Adverse events	Heshka 2003

Appendix 34: Data extraction sheet; Heshka 2003

All adverse events	2 Lymphoma participants excluded from the study (possibly not due to the study)

Appendix 35: Data extraction sheet; Lowe 2001

Bibliographic Details	
Study ID	Lowe 2001
Author (first)	Lowe MR, Miller-Kovach K, Phelan S.
Journal	International journal of obesity
Year	2001
Volume	25
Pages	325-331
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	MR Lowe, Department of Clinical and Health Psychology, Mail Stop 626, MCP Hahnemann University, Philadelphia, PA 19102, USA. E-mail: lowe@drexel.edu

Character of included studies	
Methods	Controlled before and after
Participants	Exclusion criteria Over 61 000 were ineligible due to incorrect telephone or zip code numbers Inclusion criteria All participants had formerly been Weight Watchers members and reached goal weight while in the program.
Interventions	Number of study centres: Authors do not report this. This study was after participants had used Weight Watchers Country/location: US Setting: Authors do not report this. This study was after participants had used Weight Watchers Treatment before study: Authors do not report this. Titration period: Authors do not report this.
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Maintained a loss of 5% or more Maintained a loss of 10% or more Primary outcome(s): Authors do not report this. Secondary outcome (s): Authors do not report this. Other outcome (s)
Study details	Run-in period: Authors do not report this.

Appendix 35: Data extraction sheet; Lowe 2001

	Study terminated before regular end: Authors do not report this.
Publication details	Language of publication: English Commercial funding: Authors do not report this. Non-commercial funding: Authors do not report this. Publication status (peer review journal): yes Publication status (journal supplement): Authors do not report this. Publication status (abstract): Authors do not report this.
Stated aim for study	Quote “To determine weight loss maintenance among participants in a commercial weight loss program (Weight Watchers) who had reached their goal weights 1 - 5 y previously. “
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	Low Not randomised, study had already been carried out
Allocation concealment (selection bias)	Low Authors do not report this.
Blinding (performance & detection bias)	Low Authors do not report this.
Blinding of participants and personnel (performance bias)	Low Authors do not report this.
Blinding of outcome assessment (detection bias)	Low Authors do not report this.
Incomplete outcome data (attrition bias)	Low Authors do not report this.
Selective reporting (reporting bias)	Low Authors do not report this.
Other bias	Self-report was used. However, a second sample (oversample) was used using a stratification procedure to adjest for self-reporting. Money was given as an incentive to take part in an additional survey
Comments	

Overview of study populations	Lowe 2001
Number invited	First sample was 189 780 participants, 61000 were not eligible. 1002 randomly selected lifetime members.

Appendix 35: Data extraction sheet; Lowe 2001

(number screened	First sample was 189 780 participants, 61000 were not eligible. 1002 randomly selected lifetime members.
Number randomised	Not applicable
(n) ITT Intervention Control Total	Not applicable
Number finishing study	Not applicable
(%) of randomised patients finishing study	Not applicable

Description of interventions	Lowe 2001
Intervention(s) [route, frequency, total dose/day]	The Weight Watchers program includes a food plan, an activity plan, and a behaviour modification plan focused primarily on cognitive restructuring. The food plan is a nutritionally balanced, moderate deficit diet designed to produce a weight loss of up to 0.9 kg per week. The activity plan involves the recommendation to accumulate 30 min of physical activity on most (preferably all) days of the week. Weekly group meetings, led by successful program graduates who act as role models, provide written educational materials, a weekly weigh-in, and social support. Goals weights are determined by the individual member and must be at least 5 lb less than the member's joining weight. Members are encouraged to select a weight goal within the BMI range of 20 ± 25. Because lifetime status comes with free services and most members have a substantial amount to lose, the vast majority choose a weight goal equivalent to a BMI of 25. In addition, Weight Watchers confers lifetime member eligibility to members who provide a weight goal from a qualified health professional who has stated that the prescribed weight (even if above a BMI of 25) is deemed healthy based on an individual assessment of the member.
Control(s) [route, frequency, total dose/day]	

Baseline characteristics	Lowe 2001
Number of intervention participants Number of control participants	1002 in total
Participating population	All participants had formerly been Weight Watchers members and reached goal weight while in the program.
Sex [female %]	96% in national sample 95.0% in oversample

Appendix 35: Data extraction sheet; Lowe 2001

Age [mean years (SD)]	Not in mean but in age groups 18-24 0.7% national sample 0.4% oversample 25-29 3.0% national sample 2.7% oversample 30-34 8.7% national sample 10.9% oversample 35 - 44 31.9% national sample 32.2% oversample 45 - 54 31.5% national sample 30.2% oversample 55 -64 15.7% national sample 14.0% oversample 65 and over 8.6% national sample 9.7% oversample
HbA1c [mean % (SD)]	Authors do not report this
BMI [mean kg/m2 (SD)]	Authors do not report this
Duration of disease [mean years (SD)]	Authors do not report this
Ethnic groups [%]	Authors do not report this
Duration of intervention [mean ... (SD)]	Authors do not report this
Duration of follow-up [mean ... (SD)]	1-5 years follow up
Co-medications	Authors do not report this
Co-interventions	Authors do not report this
Co-morbidities	Authors do not report this

Matrix of study endpoints	Lowe 2001
Intervention(s)	1992 (50) 70.2±11.5 self reported weight 72.3±12.2 measured weight 0.03 Discrepancy between reported and actual weight 1993 (50) 67.9±10.7 self reported weight 70.7±11.4 measured weight 0.04 Discrepancy between reported and actual weight 1994 (56) 67.1±10.5 self-reported weight 69.0±11.4 measured weight 0.03 Discrepancy between reported and actual weight 1995 (66) 64.5±7.4 self reported weight 66.4±8.1measured weight 0.03 Discrepancy between reported and actual weight 1996 (36) 65.8±7.2 self reported weight 66.8±7.8 measured weight 0.02 Discrepancy between reported and actual weight Average 67.0±9.8 self reported weight 69.0±10.5 measured weight 0.03 Discrepancy between reported and actual weight

Appendix 35: Data extraction sheet; Lowe 2001

	1992 1993 1994 1995 1996 Overall kg regain 7.4 5.8 8.4 8.3 6.0 5.6 5.7 5.4 2.9 5.1 5.7 6.1 Percentage weight loss regained 76.5 61.2 77.9 60.1 59.8 57.9 53.7 54.8 31.5 44.3 56.4 57.1 Percentage within 5 lb of goal 19.4 14.7 27.0 25.9 47.6 28.3 Percentage maintained _5% loss 42.6 46.0 54.3 60.1 69.6 56.8 Percentage maintained _10% loss 18.8 30.2 32.4 35.0 51.6 35.4 Percentage below initial weight 70.3 60.2 80.0 82.7 92.5 79.6 Percentage below goal weight 3.9 4.7 11.1 11.5 17.8 10.9
Control (s)	
Primary endpoint(s)	Authors do not report this
Secondary endpoint(s)	Authors do not report this
Other endpoint(s)	
Effect size	Based on corrected weights, weight regain from 1 to 5 y following weight loss ranged between 31.5 and 76.5%. At5 y, 19.4% were within 5 lb of goal weight, 42.6% maintained a loss of 5% or more, 18.8% maintained a loss of 10% or more, and 70.3% were below initial weight.

Adverse events	Lowe 2001
All adverse events	Authors do not report this

Appendix 36: Data extraction sheet; Morgan 2008

Bibliographic Details	
Study ID	Morgan 2008
Author (first)	Morgan LM, Griffin BA, Millward DJ, DeLooy A, Fox KR, Baic S, Bonham MP, Wallace JM, MacDonald I, Taylor MA, Truby H.
Journal	Public Health Nutrition
Year	2008
Volume	12 (6)
Pages	799–807
Language	ENGLISH
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	L.Morgan@surrey.ac.uk

Character of included studies	
Methods	Randomised controlled clinical trial (RCT) multicentred
Participants	Exclusion criteria prior history of CHD, known type 1 or 2 diabetes, liver or respiratory failure, gout, lipid-lowering or anti-hypertensive medication, history of obesity with known cause (i.e. Cushing's syndrome, hypothyroidism), previous gastric or weight-loss surgery, taking any weight-losing drugs (including Orlistat or Sibutramine), clinical depression, eating disorders, drug or alcohol abuse, any malabsorptive state (including lactose intolerance), treatment for a malignancy, pregnancy or breast-feeding. Inclusion criteria 18 to 65 years Who lived within 30 miles of a test centre and had a self reported BMI between 27 and 40 kg/m2.
Interventions	Number of study centres: five Country/location: UK Setting: testing at five different universities Treatment before: Authors do not report this

Appendix 36: Data extraction sheet; Morgan 2008

	Titration period: Authors do not report this
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) A range of outcomes were collected. However, plasma lipids and lipoproteins appear to be the key measures, related to cvd risk for this study. Primary outcome(s) Authors do not report this Secondary outcome (s) Authors do not report this Other outcome (s)
Study details	Run-in period none: The control was a delayed treatment group which involved no dietary intervention until after 6 months. Study terminated before regular end none
Publication details	Language of publication: English Commercial funding: British Broadcasting Corporation Non-commercial funding: Authors do not report this Publication status (peer review journal): yes Publication status (journal supplement): Authors do not report this Publication status (abstract): Authors do not report this
Stated aim for study	Quote “To investigate the relative efficacy of four popular weight-loss programmes on plasma lipids and lipoproteins as measures of CVD risk.”
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	Low Participants were stratified by gender (only 30% of participants were male) and randomly allocated to any of the five groups (four diets and control).
Allocation concealment (selection bias)	High Participants would have known what they were assigned too
Blinding (performance & detection bias)	Low Group leaders did not take any measures.
Blinding of participants and personnel	High

Appendix 36: Data extraction sheet; Morgan 2008

(performance bias)	Authors do not report this
Blinding of outcome assessment (detection bias)	High Authors do not report this
Incomplete outcome data (attrition bias)	Low 28% dropped out
Selective reporting (reporting bias)	High Authors do not report this
Other bias	High Money to attend the classes was reimbursed. This therefore did not arise suspicion, in that pre paid vouchers were not given. Receipts could be required for tax purposes. Travel costs were also reimbursed.
Comments	

Overview of study populations	Morgan 2008
Number invited	300 obese men and women were recruitment via a BBC advertising campaign
Number screened	Authors do not report this
Number randomised	Each centre aimed to recruit a cohort of sixty participants, to allow twelve in each diet group plus a further twelve in a control group
(n) ITT Intervention Control Total	Authors do not report this
Number finishing study	52
(%) of randomised patients finishing study	Data was available for 17.74% of participants at 6 months The authors report 28%

Description of interventions	Morgan 2008
Intervention(s) [route, frequency, total dose/day]	For the group-based programmes (Weight Watchers and Rosemary Conley), participants arranged to attend the most geographically convenient class and the costs of joining and attending one class per week for 6 months were reimbursed on presentation of receipts. Both parent companies of Weight Watchers (www.weightwatchers.co. uk) and Rosemary Conley (www.rosemary-conley.co.uk) signed a contract committing to the provision of standard care. For

Appendix 36: Data extraction sheet; Morgan 2008

	Slim-Fast, the cost of up to two meal replacements per day was reimbursed on presentation of receipts, and a copy of the Slim-Fast Support Pack was provided. The Atkins group was given a copy of Dr Atkins' New Diet Revolution.
Control(s) [route, frequency, total dose/day]	Control group subjects were asked to maintain their current diet and exercise pattern and were offered any of the diets for 6 months at the end of study, free of charge.

Baseline characteristics	Morgan 2008
Number of Intervention participants	Atkins 57 Weight watchers 58 Slim fast 59 Rosemary Connelly 58
Number of Control participants	Control 61
Participating population	18 to 65 years. Who lived within 30 miles of a test centre and had a self reported BMI between 27 and 40 kg/m2.
Sex [female %]	73.1%
Age [mean years (SD)]	Atkins 40.9 (9.7) weight watchers 39.9(10.9) slim fast 38.9(10.7) rosemary conelly 40.6(10.3) whole cohort 40.3(10.2) control 40.8(9.6)
HbA1c [mean % (SD)]	Authors did not report
BMI [mean kg/m2 (SD)]	31.7 (2.7)
Duration of disease [mean years (SD)]	Authors did not report
Ethnic groups [%]	Authors did not report
Duration of intervention [mean ... (SD)]	6 months
Duration of follow-up [mean ... (SD)]	Authors did not report
Co-medications	Authors did not report
Co-interventions	Authors did not report
Co-morbidities	Authors did not report

Matrix of study endpoints	Morgan 2008
Intervention(s)	2 months

Appendix 36: Data extraction sheet; Morgan 2008

	Weight 85.1** (10.9) atkins 84.2** (13.2) weight watchers 87.2** (12.4)slim fast 82.8** (12.4) rosemary Connelly 86.9 (14.8) control TAG mmol/l 1.07** (0.44)atkins 1.25** (0.47) weight watchers 1.47 91.04) slim fast 1.34** (0.58) rosemary Connelly 1.50 control (0.65) LDL-C mmol/L 3.59 (0.73) atkins 3.12**(0.71) weight watchers 3.29**(0.68) slim fast 3.21**(0.66) rosemary Connelly 3.79(0.78) control HDL-C mmol/L 1.24 (0.25) atkins 1.04** (0.21) weight watchers 1.15**(0.28) slim fast 1.07**(0.24) rosemary Connelly 1.22 (0.24) control Glucose mmol/l 5.52 (0.43) atkins 5.36 (0.51) weight watchers 5.41(0.49) slim fast 5.50 (0.53) rosemary Connelly 5.42(0.43) control Insulin pmol/l 75.2 (83.6) atkins 57.2 (35.9) weight watchers 80.1(67.1) slim fast 63.7(31.8) rosemary Connelly 69.2 (41.0) control 6 months Weight 83.2** 10.6 81.4** 13.6 85.4** 12.2 79.4** 12.6 88.5 15.0 Tag 83.2** 10.6 81.4** 13.6 85.4** 12.2 79.4** 12.6 88.5 15.0 Ldl-c 3.56 0.76 3.13** 0.58 3.31** 0.70 3.15** 0.57 3.55 0.73 Ldl peak density (g/l) 1.0280** 0.0021 1.0281** 0.0021 1.0286** 0.0030 1.0285** 0.0031 1.0287** 0.0032 Hdl-c 1.14 0.32 0.98** 0.15 1.09** 0.27 1.02** 0.25 1.04** 0.20 Glucose 5.30* 0.61 4.95** 0.65 5.23* 0.60 5.23** 0.54 5.18* 0.51 Insulin 54.8 32.4 52.9 30.2 64.6** 39.6 58.5 34.8 75.9 45.0

Appendix 36: Data extraction sheet; Morgan 2008

Control (s)	See above for control data
Primary endpoint(s)	Authors did not report
Secondary endpoint(s)	Authors did not report
Other endpoint(s)	
Effect size	Significant weight loss was achieved by all dieting groups (5–9 kg at 6 months) but no significant difference was observed between diets at 6 months.

Adverse events	Morgan 2008
All adverse events	Authors did not report

Appendix 37: Data extraction sheet; Rippe 1998

Bibliographic Details	
Study ID	Rippe 1998
Author (first)	Rippe JM, Price JM, Hess SA, Kline G, DeMers KA, Damitz S,Kreidieh I, Freedson P.
Journal	Obesity research
Year	1998
Volume	6 (3)
Pages	208-218
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	James M. Rippe, M.D., Director, The Center for Clinical and Lifestyle Research, 21 North Quinsigamond Avenue, Shrewsbury, MA 01545..

Character of included studies	
Methods	randomized prospective trial
Participants	Exclusion criteria Potential subjects were excluded if they had participated in a weight loss or exercise program during the previous three months. Individuals who reported orthopaedic or cardiovascular problems which would prevent participation in an exercise program were also excluded. Potential subjects were excluded if they were undergoing psychological counselling or taking any psychotropic medications or medications known to affect heart rate response to exercise or metabolic rate. Not pregnant or lactating and agreed to use adequate birth control while participating in the study. Inclusion criteria Overweight women Table of desirable weight for height participated in the study.
Interventions	Number of study centres: single centre Country/location: US

Appendix 37: Data extraction sheet; Rippe 1998

	Setting: Authors do not report this. The setting would be at the commercial weight loss setting (community centre/school etc) Treatment before study: Before and after the 12-week study intervention all subjects underwent a graded maximal exercise test with direct measurement of maximal oxygen consumption (Vojmax).Psychological inventories were administered before and after the 12-week study period. Titration period: Authors do not report this.
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Primary outcome(s) Primary outcome of interest in this investigation was the interaction between pre-to-post change and group identification (treatment or control). Secondary outcome (s) Other outcome (s) Weight change VO2 max Heart rate Systolic BP Diastolic BP Activity score Percentage change in body fat
Study details	Run-in period: Authors do not report this. Study terminated before regular end: Authors do not report this.
Publication details	Language of publication: English Commercial funding: Grant from Weight Watchers International. Non-commercial funding: Authors do not report this. Publication status (peer review journal): yes Publication status (journal supplement): Authors do not report this. Publication status (abstract): Authors do not report this.
Stated aim for study	Quote *"To study the effects of a 12-week weight loss strategy involving increased physical activity, self-selected hypocaloric diet, and group support on psychological wellbeing, quality of life, and health practices in moderately obese women."*
Notes	

Appendix 37: Data extraction sheet; Rippe 1998

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	High Women were assigned to control or intervention; it does not state how this was done.
Allocation concealment (selection bias)	High Authors do not report this.
Blinding (performance & detection bias)	High Participants knew what they were assigned too, it does not state if they were told not to discuss with the researchers taking their measures.
Blinding of participants and personnel (performance bias)	High It does not state whether the researchers knew what arm the participants were assigned too. If they did know, this could have impacted on the results if other measures were used (e.g. waist)
Blinding of outcome assessment (detection bias)	Authors do not report this.
Incomplete outcome data (attrition bias)	10 withdrew from the intervention (n=30) and 26 withdrew from the control group (n=14). 14 out of the 26 who withdrew were unhappy that they were not in the intervention group. Therefore, they must of known what the intervention was.
Selective reporting (reporting bias)	Authors do not report this.
Other bias	
Comments	

Overview of study populations	Rippe 1998
Number of intervention participants Number of control participants	Authors do not report if there were more participants initially than those listed.
Number screened	Authors do not report if there were only the 80 who took part, or if there were more participants, and after screening there were 80.
Number randomised	40 40
(n) ITT Intervention Control Total	Authors do not report this.
Number finishing the study	44 in total

Appendix 37: Data extraction sheet; Rippe 1998

	30 intervention 14 control
(%) of randomised patients finishing study	75% intervention 35% control

Description of interventions	Rippe 1998
Intervention(s) [route, frequency, total dose/day]	Weight watchers participants received no further supervision or nutritional counselling other than that provided as a standard part of this program. The nutrition portion of the program consisted of a self-selected, hypo caloric diet with a caloric range of 33,258 to 41,462 kJ. The emphasis of the nutritional portion of the program is on food that is self-selected. The food plan is designed to be hypo caloric while nutritionally balanced and in line with public health guidelines. This program also requires members to take a multiple vitamin/nutritional supplement that provides no more than 100% of the U.S. recommended daily allowance (RDA). Subjects were instructed to increase weekly physical activity to 4184 kJ during the second week, to 5232.5 kJ during the third week, and 6379 kJ each week thereafter. Most of the subjects obtained this increased physical activity through walking of moderate intensity, although a wide variety of other activities was allowed.
Control(s) [route, frequency, total dose/day]	Dietary intake was recorded by all subjects for four days immediately before the intervention, at the midpoint of the intervention, and immediately after the 12 weeks of the intervention using standard techniques. Subjects recorded everything they ate and drank for four consecutive days with one day falling on a weekend. They were instructed to measure the volume and size of foods and drink and to estimate weight of meats by comparison with sample pictures provided of actual sizes. Subjects who did not provide appropriate detail about their intake were questioned further for the needed information. Data were analysed for nutrient content using a commercially available software package. Control subjects were requested to maintain prior activity levels throughout the study period and not to initiate any new exercise program.

Baseline characteristics	Rippe 1998
Number of intervention participants Number of control participants	40 40
Participating population	Overweight women Table of desirable weight for height participated in the study.

Appendix 37: Data extraction sheet; Rippe 1998

Sex [female %]	100%
Age [mean years (SD)]	Intervention 37.4(7.9) control 35.6(5.9)
HbA1c [mean % (SD)]	Authors do not report this
BMI [mean kg/m2 (SD)]	Authors do not report this
Duration of disease [mean years (SD)]	Authors do not report this
Ethnic groups [%]	Authors do not report this
Duration of intervention [mean ... (SD)]	12 weeks
Duration of follow-up [mean ... (SD)]	Authors do not report this
Co-medications	Authors do not report this
Co-interventions	Authors do not report this
Co-morbidities	Authors do not report this

Matrix of study endpoints	Rippe 1998
Intervention(s)	See below
Control (s)	See below
Primary endpoint(s)	See below
Secondary endpoint(s)	See below
Other endpoint(s)	Weight 6.07 ± 4.01 intervention 1.31 ± 1.28 kg control Body fat 4.3% reduction in body fat (intervention) 0.2% reduction in body fat Activity level from baseline to endpoint +4.4(2.3) intervention +0.7(0.3) *control* *VO2 max change from baseline to endpoint* +3.8(3.3) intervention -2.7(3.5) control Diastolic blood pressure change from baseline to end point -4.3(9.6) intervention -2.1(7.9) control Heart rate change from baseline to endpoint +2.2(11.1) control -6.2(11.6) intervention Systolic BP baseline change to endpoint -3.2(11.8) control -6.5(13.1) intervention Psychological data (significant differences) change from baseline to endpoint Body cathexis

Appendix 37: Data extraction sheet; Rippe 1998

	0.7(8.6) control 18.6(16.7) intervention Sonstroem 0.9(5.9) control 8.1(7.1) intervention Rosenberg -0.4(2.6) control 3.5(3.3) intervention Stati trait 0.3(3.7) control 5.7(7.4) intervention Poms-vigor -0.8(4.2) control -6.5(5.6) intervention Quality of life subscales (significant differences) change from baseline to endpoint Physical function 1.4(9.5) control 13.5(16.7) intervention Vitality 2.9(20.8) control 21.7(17.9) intervention Mental health 2.3(10.1) control 10.4(16.0) intervention
Effect size	The intervention group lost significant body weight (kg) and body fat (%) compared to controls (-6.07 ± 4.01 kg vs. 1.31 ± 1.28 kg; 36.8%-32.5% vs. 36.2%-36.0%).

Adverse events	Rippe 1998
All adverse events	Authors do not report this

Appendix 38: Data extraction sheet; Rolland 2009

Bibliographic Details	
Study ID	Rolland 2009
Author (first)	Rolland C, Hession M, Murray S, Wise A, Broom I.
Journal	Journal of Diabetes
Year	2009
Volume	1
Pages	207-217
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Paper
Corresponding author and contact details	Catherine Rolland, Centre for Obesity Research and Epidemiology, Robert Gordon University, St Andrew Street, AB25 1HG Aberdeen, UK. Tel: +44 01224 262893 Fax: +44 01224 262828 Email: c.rolland@rgu.ac.uk

Character of included studies	
Methods	Randomised controlled clinical trial (RCT)
Participants	Exclusion criteria Patients with a history of hepatic or renal disease, cancer, currently pregnant or lactating, on antidepressants or anti-obesity medication, or those with eating disorders were excluded from the study. Inclusion criteria Patients referred to a Specialist Obesity Clinic were entered into a randomized controlled clinical trial (RCT) of differing dietary interventions in the management of their obesity. Men and women >18 years of age and with a body mass

Appendix 38: Data extraction sheet; Rolland 2009

	index (BMI) ≥35 kg⁄m2 were included in the study.
Interventions	Number of study centres: Authors do not report this Country/location: UK Setting: Authors do not report this Treatment before study : Authors do not report this Titration period not reported: Authors do not report this
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Primary outcome(s) Weight loss Secondary outcome (s) Other outcome (s) Bmi % body fat Fat mass Fat free mass Waist circumference
Study details	Run-in period : Authors do not report this Study terminated before regular end: Authors do not report this
Publication details	Language of publication: English Commercial funding Lighter Life uk Non-commercial funding: Authors do not report this Publication status (peer review journal): yes Publication status (journal supplement): Authors do not report this Publication status (abstract): Authors do not report this
Stated aim for study	Quote. Authors do not report this. The closest aim is: The present study assesses the effectiveness of an LCHP, a commercial very low-calorie diet (VLCD; Lighter Life (LL)), and a 600 kcal-deficient (CDD) diet in an obese population.
Notes	

Risk of bias	unclear / low / high risk

Appendix 38: Data extraction sheet; Rolland 2009

Random sequence generation (selection bias)	High Authors do not report this At the end of the screening period, patients who did not achieve a 5% weight loss were randomized to either LCHP or LL. Though it does not state how this was done, was it opaque envelopes given by an independent statistician???. It states that there were significant differences in BMI, weight and fat free mass of those who did not achieve 5% weight loss. However, it does not state how the randomisation was adjusted according to this, i.e. did they ensure that there were equal weights between groups
Allocation concealment (selection bias)	It does not state if the allocation was blind to participants or researchers. Nor does it state if the same staff carried out the data collection procedures (this would not impact on the results anyhow, as methods to collect data would not have researcher error involved)
Blinding (performance & detection bias)	High Authors do not report if the allocation was blind to participants or researchers. Nor does it state if the same staff carried out the data collection procedures (this would not impact on the results anyhow, as methods to collect data would not have researcher error involved)
Blinding of participants and personnel (performance bias)	High Authors do not report if the allocation was blind to participants or researchers. Nor does it state if the same staff carried out the data collection procedures (this would not impact on the results anyhow, as methods to collect data would not have researcher error involved)
Blinding of outcome assessment (detection bias)	High Authors do not report if the anthropometrics at three months were told to the participants. This could have impacted on the results if participants wanted to lose more weight, they potentially could have free styled and done additional exercise to lose more weight.
Incomplete outcome data (attrition bias)	20 out of 34 dropped out of lighter life, and 38 out of 38 dropped out of low carb high protein diet
Selective reporting (reporting bias)	Authors do not report this
Other bias	
Comments	

Appendix 38: Data extraction sheet; Rolland 2009

Overview of study populations	Rolland 2009
Number invited	254 patients contacted
Number screened	120
Number randomised	34 intervention 38 control
(n) ITT Intervention Control Total	Not reported
Number finishing the study	14 intervention 20 control
(%) of randomised patients finishing study	41.2% intervention 52.6% control

Description of interventions	Rolland 2009
Intervention(s) [route, frequency, total dose/day]	Lighter life The LL is a VLCD that is administered in the shape of soups, shakes, and bars to replace conventional food and provide a daily average of 550 kcal (36% carbohydrate, 36% protein, and 28% fat and at least 100% of the recommended daily allowance (RDA) of vitamins and minerals). Patients are advised to remain adequately hydrated while on the diet. The LL has two distinctive stages: (i) weight loss; and (ii) on-going weight management. During each stage, patients attend weekly single sex group meetings with seven to 12 people that are delivered by a trained LL counsellor, enabling active management of motivation and concordance, using group support and counselling to encourage long-term behavioural modification and weight management. The groups consisted of a mix of research subjects and self-referred individuals. Patients were required to remain on the weight loss phase for a minimum of 3 months, after which they were given a choice to continue for up to another 6 months or to be assigned to the management phase. On average, patients who finished the study remained on the diet for 6.9 months (range 4–9 months). For the weight management phase, solid foods are reintroduced over a 12-week period, during which patients are slowly weaned off food packs while still receiving counselling and support. Advice on healthy eating and exercise and continual support are offered. LL patients also came monthly to the trial centre to be weighed for the first 3 months and then every other month after screening, resulting in six visits over 9 months during which they discussed their on-going LL treatment. Telephone and email support was also available throughout.

Appendix 38: Data extraction sheet; Rolland 2009

Control(s) [route, frequency, total dose/day]	Low carb high protein Patients on the LCHP were restricted to ≤40 g carbohydrate⁄day. The energy intake ranged from 800 to 1500 kcal, where an 800 kcal diet was composed of 20% carbohydrate, 40% protein, and 40% fat. Patients were given a booklet with information about which foods to eat and which to avoid. Examples of recipes were also provided. The diet was supplemented with multivitamins and minerals (Forceval; Alliance Pharmaceuticals, Chippenham, UK). This is one of the standard dietary treatments currently used at the Specialist Obesity Clinic in Aberdeen, Scotland. Patients came monthly to the trial centre to be weighed for the first 3 months and then every other month after screening, resulting in six visits over 9 months. Constant support was available via telephone and email.

Baseline characteristics	Rolland 2009
Number of intervention participants Number of control participants	34 38
Participating population	Men and women >18 years of age and with a body mass index (BMI) ≥35 kg⁄m2 were included in the study.
Sex [female %]	Authors do not report this
Age [mean years (SD)]	Authors do not report this
HbA1c [mean % (SD)]	Authors do not report this
BMI [mean kg/m2 (SD)]	Low carb high protein 41.63 ± 4.8 Lighter life 46.0 ± 7.0
Duration of disease [mean years (SD)]	Authors do not report this
Ethnic groups [%]	Authors do not report this
Duration of intervention [mean ... (SD)]	Time points are 3 and nine months
Duration of follow-up [mean ... (SD)]	Authors do not report this
Co-medications	Authors do not report this

Appendix 38: Data extraction sheet; Rolland 2009

Co-interventions	Authors do not report this
Co-morbidities	Authors do not report this

Matrix of study endpoints	Rolland 2009
Intervention(s)	3 months Weight 111.0 ± 18.4* Bmi 41.8 ± 7.4* % body fat 44.8 ± 8.5* Fat mass (kg) 50.3 ± 15.1* Fat free mass (kg) 60.5 ± 11.1* Waist circumference 119.1 ± 16.4* Total cholesterol (mmol/L) 4.6 ± 1.1* Low-density lipoprotein (mmol/L) 2.9 ± 0.9* High-density lipoprotein (mmol/L) 1.25 ± 0.22* Total cholesterol/high-density lipoprotein 3.8 ± 1.0 Triacylglycerols (mmol/L) 1.2 ± 0.7 Fasting glucose (mmol/L) 4.8 ± 0.5* HbA1c (%) 5.5 ± 0.3* Systolic blood pressure (mmHg) 127.8 ± 15.2* Diastolic blood pressure (mmHg) 81.8 ± 10.8*

Appendix 38: Data extraction sheet; Rolland 2009

	9months Weight 107.5 ± 20.1* Bmi 40.3 ± 8.9* %body fat 42.2 ± 11.9*_ Fat mass (kg) 42.2 ± 11.9*_ Fat free mass (kg) 60.7 ± 11.5* Waist circumference 114.5 ± 16.0*_ Total cholesterol (mmol/L) 4.8 ± 1.0*_ Low-density lipoprotein (mmol/L) 2.9 ± 0.9* High-density lipoprotein (mmol/L) 1.38 ± 0.25*_ Total cholesterol/high-density lipoprotein 3.6 ± 1.0*_ Triacylglycerols (mmol/L) 1.1 ± 0.7* Fasting glucose (mmol/L) 4.9 ± 0.4* HbA1c (%) 5.4 ± 0.4* Systolic blood pressure (mmHg) 128.2 ± 18.0* Diastolic blood pressure (mmHg) 83.2 ± 12.4*
Control (s)	3 months Weight 108.7 ± 15.6*

Appendix 38: Data extraction sheet; Rolland 2009

	Bmi 40.6 ± 5.3* % body fat 47.6 ± 5.8* Fat mass (kg) 52.0 ± 11.3* Free fat mass (kg) 56.8 ± 9.1 Waist circumference 119.1 ± 10.0* Total cholesterol (mmol/L) 5.4 ± 0.9 Low-density lipoprotein (mmol/L) 3.3 ± 0.8 High-density lipoprotein (mmol/L) 1.44 ± 0.32 Total cholesterol/high-density lipoprotein 3.8 ± 1.0 Triacylglycerols (mmol/L) 1.5 ± 0.8 Fasting glucose (mmol/L) 5.4 ± 0.8 HbA1c (%) 5.6 ± 0.4 Systolic blood pressure (mmHg) 132.0 ± 18.6 Diastolic blood pressure (mmHg) 87.7 ± 8.2 9months Weight 109.6 ± 16.3* Bmi 40.9 ± 5.4*

Appendix 38: Data extraction sheet; Rolland 2009

	Body fat % 48.0 ± 6.1* Fat mass (kg) 53.0 ± 12.2* Fat free mass (kg) 55.5 ± 12.1 Waist circumference 119.0 ± 10.8* Total cholesterol (mmol/L) 5.3 ± 1.0 Low-density lipoprotein (mmol/L) 3.2 ± 0.8_ High-density lipoprotein (mmol/L) 1.44 ± 0.35 Total cholesterol/high-density lipoprotein 3.7 ± 1.0 Triacylglycerols (mmol/L) 1.5 ± 0.9 Fasting glucose (mmol/L) 5.3 ± 0.8_ HbA1c (%) 5.6 ± 0.4 Systolic blood pressure (mmHg) 133.1 ± 16.6 Diastolic blood pressure (mmHg) 86.6 ± 8.4
Primary endpoint(s)	
Secondary endpoint(s)	
Other endpoint(s)	
Effect size	Significantly greater weight loss was seen for patients on the LL than the LCHP at 3 (mean (±SD))11.6 ± 12.9 vs)2.8 ± 4.5 kg, respectively; P < 0.0001) and 9 months ()15.1 ± 21.1 vs)1.9 ± 5.0 kg, respectively; P < 0.0001) after screening.

Appendix 38: Data extraction sheet; Rolland 2009

Adverse events	Rolland 2009
All adverse events	Authors do not report this

Appendix 39: Data extraction sheet; Womble 2004

Bibliographic Details	
Study ID	Womble 2004
Author (first)	Womble L, Wadden T, McGuckin BG, Sargent SL, Rothman RA, Krauthamer-Ewing SE
Journal	Obesity research
Year	2004
Volume	12 (6)
Pages	1011-1018
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	Leslie G. Womble, University of Pennsylvania, Weight and Eating Disorders Program, 3535 Market St., Suite 3029, Philadelphia, PA 19104. E-mail: womble@mail.med.upenn.edu

Character of included studies	
Methods	Randomised controlled clinical trial (RCT)
Participants	Exclusion criteria Individuals had to be free of physical conditions including type 1 or 2 diabetes; uncontrolled hypertension (>140/90 mm Hg); a history of cerebrovascular, cardiovascular, kidney, or liver disease; the use of medications known to affect body weight (e.g., steroids); pregnancy or lactation; and a weight loss 5% of initial weight and/or the use of anorectic agents in the previous 6 months. Psychosocial contraindications included bulimia nervosa, major depression, or other psychiatric illness that significantly disrupted daily functioning. Inclusion criteria Limited to women, ages 18–65 years, who had a BMI of 27–40 kg/m2. Participants also were required to have daily access to the Internet.

Appendix 39: Data extraction sheet; Womble 2004

Interventions	Number of study centres: Authors do not report this Country/location: US Setting: Internet and various locations (everyday life locations) whilst using the learn programme manual Treatment before study : Authors do not report this Titration period: Authors do not report this
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Primary outcome(s) Change in body weight Secondary outcome (s) Other outcome (s) Blood pressure Fasting biochemical profile that included triglycerides, glucose, total cholesterol, high-density lipoprotein (HDL), and low-density lipoprotein (LDL)
Study details	Run-in period: Authors do not report this Study terminated before regular end: Authors do not report this
Publication details	Language of publication : English Commercial funding: Authors do not report this Non-commercial funding : Pilot Study Grant from the North American Association for the Study of Obesity (to Dr. Womble) and by NIH Grant K24-DK- 065,018 (to Dr. Wadden). Publication status (peer review journal) : yes Publication status (journal supplement): Authors do not report this Publication status (abstract): Authors do not report this
Stated aim for study	Quote “To assess, in a 1-year randomized controlled trial, the efficacy of eDiets.com (a commercial Internet weight loss program) in improving weight, cardiovascular health, and quality of life.”
Notes	

Appendix 39: Data extraction sheet; Womble 2004

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	High Does not specifically state how they were randomised. It just stated that they were assigned to ediets or the manual program. No sequence generation, no opaque envelopes, no information given.
Allocation concealment (selection bias)	High The assistants explained the two arms to potential participants, therefore those receiving the manual program knew what the other was receiving and vice versa. Assistants could have explained one of the arms more than another (i.e. the intervention). It does not state why this was done, especially when it is an RCT. The participants shouldn't know what the other group is doing under rct controls. But telling the participants the two arms could have already interfered with the results. Participants who were keen to be involved in the intervention group, and received the manual program could have meant that they didn't try as much, as they were disappointed with what they had received.
Blinding (performance & detection bias)	High Authors do not report this
Blinding of participants and personnel (performance bias)	High Participants would have known what they were receiving
Blinding of outcome assessment (detection bias)	High It does not state whether the assistants taking the outcome measures were blind to who had received what, or if the participants had been told not to tell the researchers what they were doing. it is doubtful that this would have had an impact on the results, as the project was not funded commercially, and it is very unlikely that researchers would try to tamper with the results especially when the methods used could not be tampered with (bloods being taken, blood pressure cuff, scales and high stick)
Incomplete outcome data (attrition bias)	High 15 were left at 16 weeks in the e diet group, 8 remained at 52 weeks 16 were left at 16 weeks in the e diet group, 8 remained at 52 weeks
Selective reporting (reporting bias)	Authors do not report this
Other bias	
Comments	

Overview of study populations	Womble 2004
Number invited	158 assessed for eligibility via phone, 65 ineligle
Number screened	158 assessed for eligibility via phone, 65 ineligle
Number randomised	47
(n) ITT	None reported

Appendix 39: Data extraction sheet; Womble 2004

Intervention Control Total	
Number finishing study	16 in total, eight in each group
(%) of randomised patients finishing study	65-66% in each group finished the study (16 weeks) 33-35% in each group finished the study (52 weeks)

Description of interventions	Womble 2004
Intervention(s) [route, frequency, total dose/day]	1 year membership was paid for, with the ediets group, this also paid for a virtual visit with a dietician. A tailored programme of foods, and exercise were given to match their likes, needs etc. Women with a BMI of 27 to 35 kg/m2 were provided meal plans that prescribed 1200 to 1300 kcal/d, whereas those with a BMI >35 kg/m2 were given 1300 to 1400 kcal/d. grocery lists were provided and social online meetings with a professional. Find a buddy programme allowed members to email other members participating in the programme. A psychologist was met with a baseline, 8, 16, 26 and 52 weeks for 20 minutes. The initial visit was to talk about goals and methods of treatment, log onto ediets every day, and to record and log the intake of foods. Remaining visits discuss weight loss, and satisfaction with the programme.
Control(s) [route, frequency, total dose/day]	243-page book that provided 16 step-by step lessons for modifying eating, activity, and thinking habits. 1200-1500kcal per day was required, and it was recommended that daily records of calories intake were kept. Physical activity was encouraged, and control behaviours to be practiced (i.e. slower eating). After 16 weeks, participants were given the Weight Maintenance Survival Guide (19) that reiterated concepts introduced in the LEARN Program (18). Participants in this group met with a psychologist on the same schedule (i.e., at baseline and four times over the year) as those in the eDiets.com group.

Baseline characteristics	Womble 2004
Number of intervention participants	23 ediets
Number of control participants	24 LEARN

Appendix 39: Data extraction sheet; Womble 2004

Participating population	Limited to women, ages 18–65 years, who had a BMI of 27–40 kg/m2. Participants also were required to have daily access to the Internet.
Sex [female %]	100%
Age [mean years (SD)]	44.2±9.3 ediets 43.3±11.1 manual
HbA1c [mean % (SD)]	Authors do not report this
BMI [mean kg/m2 (SD)]	33.9±3.2 ediets 33.0 ±3.0 manual
Duration of disease [mean years (SD)]	Authors do not report this
Ethnic groups [%]	Not reported
Duration of intervention [mean ... (SD)]	1 year
Duration of follow-up [mean ... (SD)]	weight and blood pressure were scheduled for both groups at baseline and weeks 2, 4, 8, 12, 16, 20, 26, 34, 42, and 52
Co-medications	Authors do not report this
Co-interventions	Authors do not report this
Co-morbidities	Authors do not report this

Matrix of study endpoints	Womble 2004
Intervention(s)	See below
Control (s)	See below
Primary endpoint(s)	0.7±2.7 kg of initial weight ediets weight loss at 16 weeks 3.0 ± 3.1 kg of initial weight with manual at 16 weeks 0.8 ±3.6 kg of baseline to 52 weeks with ediets 3.3±4.1 kg of baseline to 52 weeks with manual
Secondary endpoint(s)	Significant within-subject changes over 52 weeks for completers (N = 31) Lipids

Appendix 39: Data extraction sheet; Womble 2004

	LDL 120.4±32.2 baseline 135.5±32.7* 16weeks 125.1 ±31.2 52weeks HDL/total 3.8± 1.0 baseline 4.1 ±0.9* 16weeks 3.8±0.8 52weeks Percent reduction in initial weight for participants assigned to eDiets.com or a weight loss manual eDiets.com Week 16 completers only (n=31) 1.3 ± 3.3% Week 52 completers only (n=31 2.1 ±3.9% Weight loss manual Week 16 completers only (n=31) 4.0 ± 3.7% Week 52 completers only (n=31) 4.6% 4.4 ± 5.0% triglycerides, glucose, and blood pressure are not stated for end point data, only baseline
Other endpoint(s)	
Effect size	At week 16, participants in eDiets.com lost 0.9 ±3.2% of initial weight compared with 3.6 ± 4.0% for women assigned to the weight loss manual. At week 52, losses increased to 1.1±4.0% and 4.0±5.1%, respectively. Results of a last-observation-carried-forward analysis found that women in the manual group lost significantly (p 0.05) more weight (at both times) than those treated by eDiets.com. (Results, however, of baseline-carried-forward and completers analyses did not reach statistical significance.)

Adverse events	Womble 2004
All adverse events	Authors do not report this

Appendix 40: Data extraction sheet; Jolly 2011

Bibliographic Details	
Study ID	Jolly 2011
Author (first)	Jolly K, Lewis A, Beach J, Denley J, Adab P, Deeks JJ, Daley A, Aveyard P.
Journal	BMJ
Year	2011
Volume	343
Pages	1-16
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Full paper
Corresponding author and contact details	A.Daley@bham.ac.uk

Character of included studies	
Methods	Randomised controlled clinical trial (RCT)
Participants	<u>Exclusion criteria</u> Patients were excluded if they were unable to understand English or were pregnant. <u>Inclusion criteria</u> Eligible participants were registered with general practices in South Birmingham Primary Care Trust, were aged at least 18 years, and had a raised body mass index recorded in their primary care notes within the previous 15 months. White Europeans and all ethnic groups apart from South Asians with no comorbidities: BMI ≥30 • White Europeans and all ethnic groups apart from South Asians with comorbidities: BMI ≥28 • South Asians with no comorbidities: BMI ≥25 • South Asians with comorbidities: BMI ≥23

Appendix 40: Data extraction sheet; Jolly 2011

Interventions	Number of study centres: 17 Country/location: UK Setting: leisure centre, and pharmacy settings, community venues Treatment before study: Authors do not report this Titration period: Authors do not report this
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Primary outcome(s) weight loss at programme end (12 weeks) Secondary outcome (s) weight loss at one year, self reported physical activity, and percentage weight loss at programme end and one year Other outcome (s)
Study details	Run-in period: Authors do not report this Study terminated before regular end: Authors do not report this
Publication details	Language of publication: English Commercial funding: Authors do not report this Non-commercial funding: The study was funded by NHS South Birmingham. Publication status (peer review journal) :Yes Publication status (journal supplement): Authors do not report this Publication status (abstract): Authors do not report this
Stated aim for study	Quote “To assess the effectiveness of a range of weight management programmes in terms of weight loss.”
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	Low An independent statistician prepared two separate randomisation sequences, and, to ensure blinding, the allocations

Appendix 40: Data extraction sheet; Jolly 2011

	were placed in opaque, consecutively numbered envelopes, which the call centre staff used in order
Allocation concealment (selection bias)	Low opaque, consecutively numbered envelopes were used
Blinding (performance & detection bias)	Low Based upon the other bias
Blinding of participants and personnel (performance bias)	Low After attending the sessions, the participants would have known what arm they were allocated to. Participants allocated to the commercial providers were given vouchers for 12 free sessions; these would have been given to the group leaders, which could have meant that additional attention was given to these participants as they knew that their group was being researched. Weight date could have also been also reported inaccurately (so show larger improvements). Participants in the choice arm knew which arm they would receive as they had chosen it; women chose the commercial programmes, whereas men chose the size down programme.
Blinding of outcome assessment (detection bias)	Low A trained practice nurse, health trainer, or researcher blinded to the allocation group did the one year assessment at the participant's general practice or home.
Incomplete outcome data (attrition bias)	Low Based upon the other bias
Selective reporting (reporting bias)	Low Based upon the other bias
Other bias	Low 17.3% of weights were self reported at one year, 39.7% at 12 weeks. This could have impacted on the findings. The researchers felt this was not true, self reporters, had a smaller weight loss than those who had their weight taken by someone else.
Comments	Only 11.5% accepted the invitation, who could have already been motivated to change. This could have had an impact on the study results. The trial participants attended alongside people who paid to attend the programmes, this could

	have caused conflict amongst members. Some participants were taking weight loss drugs; this could have had quite an impact on the results.

Overview of study populations	Jolly 2011
Number invited	8810
Number screened	8810 letters sent to patients who met criteria 7799 no response
Number randomised	740 randomised to the eight arms 640 were randomised to commercial programmes, NHS led intervention, general practice or pharmacy led, or chose they wanted to attend 100 were randomised to the minimal intervention comparator group
(n) ITT Intervention Control Total	All analyses according to intention to treat were done by using Stata v11.0 and SPSS v17.0.
Number finishing study	575 intervention 83 control
(%) of randomised patients finishing study	88.9% total 85.8% intervention 83% control

Description of interventions	Jolly 2011
Intervention(s) [route, frequency, total dose/day]	Box 2 Description of interventions Weight Watchers is group based, and the participant was able to join at any time. One to one support is available for new members and during weighing. This is followed by a group talk from the leader, with discussion. Meetings took place in community venues and lasted one hour. Core programme material delivered over five weeks included a food

	points system (based on age, sex, height, weight, and activity), beating hunger, taking more physical activity, eating out, and keeping motivated. Other sessions delivered to the whole group covered recipes, health and nutrition, and keeping active. The plan aims for 500 kcal (2.09 MJ) deficit/day, leading to 0.5-1.0 kg weight loss a week. Physical activity is encouraged; the objective is to gradually build up to 10 000 steps daily. Predominant strategies used to change behaviour included stages of change, food and activity diaries, goal setting, and evaluation of progress. Rewards are given for every 3.2 kg (7 lb) lost and for loss of 5% and 10% of body weight. Slimming World is group based, and the participant was able to join at any time. Meetings took place in community venues and lasted 90 minutes. Also included is access to a website, magazines, and one to one telephone support from a consultant or other members. Members are encouraged to eat mainly foods with low energy density to achieve satiety, plus some extras rich in calcium and fibre, with controlled amounts of high energy dense foods. Weight loss goals are set by the individual. Physical activity is encouraged, with gradual build up to 30 minutes of moderately intense activity five days a week. The theoretical background is based on transactional analysis and motivational interviewing. Predominant behaviour change strategies used included weekly weighing; group support; and group praise for weight loss, new decisions, and continued commitment even in the absence of weight loss. Awards are given for 3.2 kg (7 lbs) lost and loss of 10% of body weight. Individual support, if needed, uses self monitoring of food and emotions, for and against evaluations, visualisation techniques, and personal eating plans. Rosemary Conley is group based, and the participant was able to join at any time. Meetings took place in community venues and lasted 90 minutes. One to one support is offered during weighing and to establish a calorie allowance. Additional support is available by email and telephone. Goals are staged: either 1-1.5 kg/week with a goal of 6.35 kg (1 stone) loss or 0.5-1 kg/week with an initial goal of 3.2 kg (7 lb).Sessions include a 45 minute optional exercise class. Extra exercise sessions may be offered for an additional fee. The theoretical background is based on role modelling and group support and uses visualisation and reframing to support behavioural change. Predominant behaviour change strategies used include rewards for slimmer's who maintain or lose weight, slimmer of the week, and certificates for 3.2 kg and 6.35 kg milestones. The Size Down Programme was an NHS group based programme run in community venues by support workers trained by the dietetics service. This provided six weekly two hour sessions, with follow-up sessions at nine and 12 weeks. All participants joined together in week one of the programme. Its particular focus was on long term changes in patterns of eating behaviour, achieving a balanced diet, and increasing physical activity in daily life, and it used an interactive style. Topics covered included managing behaviour around food and prevention of relapse, the eatwell plate, nutritional information, planning strategies to deal with lapses into previous dietary behaviours, interactive visual aids to show the fat and sugar content of foods, and adaptation of recipes. The theoretical background was based on

Control(s) [route, frequency, total dose/day]	the cycle of change (Prochaska and Di Clemente). The benefits of physical activity, setting goals, and finding activities to fit into life were discussed. Predominant behaviour change strategies used included goal setting, stages of change, and self monitoring with a food diary. The general practice and pharmacy programmes comprised 12 one to one sessions in the general practice or pharmacy. The first session was planned to last 30 minutes, with follow-up sessions of 15-20 minutes. Sessions were client led and based around a problem solving approach. Sessions included weight and dieting history, exploration of goals and expectations of patients, the eatwell plate, setting goals to reduce calorie intake and increase physical activity, planning strategies to deal with challenging situations, use of food diaries, and maintaining weight loss. Weight loss goals were 5-10% of starting body weight, at a rate of 0.5-1 kg/week over three to six months, followed by maintenance. Physical activity goals were to aim to slowly increase activity levels to achieve 30 minutes of moderate activity on five days each week. The theoretical basis used stages of change and motivational interviewing. Predominant behaviour change strategies included goal setting, self monitoring with food diaries, hunger scale, waist measurements, and physical activity. Resources were provided as homework for discussion in the next session or for personal reflection. Participants were encouraged to reward themselves for success. Participants allocated to the comparator group were sent vouchers for 12 free sessions at a local authority run leisure centre (a council run facility open to all members of the public and usually consisting of a swimming pool, fitness suite, and other sports halls or courts). Participants were not given an appointment to attend and were given no individual advice or support on diet or physical activity

Baseline characteristics	Jolly 2011
Number of intervention participants Number of control participants	640 100
Participating population	Eligible participants were registered with general practices in South Birmingham Primary Care Trust, were aged at least 18 years, and had a raised body mass index recorded in their primary care notes within the previous 15 months. The body mass index threshold for invitation was that which makes them eligible for primary care obesity management services in the NHS and varied according to ethnic group and the presence or absence of comorbidities (box 1). The threshold for invitation for people with no obesity

Appendix 40: Data extraction sheet; Jolly 2011

Sex [female %]	72 (weight watchers) 65 (slimming world) 69 (rosemary Connelly) 64 (size down) 67(general practice) 73 (pharmacy) 70 (choice) 75 (comparator)
Age [mean years (SD)]	50.71 (14.56 weight watchers) 48.84 (14.91;slimming world) 49.76 (14.51;rosemary Connelly) 48.75 (15.63;size down) 50.48 (13.79;general practice) 48.94 (15.82;pharmacy) 47.45 (14.35;choice) 49.67 (13.83;comparator)
HbA1c [mean % (SD)]	Authors do not report this
BMI [mean kg/m2 (SD)]	33.96 (3.9;weight watchers) 33.83 (3.8;slimming world) 33.38 (3.5;rosemary Connelly) 33.77 (3.9;size down) 33.06 (3.5;general practice) 33.44 (3.5; pharmacy) 33.41 (3.4;choice) 33.88 (4.4;choice)
Duration of disease [mean years (SD)]	Authors do not report this
Ethnic groups [%]	1 (weight watchers) 3 (slimming world) 0 (rosemary Connelly) 3 (size down) 0 (general practice) 0 (pharmacy) 1 (choice) 3 (comparator) (south Asian) 5 (weight watchers) 5(slimming world) 12(rosemary Connelly) 3(size down) 6(general practice) 9(pharmacy) 10(choice) 9 (comparator) (black British/Caribbean/African) 7 (weight watchers) 4(slimming world) 5(rosemary Connelly) 3(size down) 4(general practice) 4(pharmacy) 6(choice) 4(comparator) (mixed and other)
Duration of intervention [mean ... (SD)]	12 months
Duration of follow-up [mean ... (SD)]	Authors do not report this
Co-medications	Weight loss drug (%) 3 (3weight watchers) 4 (4 slimming world) 3 (3 rosemary Connelly) 2 (2 size down) 1 (1 general practice) 3 (4 pharmacy) 3 (3 choice) 3 (3 comparator)
Co-interventions	Authors do not report this
Co-morbidities	Authors do not report this

Matrix of study endpoints	Jolly 2011
Intervention(s)	
Control (s)	
Primary endpoint(s)	Programme end Weight loss (95% CI) 12 week 4.43 (3.6-5.3**; weight watchers) 3.56 (2.7-4.4**; slimming world) 4.23 (3.2-5.2**; rosemary Connelly) 2.38 (1.7-3.1**;size down) 1.37 (0.4-2.3*; general practice) 2.11 (1.0-3.2**;pharmacy) 3.32(2.5-4.1; choice) 2.01(1.02-2.8**;comparator)
Secondary endpoint(s)	Programme end Proportion of each group that achieved 5% loss (95% CI) percentage

	46.0 (36.0 to 56.3;weight watchers) 35.0 (25.7 to 45.2; slimming world) 42.0 (32.2 to 52.3; rosemary Connelly) 18.0 (11.0 to 26.9; size down) 15.7 (8.1 to 26.4; general practice) 21.4 (12.5 to 32.9; pharmacy) 35.0 (25.7 to 45.2; choice) 22.0 (14.3 to 31.4;comparator) Median (IQR) physical activity (kcals/week) 19.26 (12.25-2629**;weight watchers) 1899(1226-2571**;slimming world) 1801(1155-2447**;rosemary Connelly) 1480(701-2259**; size down**) 1895(963-2826**; general practice) 2720(1790-3649**; pharmacy) 1986(1245-2727**; choice) 1608(988-2228; comparator) Change in physical activity to programme end (minutes/week)§ §Change from baseline in minutes/week using baseline observation carried forward. 58(42-75;weight watchers) 60(42-79; slimming world) 49(33-65; rosemary Connelly) 55(35-75;size down) 47(25-70;general practice) 73(59-94; pharmacy) 59(40-77; choice) 51(36-67; comparator) 1 year Proportion of each group that achieved 5% loss (95% CI) percentage 31.0 (22.1 to 41.0;weight watchers) 21.0 (13.5 to 30.3;slimming world) 26.0 (17.7 to 35.7;rosemary Connelly) 21.0 (13.5 to 30.3;size down) 15.7 (8.1 to 26.4; general practice) 14.3 (7.1 to 24.7;pharmacy) 28.0 (19.5 to 37.9;choice) 17.0 (10.2 to 25.8;comparator) Weight loss (95% CI) 3.46(2.1-4.8**;weight watchers) 1.89(0.9-2.9**;slimming world) 2.12(0.9-3.4**;rosemary Connelly) 2.45(1.3-3.6**;size down) 0.83(-0.4-2.0**; general practice) 0.66(-0.4-1.7; pharmacy) 2.15(0.9-3.4**; choice) 1.08(0.1-2.1**;comparator) Physical activity change to one year (kcal/week) 2048 (1262-2834**; weight watchers) 1362(645-2078**;slimming world) 1429(657-2202**;rosemary Connelly) 1429(644-2213**;size down) 861(256-1467**; general practice) 1473(742-2203**;pharmacy) 1642(837-2448**;choice) 1766(1044-2487**;comparator) Change in physical activity to one year (minutes/week)§ Change from baseline in minutes/week using baseline observation carried forward. 60(40-79;weight watchers) 21(3-39; slimming world) 25(10-40;rosemary Connelly) 19(4-33;size down) 14(-4-35;general practice) 27(3-51; pharmacy) 32(14-50; choice) 42(25-60;comparator)

Appendix 40: Data extraction sheet; Jolly 2011

Other endpoint(s)	
Effect size	All programmes achieved significant weight loss from baseline to programme end (range 1.37 kg (general practice) to 4.43 kg (Weight Watchers)), and all except general practice and pharmacy provision resulted in significant weight loss at one year. At one year, only the Weight Watchers group had significantly greater weight loss than did the comparator group (2.5 (95% confidence interval 0.8 to 4.2) kg greater loss,). The commercial programmes achieved significantly greater weight loss than did the primary care programmes at programme end (mean difference 2.3 (1.3 to 3.4) kg).

Adverse events	Jolly 2011
All adverse events	Authors do not report this

Appendix 41: Data extraction sheet; Rock 2007

Bibliographic Details	
Study ID	Rock 2007
Author (first)	Rock CL, Pakiz B, Flatt SW, Quintana EL.
Journal	Obesity
Year	2007
Volume	15
Pages	939 –949
Language	English
Type (e.g. full paper, conference proceeding, unpublished report)	Paper
Corresponding author and contact details	Cheryl L. Rock, University of California, San Diego, 9500 Gilman Drive, Dept. 0901, La Jolla, CA 92093-0901. E-mail: clrock@ucsd.edu

Character of included studies	
Methods	Randomised controlled clinical trial (RCT)
Participants	Exclusion criteria Those who were unable to be physically active because of severe disability (e.g., severe arthritic conditions) or who reported a history or presence of a comorbid disease for which diet modification and increased physical activity might be contraindicated were not included, as well as those who reported being currently pregnant or breastfeeding or planning a pregnancy within the next 2 years. Current active involvement in another diet intervention study or organized weight loss program; and having a history or presence of a significant psychiatric disorder or any other condition that, in the investigator's judgment, would interfere with participation in the trial also disqualified women from participating. Inclusion criteria 18 years and older; initial BMI 25.0 kg/m2 (overweight or obese) and <40 kg/m2, and a minimum of 15 kg over ideal

Appendix 41: Data extraction sheet; Rock 2007

	weight as defined by the 1983 Metropolitan Life Insurance tables. willing and able to participate in clinic visits and JC facility interactions at specified intervals and to maintain contact with the investigators for two years; willing to allow blood collections; and capable of performing a simple step test for assessing cardiopulmonary fitness.
Interventions	Number of study centres: one Country/location: US Setting: clinic and community facility Treatment before study: Authors do not report this Titration period: Authors do not report this
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Does not specifically state what the primary and secondary outcome measures were. Change in weight (kg) Change in percent weight Change in BMI (kg/m2) Change in waist circumference (cm) Change in hip circumference (cm) Change in step test (heart rate per 30 seconds) Alpha-carotene (_M) Beta-carotene (_M) Lutein (_M) Lycopene (_M) Beta-cryptoxanthin Total carotenoids HDL cholesterol (mg/dL) LDL cholesterol (mg/dL) Total cholesterol (mg/dL) Triglycerides (mg/dL) Sex hormone binding globulin Insulin (_U/mL) Primary outcome(s) Authors do not report this Secondary outcome (s) Authors do not report this

Appendix 41: Data extraction sheet; Rock 2007

	Other outcome (s)
Study details	Run-in period: Authors do not report this Study terminated before regular end: Authors do not report this
Publication details	Language of publication: English Commercial funding: This study was supported by Jenny Craig, Inc. Non-commercial funding: Authors do not report this Publication status (peer review journal): yes Publication status (journal supplement): Authors do not report this Publication status (abstract): Authors do not report this
Stated aim for study	Quote “To test whether a commercial weight loss program promotes greater weight loss in overweight or obese women compared with control conditions and to describe the effect on plasma lipids, carotenoids, hormones, and fitness.”
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	Unclear After enrolment and successful completion of the baseline data collection and assessment activities, participants were stratified by BMI (25.0 –29.9 vs. 30.0 kg/m2) and age (≤40 and >40 years) and randomly assigned to one of the two study groups.
Allocation concealment (selection bias)	High Authors do not report this
Blinding (performance & detection bias)	High Authors do not report this It does not state if an independent person assigned the participants to the study groups, or whether many researchers were involved in assigning the participants to their group according to age and BMI
Blinding of participants and personnel	High

Appendix 41: Data extraction sheet; Rock 2007

(performance bias)	Authors do not report this Participants would have known that they were either control or intervention, one would attend the group, one would not
Blinding of outcome assessment (detection bias)	High Authors do not report this It does not state whether the researchers who were taking the measures were blind. Participants were not told not, not to tell the researchers what they were doing (which could have happened). As the study was funded by the commercial provider, subconsciously the researchers could have swayed the results (i.e. pulling the tape measure tighter)
Incomplete outcome data (attrition bias)	Low At six months two left (lost to follow up, decided to stop taking part) in the control group (n=33), and no more drop outs occurred. Three left in the commercial group (lost to follow up, decided to stop taking part, became pregnant), no more drop outs occurred
Selective reporting (reporting bias)	Authors do not report this
Other bias	It does not state whether the intervention participants joined current members of the JC programme, this could have impacted on the results if the counsellor was paying more attention to new clients.
Comments	

Overview of study populations	Rock 2007
Number invited	A total of 276 women were screened by telephone.
Number screened	A total of 276 women were screened by telephone.
Number randomised	70 women were enrolled in the study and were randomized.
(n) ITT Intervention Control Total	an intent-to treat and completers analysis on the 12-month data, substituting baseline values for any subjects for whom 12-month data were missing.
Number finishing the study	33 (control) 32 (intervention)
(%) of randomised patients finishing study	94.3% control 91.4% intervention

Description of interventions	Rock 2007

Appendix 41: Data extraction sheet; Rock 2007

Intervention(s) [route, frequency, total dose/day]	The intervention arm consisted of referral to a conveniently located community-based JC facility, including the establishment of an initial appointment to begin the program. Subjects assigned to the commercial weight loss program intervention received all program materials, including pre-packaged prepared foods as needed to achieve a meal plan, free-of-charge. The core components of the JC weight loss program are described as addressing food, body, and mind. Interactions between corporate-trained and supervised staff and the clients consist of weekly one-to-one contacts with a counsellor who is described as a consultant, with follow-up telephone and e-mail contacts and web site/message board availability. The food component consists of prescribing an energy reduced diet (typically 1200–2000 kcal/d, individualized based on energy requirements) that includes pre-packaged prepared food items that incorporate (and are accompanied by) increased vegetables, fruit, and other additional strategies to reduce the energy density of the diet. The goal is 30 minutes of physical activity on 5 or more days of the week. Finally, the mind component describes the cognitive aspects of promoting weight loss and maintenance, including self-acceptance, improved body image, and interpretation of one's attitudes, behaviour, and thinking patterns, as these factors can be monitored and/or modified to promote successful weight loss and maintenance.
Control(s) [route, frequency, total dose/day]	The usual care control group were provided consultation, at baseline (after randomization) and again at 16 weeks, with a research staff dietician, who also provided publicly available print material that described dietary and physical activity guidelines to promote weight loss and maintenance. The dietician initially discussed the interpretation of the participant's anthropometric data and the concepts of healthy weight and energy balance. Baseline energy requirements for weight maintenance were then calculated, and an energy intake level (accompanied by a menu plan based on food groups) to achieve a weight loss of 10% over a 6-month period was prescribed, involving a deficit of 500 to 1000 kcal/d, as per current recommendations . Specific sample meal plans and recommendations to increase physical activity were provided to each participant. Written materials and resources for useful strategies and skills, such as reading food labels, estimating serving sizes, and eating outside the home, were provided, as well as information for healthy food choices (e.g., the U.S. Department of Agriculture Food Guide Pyramid). Progress was reviewed and concepts and strategies were further discussed in the follow-up counselling session.

Baseline characteristics	Rock 2007
Number of intervention participants Number of control participants	35 35
Participating population	18 years and older; initial BMI 25.0 kg/m2 (overweight or obese) and <40 kg/m2, and a minimum of 15 kg over ideal

Appendix 41: Data extraction sheet; Rock 2007

	weight as defined by the 1983 Metropolitan Life Insurance tables. willing and able to participate in clinic visits and JC facility interactions at specified intervals and to maintain contact with the investigators for two years; willing to allow blood collections; and capable of performing a simple step test for assessing cardiopulmonary fitness.
Sex [female %]	100%
Age [mean years (SD)]	42 (11) (intervention) 40 (12) (control)
HbA1c [mean % (SD)]	Authors do not report this
BMI [mean kg/m2 (SD)]	34.2 (3.7) (intervention) 33.8 (3.4) (control)
Duration of disease [mean years (SD)]	Authors do not report this
Ethnic groups [%]	White non-Hispanic 20 (57) intervention 20 (57) control Hispanic 5 (14) intervention 11 (31) control African-American 6 (17) intervention 1 (3) control Asian-American 1 (3) intervention 1 (3) control Other 3 (9) intervention 2 (6) control
Duration of intervention [mean ... (SD)]	6 months
Duration of follow-up [mean ... (SD)]	12 months
Co-medications	Authors do not report this
Co-interventions	Authors do not report this
Co-morbidities	Authors do not report this

Matrix of study endpoints	Rock 2007
Intervention(s)	Change in weight (kg)† -7.2 (6.7) 6 months -6.6 (10.2) 12 months Change in percent weight†-7.8 (7.2) 6 months -7.1 (10.8) 12 months Change in BMI (kg/m2)†-2.6 (2.5) 6 months -2.4 (3.8) 12 months Change in waist circumference (cm)† -7.1 (8.4) 6 months -8.2 (10.5) 12 months

Appendix 41: Data extraction sheet; Rock 2007

	Change in hip circumference (cm)†-5.7 (5.1) 6 months -6.2 (7.8) 12 months Change in step test (heart rate per 30 seconds)‡ -6.4 (6.4) 6 months -4.1 (6.8) 12 months Alpha-carotene (M)* 0.12 (0.14) baseline 0.13 (0.11) 6 months 0.18 (0.15)† 12months Beta-carotene (M)* 0.48 (0.65) baseline 0.73 (0.73)‡ 6months 0.67 (0.57)† 12months Lutein (M) 0.36 (0.19) baseline 0.38 (0.23) 6months 0.40 (0.23) 12months Lycopene (M) 0.71 (0.35) baseline 0.69 (0.27) 6months 0.94 (0.35)† 12months Beta-cryptoxanthin (M) 0.15 (0.13) baseline 0.20 (0.16)‡ 6months 0.15 (0.07) 12months Total carotenoids (M)* 1.82 (1.2) baseline 2.12 (1.18) 6months 2.33 (1.04) 12months HDL cholesterol (mg/dL) 50 (15) baseline 51 (13) 6months 61 (15)† 12months LDL cholesterol (mg/dL) 113 (40) baseline 109 (32) 6months 104 (26) 12 months Total cholesterol (mg/dL) 189 (37) baseline 181 (33) 6months 188 (30) 12months Triglycerides (mg/dL)§ 112 (52) baseline 98 (42) 6months 107 (59) 12months Sex hormone binding globulin (nM) 56.4 (49.6) baseline 72.7 (59.3) 12months 72.8 (50.7) 12months Insulin (U/mL)* 22.7 (12.3) baseline 17.7 (9.9)‡ 6 months 18.8 (10.8) 12months
Control (s)	Change in weight (kg)† -0.3 (3.9) 6 months -0.7 (5.5) 12months

Appendix 41: Data extraction sheet; Rock 2007

	Change in percent weight† -0.3 (4.5) 6months -0.7 (6.0) 12months Change in BMI (kg/m2)† -0.2 (1.5) 6months -0.3 (2.1) 12months Change in waist circumference (cm)† -1.1 (6.5) 6months -0.2 (7.0) 12months Change in hip circumference (cm)† - 0.3 (3.3) 6 months -0.3 (5.0) 12months Change in step test (heart rate per 30 seconds)‡ - 2.9 (6.3) 6 months -3.4 (6.3) 12months Alpha-carotene (M)* 0.13 (0.11) baseline 0.09 (0.07)‡ 6 months 0.16 (0.14) 12months Beta-carotene (M)* 0.46 (0.39) baseline 0.42 (0.32) 6 months 0.50 (0.31)† 12 months Lutein (M) 0.37 (0.16) baseline 0.40 (0.16) 6 months 0.41 (0.17) 12 months Lycopene (M) 0.77 (0.24) baseline 0.74 (0.23) 6 months 1.03 (0.32)† 12months Beta-cryptoxanthin (M) 0.16 (0.10) baseline 0.18 (0.15) 6months 0.16 (0.10) 12months Total carotenoids (M)* 1.90 (0.81) baseline 1.81 (0.65) 6 months 2.26 (0.69) 12months HDL cholesterol (mg/dL) 52 (13) baseline 53 (11) 6months 56 (17) 12months LDL cholesterol (mg/dL) 121 (35) baseline 119 (26) 6months 120 (31) 12months Total cholesterol (mg/dL) 193 (42) baseline 196 (34) 6months 196 (37) 12months Triglycerides (mg/dL)§ 99 (50) baeline 102 (51) 6months 102 (50) 12months

Appendix 41: Data extraction sheet; Rock 2007

	Sex hormone binding globulin (nM) 68.9 (74.5) baseline 79.4 (69.3) 6months 69.8 (43.2) 12months Insulin (U/mL)* 17.9 (8.4) baseline 19.6 (10.0) 6 months 19.7 (9.2) 12months
Primary endpoint(s)	
Secondary endpoint(s)	
Other endpoint(s)	
Effect size	At 6 months, change in weight by intent-to-treat (ITT) analysis was -7.2 (6.7) kg and -7.8% (7.2%) in the intervention group vs. -0.3 (3.9) kg and -0.3% (4.5%) in the control group (n =35 for each; p <0.01). One-year ITT analysis revealed significantly greater change in weight, percent weight, BMI, and waist and hip circumferences in the intervention vs. control group. Completers at 1 year exhibited change in weight of -7.3 (10.4) kg for the intervention group (n =32) vs. -0.7 (5.6) kg for controls (n 33) (p < 0.01), and -7.8% (11.1%) weight change for the intervention group vs. -0.7% (6.2%) for controls (p < 0.01).

Adverse events	Rock 2007
All adverse events	Authors do not report this

Appendix 42: Data extraction sheet

Bibliographic Details	
Study ID	
Author (first)	
Journal	
Year	
Volume	
Pages	
Language	
Type (e.g. full paper, conference proceeding, unpublished report)	
Corresponding author and contact details	

Character of included studies	
Methods	Randomised controlled clinical trial (RCT) Randomisation ratio Superiority design Non-inferiority design Equivalence design Parallel/ crossover/cluster/factorial RCT Controlled clinical trial (CCT)
Participants	Exclusion criteria Inclusion criteria Diagnostic criteria
Interventions	Number of study centres Country/location Setting Treatment before study Titration period
Outcomes	Outcome(s) (as stated in the protocol/registered trial documents or publication of study design) Primary outcome(s) Secondary outcome (s) Other outcome (s)
Study details	Run-in period Study terminated before regular end

Appendix 42: Data extraction sheet

Publication details	Language of publication Commercial funding Non-commercial funding Publication status (peer review journal) Publication status (journal supplement) Publication status (abstract)
Stated aim for study	Quote “ “
Notes	

Risk of bias	unclear / low / high risk
Random sequence generation (selection bias)	
Allocation concealment (selection bias)	
Blinding (performance & detection bias)	
Blinding of participants and personnel (performance bias)	
Blinding of outcome assessment (detection bias)	
Incomplete outcome data (attrition bias)	
Selective reporting (reporting bias)	
Other bias	
Comments	

Overview of study populations	Study ID
Intervention Control Total	
(n) screened Intervention Control Total	
(n) randomised Intervention Control	

Total	
(n) safety Intervention Control Total	
(n) ITT Intervention Control Total	
(n) finishing study Intervention Control Total	
(%) of randomised patients finishing study Intervention Control Total	
Total I C T	

Description of interventions	Study ID
Intervention(s) [route, frequency, total dose/day]	
Control(s) [route, frequency, total dose/day]	

Baseline characteristics	Study ID
Intervention	
Control	
Participating population	
Sex [female %]	
Age [mean years (SD)]	

Appendix 42: Data extraction sheet

HbA1c [mean % (SD)]	
BMI [mean kg/m2 (SD)]	
Duration of disease [mean years (SD)]	
Ethnic groups [%]	
Duration of intervention [mean ... (SD)]	
Duration of follow-up [mean ... (SD)]	
Co-medications	
Co-interventions	
Co-morbidities	

Matrix of study endpoints	Study ID
Intervention(s)	
Control (s)	
Primary endpoint(s)	
Secondary endpoint(s)	
Other endpoint(s)	

Adverse events	Study ID
I: Intervention (s)	
C: Control (s)	
T: Total	
Deaths [n]	
I:	
C:	
T:	
All adverse events [n] I: C: T:	
Severe / serious adverse events [n] I: C: T:	

Appendix 42: Data extraction sheet

Drop-outs due to adverse events [n] I: C: T:	
Hospitalisation [n] I: C: T:	
Out-patient treatment [n] I: C: T:	
All hypoglycaemic episodes [n] I: C: T:	
Severe / serious hypoglycaemic episodes [n] I: C: T:	
Definition of severe / serious hypoglycaemia	
Nocturnal hypoglycaemic episodes [n] I: C: T:	
Definition of nocturnal hypoglycaemia	
Symptoms [n] I: C: T:	

Author survey	unclear / low / high risk
Intervention(s)	

Appendix 42: Data extraction sheet

Control (s)	
study author contacted	
study author replied	
no communication possible	

Appendix 43: Groupon advertising

Exante Meal Replacement Packs: Two, Four or Six Week Plans from £37.59 With Free Delivery (Up to 70% Off)

More Info!

Amount:
from £37.59

Discount67% **You save**£75.76

Highlights

- Two, four or six week meal replacement plan
- Three packs per day
- Packs consist of shakes, soup and carbonara
- Calorie-controlled plan
- Includes shaker
- Suitable for vegetarians

The Goods Stuff
GROUPON
FREE Shipping

Fine Print

Purchase: May buy up to 5; limit 1 per redemption.
Further information: Valid on option purchased only. By purchasing a Groupon, you are purchasing a voucher for the underlying products or services described above. Orders fulfilled by Exante. Original values verified on 1 May 2013 at 1.13pm.
See the rules that apply to all deals.

Delivery: Free. Allow up to 2 working days for delivery.

Using Your Groupon: Place order by 18 May at www.exantediet.com/groupon-uk, by copying and pasting your Groupon code into required field.

For more on Groupon Goods, pricing and delivery, see the FAQ.

Appendix 43: Groupon advertising

Box of 84 Alli Weight Management Tablets from £31.99 (39% Off)

mHnPaq9TQanxp

More Info!

Amount:
from £31.99

Discount39% **You save**£20.14

Highlights

- Designed to support weight management programmes
- Three capsules per day, taken with meals
- Recommended for those with a BMI of 28 or above
- Each box contains 84 tablets, lasting up to four weeks
- One, two or three boxes available

Fine Print

Purchase: May buy up to 2; limit 1 per redemption.
Further information: Must be aged 18 or over. Suitable for those with a BMI of 28 or above. Consult a doctor before taking Alli if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Not suitable for pregnant or breast-feeding women, those taking Ciclosporin, Warfarin or other blood thinning medications, if allergic (hypersensitive) to orlistat or any of the ingredients of Alli, or those with cholestatis or with problems absorbing food (chronic malabsorbtion syndrome) as diagnosed by a doctor. Valid on option purchased only.By purchasing a Groupon, you are purchasing a voucher for the underlying products or services described above. Orders fulfilled by Golds Pharmacy.
See the rules that apply to all deals.

Delivery: £3.95. Allow up to 7 working days via Royal Mail or UK Mail. Signature required.

Using Your Groupon: Place order by 24 November 2013 at http://www.goldspharmacy.co.uk/search/alli, by selecting your required product and copying and pasting your Groupon code into required field.

For more on Groupon Goods, pricing and delivery, see the FAQ.

Appendix 44: Output data

Figure 19 output data:

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.140[a]	.020	.007	619.03122

a. Predictors: (Constant), Age

b. Dependent Variable: Total_cost_cwlps

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B	
		B	Std. Error	Beta			Lower Bound	Upper Bound
1	(Constant)	114.381	236.893		.483	.631	-357.143	585.904
	Age	6.435	5.108	.140	1.260	.211	-3.732	16.601

a. Dependent Variable: Total_cost_cwlps

Appendix 44: Output data

Figure 20 output data:

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.109[a]	.012	-.001	621.50954

a. Predictors: (Constant), imd_score

b. Dependent Variable: Total_cost_of_cwlps

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B	
		B	Std. Error	Beta			Lower Bound	Upper Bound
1	(Constant)	482.447	109.367		4.411	.000	264.756	700.137
	imd_score	-4.115	4.231	-.109	-.973	.334	-12.537	4.307

a. Dependent Variable: Total_cost_of_cwlps