

Behavioural weight management practices within primary care

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ABSTRACT

The prevalence of obesity is high and the primary care setting enables treatment to be offered to large numbers of people. This thesis investigates behavioural weight management interventions in primary care. A noninferiority analysis was used to examine whether four behavioural weight management programmes differed in weight loss at three and 12 months. Commercial programmes resulted in similar weight losses and the NHS programme was inferior at three months, with an inconclusive result at 12 months.

GPs can refer patients to commercial weight management programmes, however not all people use these types of programmes. There is a need to find simple effective interventions that can be offered in primary care. Self-weighing may be one such strategy for weight loss; a randomised controlled trial investigated this. There were no significant differences in weight loss between baseline and three months. Self-weighing may be more effective for weight loss maintenance as people have developed skills to manage their weight. A quasi randomised controlled trial was used to investigate this and found encouragement to self-weigh prevented 0.7 kg weight regain. A systematic review and meta-analysis investigated the effect of self-weighing. Overall, self-weighing as part a multicomponent weight loss intervention resulted in greater weight loss but isolated there was no evidence of effectiveness.

In conclusion commercial weight management programmes result in similar weight losses and patients could be referred to such programmes by primary care. Self-weighing may be an effective strategy that primary care practitioners could advise patients to use combined with other behavioural strategies.

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LIST OF ABBREVIATIONS

Adult	Aged ≥ 18 years
BMI	Body Mass Index
BOCF	Baseline Observation Carried Forward: a method to handle missing data in which people who were not followed up are assumed to weigh the same amount as they did at the beginning of the study.
CI	Confidence Interval: an estimated range of values within which the population parameter lies within it, and is used to indicate the reliability of an estimate.
Completer	An individual who provided weight-loss data at the follow-up assessment
CVD	Cardiovascular Disease
GP	General Practitioner
HR	Hazard Ratio
IMD	Index of Multiple Deprivation
Kcal	Kilo calorie: a measure of energy intake
LOCF	Last Weight Observed Carried Forwards: a method of imputation for missing weight data
MET	Metabolic Rate
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PCT	Primary Care Trust
QOF	Quality Outcomes Framework
RCT	Randomised Controlled Trial
RR	Relative Risk
SBPCT	South Birmingham Primary Care Trust
SD	Standard Deviation: a statistic that describes the variation or 'spread' in individual data around the mean
SE	Standard Error: like standard deviation this is a measure of the variation in data around the mean; however, SE accounts for the sample size.
SES	Socioeconomic Status: an economic and sociological combined total measure of a person's work experience and of an individual's or family's economic and social position in relation to others, based on income, education and occupation.

TABLE OF CONTENTS

Abstract.....	II
Acknowledgements	II
List of Abbreviations	III
List of Tables.....	XI
List of Figures.....	1
CHAPTER 1	1
1.0 Introduction.....	1
CHAPTER 2.....	3
2.0 Literature review.....	3
2.1 What is obesity?	3
2.2 Obesity prevalence: International and England.....	4
2.3 Consequences of obesity	6
2.3.1 Public health consequences.....	6
2.3.2 Economic consequences.....	10
2.4 Epidemiology of obesity.....	10
2.4.1 Ethnicity	10
2.4.2 Gender and age.....	11
2.4.3 Socioeconomic status	12
2.4.3.1 Income.....	12
2.4.3.2 Education.....	12
2.5 Causes and influences of obesity.....	13
2.5.1 Energy expenditure	14
2.5.2 Energy intake.....	16

2.5.3 Environmental causes.....	17
2.5.4 Physical activity environment	17
2.5.5 Food environment	18
2.5.6 Biological causes of obesity.....	20
2.5.7 Psychosocial influences.....	20
2.5.8 Summary of causes of obesity.....	21
2.6 Treatment of obesity.....	22
2.6.1 Weight loss and weight maintenance for clinical benefits	22
2.6.2 Current weight management guidelines in the UK	25
2.6.3 Behavioural weight management interventions in primary care.....	27
2.6.4 Summary	30
2.6.5 Weight loss maintenance.....	31
2.6.6 Behaviour change techniques.....	33
2.7 Self-monitoring of behaviour	35
2.7.1 Self-regulation theory.....	35
2.7.2 Self-monitoring of diet and physical activity	35
2.7.3 Self-weighing	36
2.7.3.1 Evidence for self-weighing	36
2.7.3.2 Self-weighing isolated and as part of a multi-component intervention.....	38
2.7.3.3 Adverse effects of self-weighing.....	38
2.8 Summary of the evidence	40
2.8.1 Objectives.....	41
CHAPTER 3.....	42
3.0 Which weight loss programmes are as effective as Weight Watchers: A prospective cohort noninferiority analysis.....	42
3.1 Introduction	42
3.2 Participants and methods.....	45
3.2.1 Study design	45
3.2.2 Setting and recruitment of participants	45

3.2.3 Allocation.....	46
3.2.4 Measurements.....	46
3.2.5 Demographic and baseline information	46
3.2.6 Weight loss interventions	46
3.2.7 Data analyses.....	47
3.2.8 Noninferiority analyses	48
3.3 Results	50
3.3.1 Baseline characteristics	50
3.3.2 Noninferiority analyses	52
3.4 Discussion.....	55
3.4.1 Findings in relation to other research.....	56
3.4.2 Strengths and limitations.....	57
3.5 Conclusion.....	58
CHAPTER 4.....	59
4.0 A randomised controlled trial of the effectiveness of self-weighing as an isolated weight loss intervention (SCALE DOWN).....	59
4.1 Introduction	59
4.2 Patients and methods	61
4.2.1 Design	61
4.2.2 Participants.....	61
4.2.3 Inclusion criteria.....	61
4.2.4 Exclusion criteria.....	62
4.2.5 Settings.....	62
4.2.6 Components across both groups.....	62
4.2.7 Intervention group.....	63
4.2.8 Control group	66
4.2.9 Outcomes.....	66
4.2.10 Sample size.....	67
4.2.11 Allocation and randomisation	67

4.2.12 Blinding.....	68
4.2.13 Data analysis	68
4.3 Results	70
4.3.1 Primary outcome	72
4.3.2 Adherence to self-weighing	73
4.3.3 Implementation of self-weighing	76
4.3.4 Weight management strategies.....	76
4.3.5 Physical activity	78
4.3.6 Adverse Events.....	78
4.3.7 Feedback from participants	79
4.4 Discussion.....	80
4.4.1 Strengths and limitations	81
4.4.2 Results in the context of other studies	82
4.5 Conclusions	84
CHAPTER 5	85
5.0 Regular self-weighing to promote weight maintenance after intentional weight loss: a quasi-randomised controlled trial	85
5.1 Introduction	85
5.1.1 Lighten Up.....	86
5.2 Methods and procedures	88
5.2.1 Setting and recruitment of participants	88
5.2.2 Allocation.....	89
5.2.3 Primary outcome and assessments	90
5.2.4 Demographic information	90
5.2.5 Weight loss maintenance intervention	90
5.2.6 Data analysis	91
5.2.6.1 Imputation of missing weight data	91
5.2.6.2 Analyses	93
5.3 Results	94

5.3.1 Characteristics at the start of weight loss maintenance intervention.....	94
5.3.2 Baseline characteristics of those with missing and recorded weight data.....	97
5.3.3 Primary analysis.....	98
5.3.4 Per protocol analysis.....	99
5.3.5 Effect modification by type of weight loss treatment received and amount of initial weight loss.....	100
5.4 Discussion.....	101
5.4.1 Main findings of the study.....	101
5.4.2 What is already known on this topic.....	101
5.4.3 What this study adds.....	102
5.4.4 Limitations of this study.....	103
5.5 Conclusion.....	104
CHAPTER 6.....	105
6.0 Is self-weighing an effective weight management tool: A systematic literature review and meta-analysis.....	105
6.1 Introduction.....	105
6.2 Methods.....	107
6.2.1 Trial eligibility criteria.....	107
6.2.2 Search strategy.....	108
6.2.3 Study selection.....	109
6.2.4 Data collection process.....	110
6.2.5 Data items.....	110
6.2.6 Risk of bias in individual trials.....	110
6.2.7 Summary measures.....	111
6.2.8 Synthesis of results.....	112
6.2.9 Analysis strategy.....	112
6.3 Results.....	113
6.3.1 Study selection.....	113
6.3.2 Study characteristics.....	114

6.3.3 Risk of bias.....	123
6.3.4 Synthesis of results.....	128
6.3.5 Weight loss.....	128
6.3.6 Weight maintenance.....	134
6.3.7 Weight loss maintenance.....	134
6.3.8 Adverse events	135
6.4 Discussion.....	135
6.4.1 Strengths and limitations.....	139
6.4.2 Future research	140
6.5 Conclusions and implications.....	140
CHAPTER 7.....	141
7.0 Discussion, implications and conclusions	141
7.1 Summary of findings	141
7.2 Strengths and weaknesses.....	143
7.3 Research in relation to other findings.....	146
7.4 Future research	148
7.5 Implications and conclusions	149
7.5.1 For commissioners	149
7.5.2 For patients.....	150
7.5.3 For healthcare professionals.....	150
7.6 Conclusions	150
References	152
Appendix 1	162
Appendix 2	164
Appendix 3	168

Appendix 4	169
Appendix 5	170
Appendix 6	173
Appendix 7	175
Appendix 8	177
Appendix 9	178

LIST OF TABLES

Table 1: The international classification of weight status*	3
Table 2: Pros and cons of daily versus weekly weighing.....	37
Table 3: Weight loss at three and 12 months in the Lighten Up trial ¹²⁴	49
Table 4: Characteristics of participants at baseline according to weight loss programme	52
Table 5: Mean weight differences compared to Weight Watchers at three and 12 months	53
Table 6: Behavioural change techniques used in the intervention based on CALO-RE taxonomy ⁹⁵	65
Table 7: Baseline characteristics of participants	72
Table 8: Analyses of weight change between baseline and three months.....	73
Table 9: Mean number of weight loss strategies used at baseline and three months	77
Table 10: Change in physical activity levels between baseline and three months	78
Table 11: Participants ratings about the study and the weight management practitioners.....	80
Table 12: Weight change using different methods to impute missing weight data.....	93
Table 13: Baseline characteristics of participants	96
Table 14: Baseline data of participants providing weight data and those missing weight data	99
Table 15: Mean weight change and difference in weight change between the control and intervention groups.	100
Table 16: PICO for review	108
Table 17: Search strategy	108
Table 18: Study characteristics.....	116
Table 19: Risk of bias.....	124
Table 20: Weight change outcomes.....	131
Table 21: Behavioural strategies used in interventions	133

LIST OF FIGURES

Figure 1: Global prevalence of obesity ⁸	5
Figure 2: Number of years of obesity and all-cause mortality risk ¹⁸	8
Figure 3: Number of years of obesity and risk of mortality from CVD ¹⁸	8
Figure 4: Number of years of obesity and risk of mortality from cancer ¹⁸	9
Figure 5: Obesity prevalence in men and women (aged ≥ 16 years) ²⁷	11
Figure 6: Change in risk factors by weight loss category in the Look Ahead study ⁶⁷	24
Figure 7: An example of an adult obesity care pathway ⁸⁰	26
Figure 8: Weight regain in the Finnish Diabetes Prevention study ⁹²	31
Figure 9: Weight regain in the Diabetes Prevention Programme	32
Figure 10: Weight loss and regain (kg) of Lighten Up trial groups ¹²⁴	49
Figure 11: Participant inclusion flow diagram	51
Figure 12: Noninferiority plot: adjusted mean difference in weight change at three months ..	54
Figure 13: Noninferiority plot: adjusted mean difference in weight change at 12 months	55
Figure 14: CONSORT flow diagram	71
Figure 15: Frequency of self-weighing and weight change with a line of best fit using an objective measure	75
Figure 16: Frequency of self-weighing and weight change with a line of best fit using self- reported measures	75
Figure 17: Study design	89
Figure 18: Exclusions and participant flow for control and intervention groups	97
Figure 19: Prisma diagram	114
Figure 20: Forest plot of weight loss studies at programme end	132
Figure 21: Forest plot of weight loss studies with follow-up	132

Figure 22: Forest plot of weight maintenance trials 134

CHAPTER 1

1.0 INTRODUCTION

This research was funded by a National Institute of Health Research and Research Support Facility studentship. My supervisors (Dr Amanda Daley, Professor Kate Jolly and Dr Amanda Lewis) and Professor Paul Aveyard formed and helped develop a draft research proposal to gain funding for the studentship. I further developed the research proposal and was principal investigator for the individual studies included. I have described the involvement of the other researchers at the start of each chapter. A list of publications arising from the work can be found in Appendix 1.

Chapter 2 explores the literature about the prevalence, causes and treatment of obesity in adults (aged ≥ 18) in the primary care setting. Chapter 3 investigates whether four behavioural weight management programmes offered by weight management services in Birmingham, result in similar weight losses to each other, using a noninferiority analysis. This is important because patients, commissioners and primary care practitioners need to understand which services are helpful to people to manage their weight.

Chapter 4 explores the role of self-weighing as an isolated weight loss strategy using a randomised controlled trial design. There is limited time placed on consultations with health care professionals which necessitates short and simple weight loss strategies. Self-weighing may be one such strategy that individuals who want to lose weight can be encouraged to use.

In addition to helping people lose weight, it is important to find ways to help people maintain weight loss for sustained health benefits. Chapter 5 examines whether a pragmatic weight loss maintenance intervention, delivered after receiving a weight loss programme results in less

weight regain at 12 months follow-up, relative to a comparator group (quasi-randomised controlled trial). This maintenance intervention focuses on promoting self-weighing as a weight management tool to prevent weight regain.

Chapter 6 presents a systematic review of self-weighing for weight management, this includes the trial presented in chapter 4. Chapter 7 discusses the findings, areas for future research and the implications for healthcare services.

CHAPTER 2

2.0 LITERATURE REVIEW

The aim of this chapter is to present an overview of the literature related to obesity. This includes the definition and measurement of weight status, health consequences and possible causes and treatment of obesity. This overview will provide justification for the research I have conducted and presented in this thesis. As the focus of my thesis is about the treatment of adult obesity using behavioural practices within primary care, I have not reviewed in depth the literature about obesity prevention, treatment outside of primary care or literature involving children.

2.1 What is obesity?

Obesity is an accumulation of excess body fat that can result in health being endangered either through medical illness or early mortality^{1,2}. The most common measure of weight status is body mass index (BMI) which is calculated by dividing the weight of the person (kg) by their squared height in metres³. Based on this index, people can be classified into weight status categories of increasing health risk as shown in Table 1.

Table 1: The international classification of weight status*

Classification	BMI range kg/m²
Underweight	≤18.5
Healthy weight	18.5 to 24.99
Overweight	25.0 to 29.99
Obese class I	30.0 to 34.99
Obese class II	35.0 to 39.99
Obese class III	≥40

* Adapted from the WHO global database on BMI³

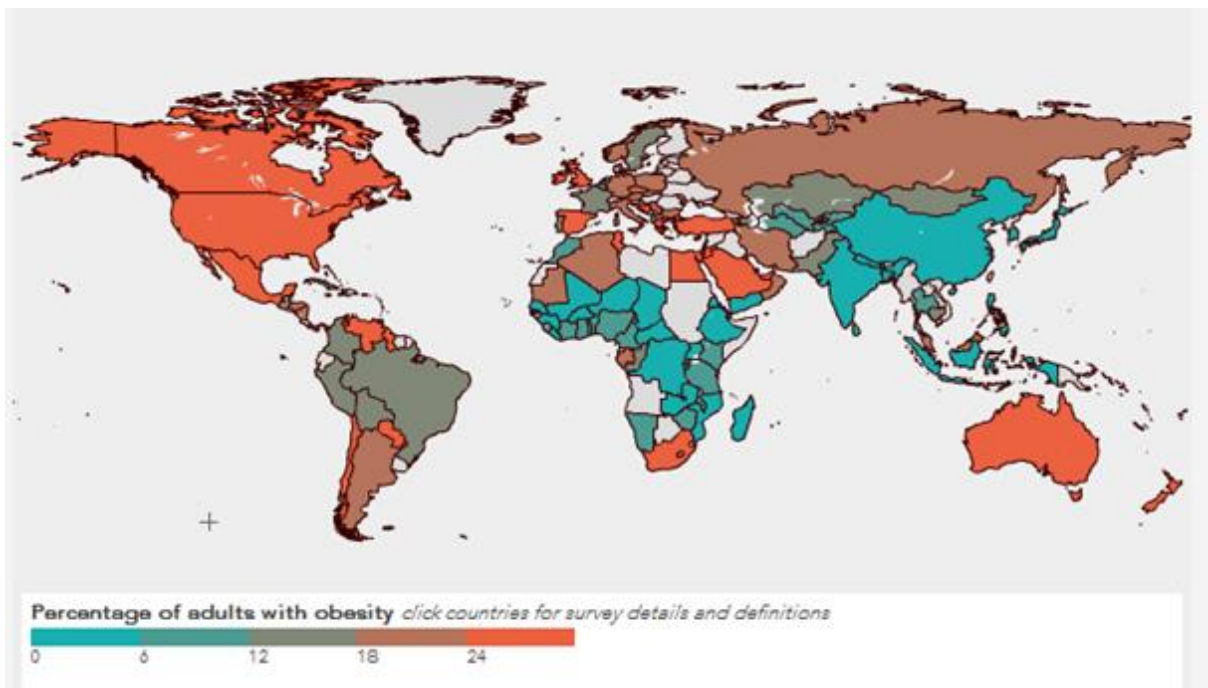
Whilst BMI is currently the most common method for classifying weight status at a population level there are limitations to this approach. For example, BMI is not a direct measure of body fat and therefore does not take into account the difference between muscle and fat, or that body composition changes as people age^{2,4}. This is important as people can be mistakenly classified as overweight, but not experience health consequences associated with such weight classification. However, they could be considered to have a lower health risk when it is plausible they have a higher fat percentage. The limitations of BMI should be considered by health care professionals when offering weight management advice and services, to ensure the people who need help are given it.

Another consideration for health care professionals when offering weight management and advice to patients is ethnicity. The recommended cut off points for weight classifications are derived from research using mainly white participants. There is evidence that some Asian populations have a higher risk of type 2 diabetes and cardiovascular disease (CVD) at lower BMIs, which may need to be considered in the treatment of obesity when using BMI classifications⁵. However, it is not clear what these BMI thresholds should be, therefore commissioners of weight management services are asked to make a clinical judgement for the needs of patients they are responsible for⁶.

2.2 Obesity prevalence: International and England

The prevalence of obesity varies across the world but has globally increased in the last 20 years⁷. Figure 1 illustrates the global prevalence of obesity for adults. Whilst the data that has been used to develop this map is not strictly comparable or age standardized, it provides an illustration of the global obesity prevalence⁸. As shown, at least 24% of the adult population are classified as obese in many countries, presenting a global problem that needs addressing.

Figure 1: Global prevalence of obesity⁸



In England there has been a sharp increase in the prevalence of adult overweight and obesity. In 1993 58% of adult men and 49% of women were classified as overweight and obese compared to 65% and 58% respectively in 2011⁹. Subsequently health care practitioners within primary care will have many patients who would benefit from weight loss. An example was given in a report of brief weight loss interventions in primary care: “physicians with a patient list of 2000 adults will typically have 520 (26 %) patients who are obese (BMI ≥ 30 kg/m²), and 840 men and 640 women (42 % and 32 % respectively) who are overweight (BMI 25.0–29.9 kg/m²)”¹⁰. Additionally many more patients will be gaining weight and at subsequent high risk of becoming overweight or obese.

2.3 Consequences of obesity

2.3.1 Public health consequences

The well-established consequences of having an unhealthy weight include an increased risk of development of type 2 diabetes, CVD, musculoskeletal problems, many cancers and subsequently early mortality¹¹⁻¹³. A systematic review and meta-analysis has found a 5 kg/m² increase in BMI, in men, was associated with increased relative risk (RR) of oesophageal adenocarcinoma (RR 1.55 95% CI 1.33 to 1.74), thyroid (RR 1.33 95% CI 1.04 to 1.70), colon (RR 1.24 95% CI 1.20 to 1.28) and renal (RR 1.24 95% CI 1.15 to 1.34) cancers¹². In women there were strong associations with endometrial (RR 1.59 95% CI 1.50 to 1.68), gallbladder (RR 1.59 95% CI 1.02 to 2.45), oesophageal adenocarcinoma (RR 1.51 95% CI 1.31 to 1.74) and renal (RR 1.34, 95% CI 1.25 to 1.43) cancers¹².

The risk of developing diabetes is much greater for obese persons. A meta-analysis of cohort studies found obese persons had a 7.19 (95% CI 5.74 to 9.0) higher RR of developing diabetes compared to normal weight persons. Additionally for persons that were overweight the risk was 2.99 (95% CI 2.42 to 3.72), which is still high¹⁴. As well as greater risks of diabetes and cancer, musculoskeletal problems are associated with obesity. Hooper suggests increasing BMI is associated with osteoarthritis of the knee, carpal tunnel syndrome and rotator cuff tendinitis¹⁵. There is also some evidence of increasing BMI being associated with lower back pain. Although there is some difficulty interpreting this data due to differing methods of classification of back pain¹⁵.

Another method of examining public health consequences of obesity/excess body weight is exploring mortality. A collaborative meta-analysis was undertaken on 57 prospective studies to examine baseline BMI and risk of mortality¹⁶. There were approximately 900,000 adults

(61% male) and the mean follow-up was 13 years. The lowest mortality risk was for participants whom had a BMI between 22.5 to 25 kg/m². A 5 kg/m² increase in BMI above 25 kg/m² was associated with a 29% increase in overall mortality (hazard ratio (HR) 1.29 95% CI 1.27 to 1.32) ¹⁶. Results were adjusted for age, sex and smoking status at baseline, but there was no measure of physical activity, diet or change in weight over time. Although, this analysis did not take into account participants losing or gaining weight during follow-up, it does indicate that having a higher BMI at baseline is associated with an increased risk of early mortality independent of weight change.

Flegal and colleagues found similar findings to the collaborative analysis (above) in a meta-analysis of all-cause mortality and BMI category (97 articles, 2.88 million participants) ¹⁷. A BMI ≥ 30 kg/m² resulted in a HR of 1.18 (95% CI 1.12 to 1.25) greater risk of mortality compared to healthy weight participants (BMI 18.5 to 24.9 kg/m²) ¹⁷. The authors further examined whether different classes of obesity resulted in greater mortality, and found only those with a BMI ≥ 35 kg/m² had a significantly higher HR (1.29 95% CI 1.18 to 1.41) compared to healthy weight participants ¹⁷. Findings suggest higher classifications of obesity result in greater risk of early mortality. This study only included mortality as an outcome measure and the number of years of morbidity was not measured. Quality of life is an important issue as well as the potential cost of ill health to health care services and employment ¹⁷.

Other research has explored the duration of being obese and risk of mortality using data from the Framingham Heart Study (n=5036) ¹⁸. This cohort study followed up adult participants for 48 years from enrolment (aged 28-82 years at enrolment), with objective examinations at two year intervals ¹⁸. Seventy five percent of the cohort were not obese at any examination,

however for 25% of the cohort the onset of obesity was at approximately 50 years of age¹⁸. As the number of years being classified as obese increased, so did the HR of mortality (see Figure 2). Although this slightly decreased if participants had been obese over 25 years, it could be plausible that most obese participants had died earlier. The authors also examined mortality risk from CVD and cancer separately and report similar patterns (Figure 3 and Figure 4).

Figure 2: Number of years of obesity and all-cause mortality risk¹⁸

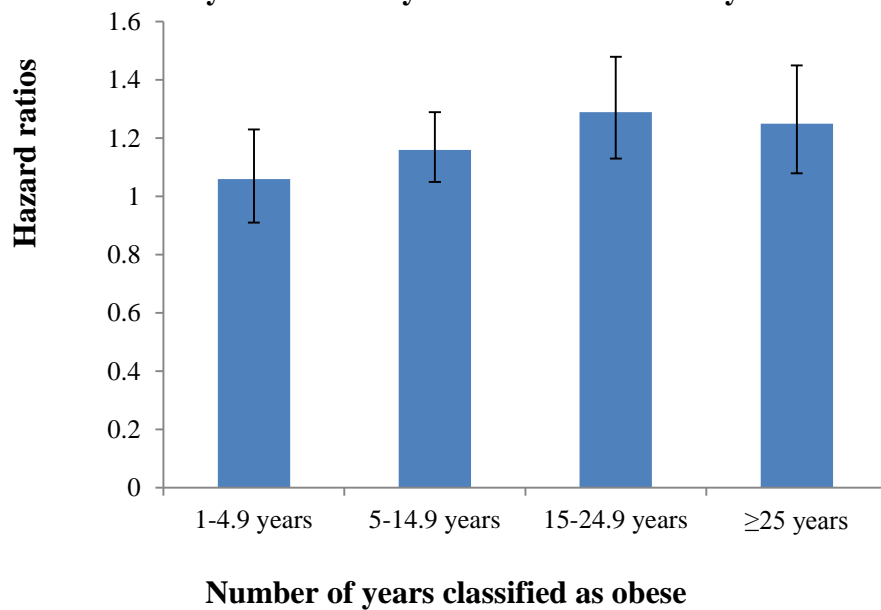


Figure 3: Number of years of obesity and risk of mortality from CVD¹⁸

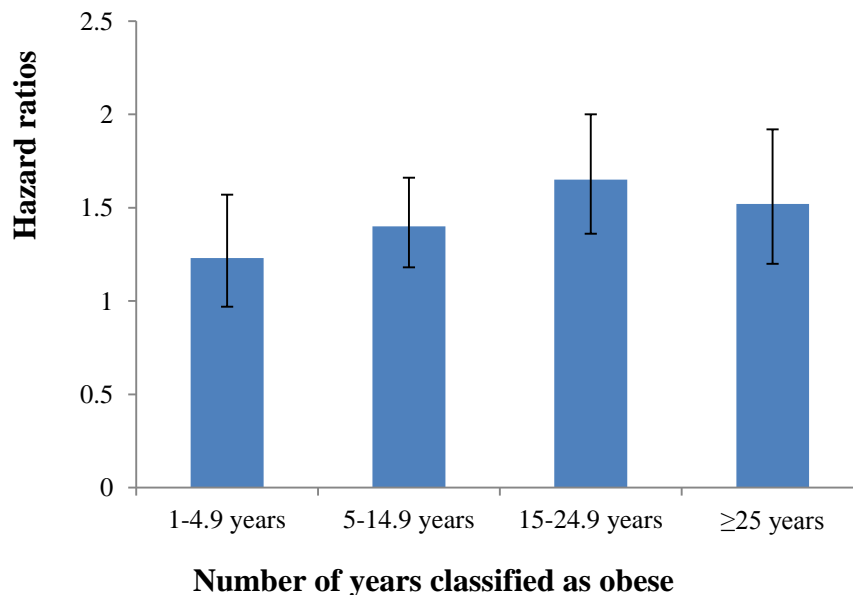
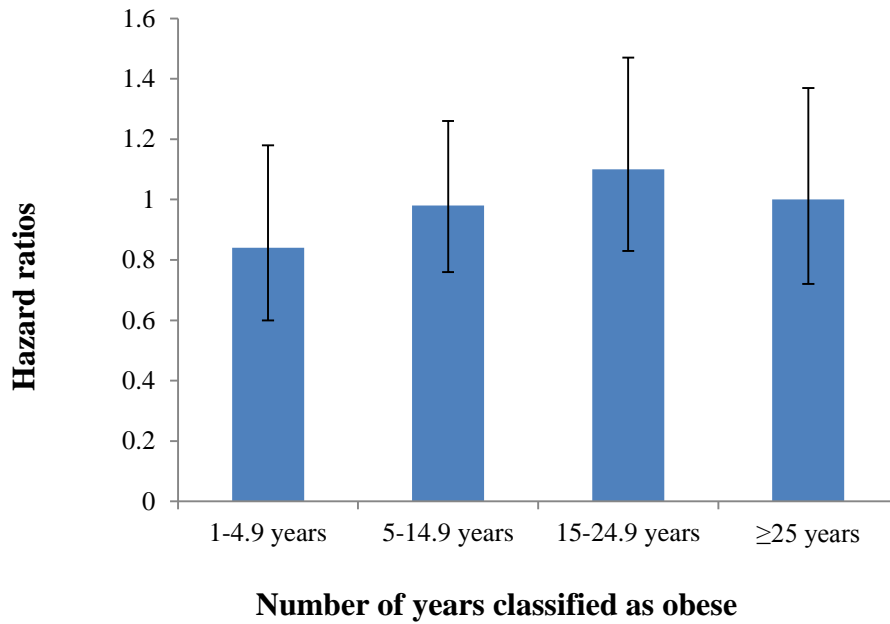


Figure 4: Number of years of obesity and risk of mortality from cancer¹⁸



Participants in this cohort study ¹⁸ probably had a later onset of obesity than the current population and so there may be greater health implications in the future. Particularly as obesity prevalence in children has increased and obesity tracks into adulthood ¹⁹. These data illustrate that treatment of obesity is vital to help individuals to lose weight and sustain weight loss to reduce the likelihood of early mortality from a range of diseases.

In conclusion, obesity contributes to a range of diseases and may lead to early mortality. Independent of mortality we also need to try and reduce incidences of cancer, CVD, diabetes and musculoskeletal problems which are partially caused by poor/unhealthy lifestyles, and in particular associated with obesity. The number of years being classified as obese seems to be important for health outcomes. If we can find ways to help the population lose weight and maintain weight loss the incidence of diseases may decrease.

2.3.2 Economic consequences

There are two main costs associated with obesity, these being health and employment costs²⁰. The economic burden of obesity is largely driven by the increased risk of type 2 diabetes, CVD and cancer, and the utilisation of health services associated with these diseases²¹. However the costs related to employment include premature mortality and morbidity through certified sick leave and welfare costs²⁰. Overweight and obesity alone was estimated to cost the NHS in 2007 £4.2 billion and is predicted to rise to £9.7 billion by 2050²². However, it is extremely difficult to predict future costs as the results are based on extrapolating data and predicting futures trends and costs of services.

2.4 Epidemiology of obesity

Identifying demographics associated with energy imbalance may mean we can target services at specific groups of people who may need different interventions to change behaviour. This section will examine ethnicity, age, gender, socioeconomic status and the association with obesity.

2.4.1 Ethnicity

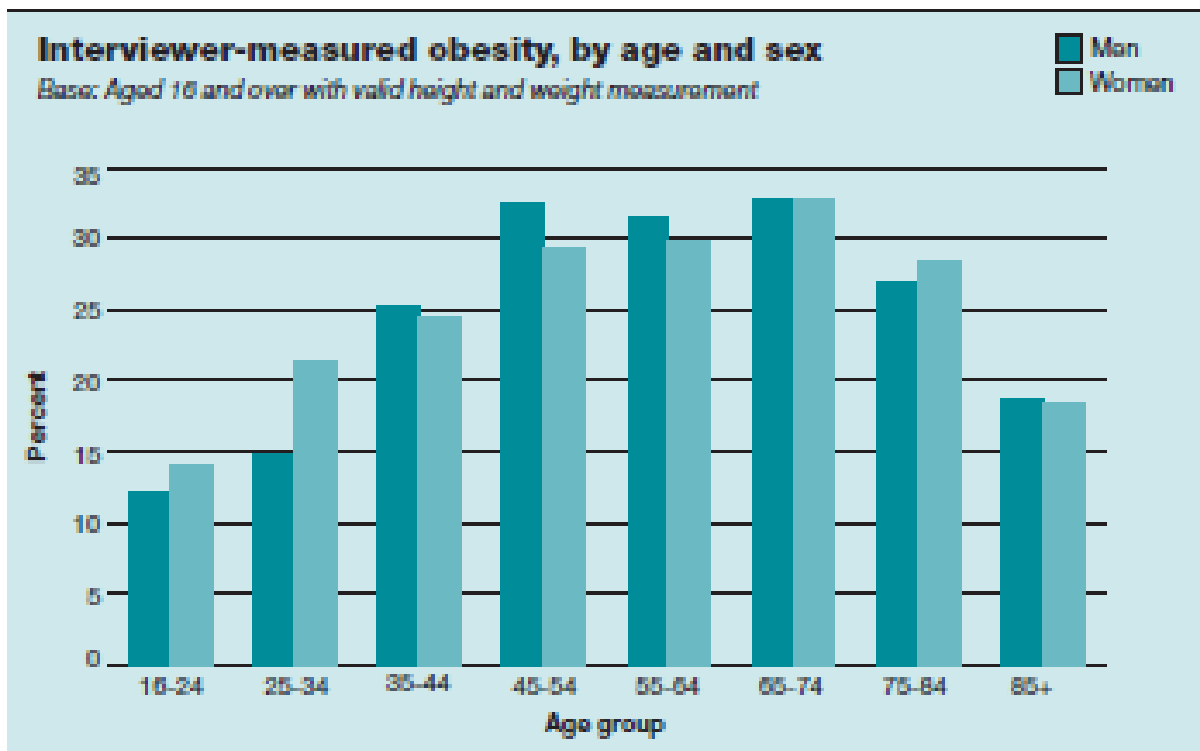
There are health disparities within ethnic minority groups in the UK, for example accessing services and having poorer health outcomes²³. There is, however, limited evidence to determine if ethnicity is associated with obesity in the UK. A systematic review (15 studies) found that data was equivocal for the prevalence of obesity between Caucasians and South Asians, although the research inferred that South Asian people tended to have higher measures of abdominal fat. Chinese populations had the lowest BMIs and black populations had the highest BMIs²⁴. It has been suggested that BMI cut offs should be lower for Asian ethnic groups, however NICE have concluded that there is not enough evidence for such an

approach ⁶. Additionally the National Obesity Observatory have suggested that there is no straight forward relationship between obesity and ethnicity and there is a lack of nationally representative data ²⁵.

2.4.2 Gender and age

National survey data (74 countries, objectively measured) indicates the prevalence of obesity can differ between men and women and different age groups ²⁶. The analysis found that for every two obese adult males there were three obese females ²⁶. In the UK there are a slightly higher percentage of obese females compared to males (26% versus 24%) but more males were classified as overweight compared to females (41% males versus 33% females) ⁹. However the prevalence of obesity varied by age, as seen in Figure 5 ²⁷. Obesity prevalence generally increases with age; for men the greatest increase is seen at ages 45-54 years compared with ages 25-34 years for women.

Figure 5: Obesity prevalence in men and women (aged ≥16 years) ²⁷



2.4.3 Socioeconomic status

2.4.3.1 Income

Income, as a measure of socioeconomic status, is associated with the prevalence of obesity i.e. countries with higher incomes having greater obesity levels. Nevertheless, there is within-country variance in the association between socioeconomic status and obesity. An analysis of women aged 15-49 years in 54 low and middle income countries found that increases in wealth resulted in rises in BMI²⁸. Participants in the highest income quartile had 2.6 greater odds (95% CI 2.56 to 2.66) of being overweight compared to the lowest quartile (poorest)²⁸. For example, evidence from Brazil partially supports these findings as across a 28 year period obesity was initially associated with higher income but now appears to effect the poor more disproportionately²⁹. In England there is no association with household income and BMI in men, however women with lower household incomes have a higher BMI (mean 27.7 kg/m²) than those in the most affluent quintile (mean 26.5 kg/m²)³⁰.

2.4.3.2 Education

Educated people may be more informed about the health risks of behaviours and therefore obesity levels may be lower in these people, or the relationship of education may be confounded by income. Roskam and colleagues collated evidence from European national health surveys (n=127,018, aged 25-44 years) in 19 countries to examine the association of education and being overweight or obese³¹. All analyses were conducted separately by gender, and education was classified into four different groups ranging from higher education to none or primary education. A relative index of inequalities was calculated which measured the risk of being overweight/obese in the lowest education group compared to the highest education group, adjusted for age and weighted by country population. The total relative

index of inequalities was 1.10 (95% CI 1.07 to 1.13), suggesting that lower education is associated with higher risk of overweight and obesity. In women, overweight and obesity was more common in those with lower educational levels; relative index of inequalities 1.98 (95% CI 1.91 to 2.06). This may suggest that some people lack the appropriate education about diet and physical activity to manage their weight, although the analysis did not take into account income of individual participants, which may be a confounding factor.

As identified there are a range of factors that appear to be negatively associated with obesity. For some population groups managing their weight may be harder than others. In particular a higher socioeconomic status is associated with obesity as countries develop; however this inverts to an association with deprivation, including being less educated. Weight management services particularly in the UK may need to be targeted towards those who are socio-economically disadvantaged to try and reduce inequalities in health.

2.5 Causes and influences of obesity

The simplistic cause of obesity is an imbalance between energy intake and expenditure. However, as documented in the Foresight Report, underlying causes of weight gain can be complex and are often interrelated³². The authors of the Foresight Report developed a system map of the influences of energy balance³². This map clearly demonstrates there are many biological, environmental, and social factors that influence energy balance that also interact with each other. Over 100 variables are included and as such the map is too complex to present in a thesis. This section will explore research about the main causes of obesity (i.e. energy expenditure and intake) but will also recognise the environmental, biological and psychosocial influences.

2.5.1 Energy expenditure

Physical activity is one part of the energy equation and may contribute to obesity prevalence by people not being active enough for the energy they are consuming. Physical activity is defined as ‘any bodily movement produced by skeletal muscles that results in energy expenditure’³³. Recommendations in the UK are for adults to take part in at least 150 minutes of moderate intensity physical activity per week to benefit health³⁴. However this recommendation is mainly based on self-reported physical activity in longitudinal observational studies and therefore more physical activity may be needed. It has been suggested obese populations may need more physical activity, approximately one hour per day for weight loss and weight loss maintenance³⁵.

Worldwide it has been found (122 countries surveillance data) that 31.1% (95% CI 30.9-31.2) of adults are physically inactive³⁶. One explanation for decreased physical activity is that occupational physical activity (data from the USA) has decreased in the past five decades with 48% of the workforce in moderate intensity occupations in 1960 compared to only 20% in 2008³⁷. Overall estimated energy expenditure from occupational activity has thought to have reduced by 100 calories per day³⁷. In contrast leisure time physical activity seems to have increased in the past 20 to 30 years in higher income countries and may be as a result of decreased occupational physical activity³⁸. Activity levels are still low despite of this increase.

The Health Survey for England provides data about physical activity using a complex random probability design based on post codes to enable representation of the population living in private households³⁹. Participants (n=15,102) were asked to recall their physical activity in the past four weeks prior to interview. In 2008 a subset of participants were asked to wear an

accelerometer (n=4507) for seven days which gave an objective measurement of physical activity. Using self-reported data only 39% of men and 29% of women met the recommended physical activity levels. This decreased further using accelerometer data: only 6% of men and 4% of women achieved recommended levels ³⁹.

There is limited evidence about sedentary behaviours and patterns across countries but due to decreased occupational physical activity, it might be hypothesised that sedentary behaviour has increased. Sedentary behaviour is defined as individual behaviours where sitting or lying is the dominant posture and energy expenditure is low ⁴⁰. This includes activities such as screen time, motorised transport, sitting to read and listening to music. A review of sedentary behaviour and health outcomes (in particular overweight and obesity) found that two thirds of adults self-reported spending more than two hours per day during their leisure time watching TV and using a computer ⁴⁰. However one study within the review used accelerometers to objectively assess sedentary behaviour and found men spent on average 7.5 hours sedentary and women 7 hours across the day ⁴⁰. These increases in technology and energy saving devices may be contributing to energy imbalance.

To summarise, occupational physical activity has decreased and although leisure time physical activity has increased it seems the amount is not enough to influence the prevalence of obesity. Very few people appear to meet the recommended physical activity targets and to reduce weight, more physical activity may be needed. The public should be advised to increase their physical activity and reduce sedentary behaviour to meet the recommendations. Increasing physical activity is a potential way to assist the energy imbalance.

2.5.2 Energy intake

The second component of the energy balance equation is consuming too many calories for the energy being expended. The change in food consumption is difficult to measure as diet is usually self-reported and underestimated, therefore we do not have robust data about how food consumption has directly contributed to increased obesity levels ⁴¹. Research suggests that the population has moved towards a diet high in saturated fats, sugars, refined foods and low fibre ⁴².

Using nationally repeated cross sectional surveys in the USA (1977 to 2006) Duffey and Popkin examined the contribution of energy density, portion sizes and eating and drinking occasions with change in daily total energy ⁴³. Total daily energy intake increased between 1997 and 2006 from 1803 kcal (SD 12.6) to 2374 (SD 17.8) kcal. Portion sizes also increased from 523 g (SD 3.2) per eating occasion to 588 g (SD 7.6). Energy density did not change, however the frequency of eating occasions increased from 3.8 (SD 0.03) to 4.9 (SD 0.04) times per day. Using national survey data, Hill and colleagues estimated that an excess of even 100 kilocalories per day through limited expenditure and/or excess intake, could be responsible for the population level weight gain ⁴⁴. In the UK annual data about food intake and purchases is collected in a sample of households (n=13,196) through self-reported food diaries over a two week period ⁴⁵. It has been found that energy intake is estimated to be approximately 5% higher than the estimated average requirement for adults. However in 2012 and since 2009 there has been a 4.1% decrease in intake ⁴⁵. Over consumption of food is part of the cause of obesity but it is unclear which aspect contributes the most and needs to be targeted for intervention. People should be advised to reduce energy consumption and given the strategies to do so.

2.5.3 Environmental causes

It has been suggested that obesity is the result of people responding normally to the obesogenic environment and thus increasing energy consumption and decreasing energy expenditure. The environment is thought to be a major contributor, due to the rapid rises seen in obesity prevalence. This rapid rise cannot solely be explained by genetics or psychosocial factors⁴⁶. This section will explore the physical activity and food environment to consider the constraints and context of the environment when trying to change individuals' behaviour.

2.5.4 Physical activity environment

The built environment may contribute to causing obesity by reducing opportunities and discouraging people to be physically active. There has been an increasing amount of research in this area with one review finding 60 articles out of 70 were published since 2005⁴⁷. This systematic review summarised European specific evidence on the relationship between the physical environment and different physical activity domains in adults⁴⁷. Convincing evidence was classified as 51-100% of studies being associated in one direction, with less than 25% of studies having an association in the other direction. There were positive associations of walk ability (how friendly the area is to walk in) for total physical activity, and specifically walking for transport. It was found that leisure time physical activity was not associated with the number of recreational facilities. The environment may be more important for active transport as leisure time physical activity may be more purposeful and planned. The review was limited by the research available; most studies were cross sectional and only one was longitudinal. The authors excluded interventions and experiments but there is a lack of experimental evidence in this area in any case^{48,49}.

There are many interrelated variables and methods of measurement that need to be established when investigating environmental influences on physical activity. It is difficult to distinguish the different effects of the built environment and different facets of physical activity⁴⁹. Data should also be stratified by age as there may be individual differences in behaviour due to autonomy. Having an understanding of how the environment may constrain participant's physical activity may help tailor advice health professionals give to patients. For example if people do not feel their neighbourhood is safe to walk in then asking them to do so is unlikely to result in behaviour change.

2.5.5 Food environment

Articles in the Lancet's series on obesity suggested the changes in the global food system, including reductions in the costs and time it takes to get food is one of the main drivers of the rise in prevalence of obesity⁴⁶. Cohen suggests that people do not tend to make decisions about food and eating in rational and conscious ways. Therefore as a society, we need, to regulate the food environment⁵⁰. A systematic review (n=38 studies) evaluated the relationship between the local food environment and diet, and explored five different aspects⁵¹:

1. Availability- the adequacy of supply of healthy foods
2. Accessibility – the ease of getting healthy foods
3. Affordability – food prices and perceptions
4. Acceptability – attitudes and attributes of the food environment
5. Accommodation – how well local sources accept and adapt to local resident's needs.

There were positive associations found between availability of healthy food and diet, although the literature was inconsistent for accessibility and affordability. There were very few studies

that included acceptability and accommodation, however in particular fruit and vegetable consumption (an indirect measure of a healthy diet) was associated with food quality and store opening hours ⁵¹. It was problematic to compare studies as each study differed in the measurement of environment and diet, also a common limitation found in studies investigating the environment and physical activity. This review included studies only investigating areas surrounding residence, however, people spend a lot of their time at work which could also be taken into account. The research suggests that the availability of healthy food is associated with a healthier diet.

Another review examined factors influencing food choices in social, physical and macro environments ⁵². There were a range of factors that influenced food choice including social norms, size of dinnerware and utensils, and media use whilst eating. Furthermore people are eating outside of the home more, which is associated with increased food consumption. Access to a supermarket was associated with a healthier diet ⁵². Marketing of foods was also associated with consumption and it tends to be the energy-dense nutrient poor products that are heavily marketed ⁵². Levitsky and Pacanowski suggest that people believe they have free will and choices about what they eat, however there are unconscious nudges to eat in the environment ⁵³.

In conclusion the relationship between behaviour (energy intake and expenditure) and the environment is complex and multifaceted. The population must be eating too much relative to the amount of expenditure because of the high prevalence of overweight and obesity ⁴⁶. Understanding the constraints of an obesogenic environment is important when trying to get individuals to change their behaviour.

2.5.6 Biological causes of obesity

Genetics influence how the body controls ingestion, digestion, absorption and metabolism, and how nutrients are distributed among various tissues, organs and systems⁵⁴. It has been theorised that some genes may impair these systems and thus people gain weight. It has also been suggested that heritable factors are likely to be responsible for 45-75% of the inter-individual variation in BMI⁵⁵.

Research investigating the association between genetics and obesity is in the early stages and there is no current prevailing theory^{54,56}. It is also recognised that the rapid rise in obesity prevalence cannot be explained by a change in genetics as this takes many years, therefore only lifestyle factors can explain the sudden rise. Conversely it has been found that those more susceptible to obesity are getting heavier and it may be because of the interaction between genes and the obesogenic environment⁵⁷. Some people are able to maintain a healthy weight in the obesogenic environment and therefore genetics are likely to be one of many factors contributing to this⁵⁸. Health professionals need to be aware that some people may have more difficulty managing their weight, although it is problematic to identify these individuals.

2.5.7 Psychosocial influences

There are many different societal influences on obesity, including, but not limited to media/marketing, family, social networks and culture that could contribute to the causes of obesity. One large longitudinal (n=12,067) study investigated weight gain and the association in weight gain in their friends, siblings, spouse and neighbours over a 32 year period⁵⁹. Results inferred that geographic location was not associated with increased weight gain but social distance was. This means that if a friend became obese then the persons chances of becoming

obese increased by 57% (95% CI 6 to 123) and if the social networks were of the same sex, the probability of becoming obese increased by 171% (95% CI 59 to 326). The authors suggested there may be a person to person spread of obesity due to social networks especially as immediate neighbours becoming obese did not increase the probability of becoming obese. These social networks may also affect individuals' psychological beliefs and behaviours through normalisation.

Identifying why some individuals are able to manage their weight may provide us with information to develop interventions. Restraint and self-regulation are some of the individual factors that may influence weight management. Dietary restraint is described as the intentional control of food intake to lose weight or avoid weight gain⁶⁰. Self-regulation is a process involving conscious efforts to monitor oneself, evaluate and appraise against goals which can reinforce behaviour^{61,62}. A review has discussed the evidence of dietary restraint and self-regulation to examine the effect on weight management⁶³. Having higher dietary restraint is associated with having a lower weight in cross sectional designs⁶³. Self-regulation ability or skills may be linked to the success of dietary restraint and successful resistance may improve self-regulation and transfer to domains other than weight management⁶³. Patients could potentially learn and improve self-regulatory behaviours, however there is a lack of research using experimental designs⁶³.

2.5.8 Summary of causes of obesity

Collectively the evidence suggests the causes of obesity are complex and inter related. The changes in environment are a major contributor and could explain the rapid rise in prevalence due to decreased occupational physical activity and increased availability of food. Despite this evidence, the environment cannot explain why half of the population can manage their

weight. There is a need to find ways to help people manage their weight in the obesogenic environment by giving them the tools to do so and improve self-regulation of eating and physical activity behaviours.

2.6 Treatment of obesity

The treatment of obesity can consist of behavioural modification, surgery or pharmacological means; here the focus is on behavioural modification in primary care settings. The following section will explore weight loss and weight maintenance for clinical benefits and behavioural interventions.

2.6.1 Weight loss and weight maintenance for clinical benefits

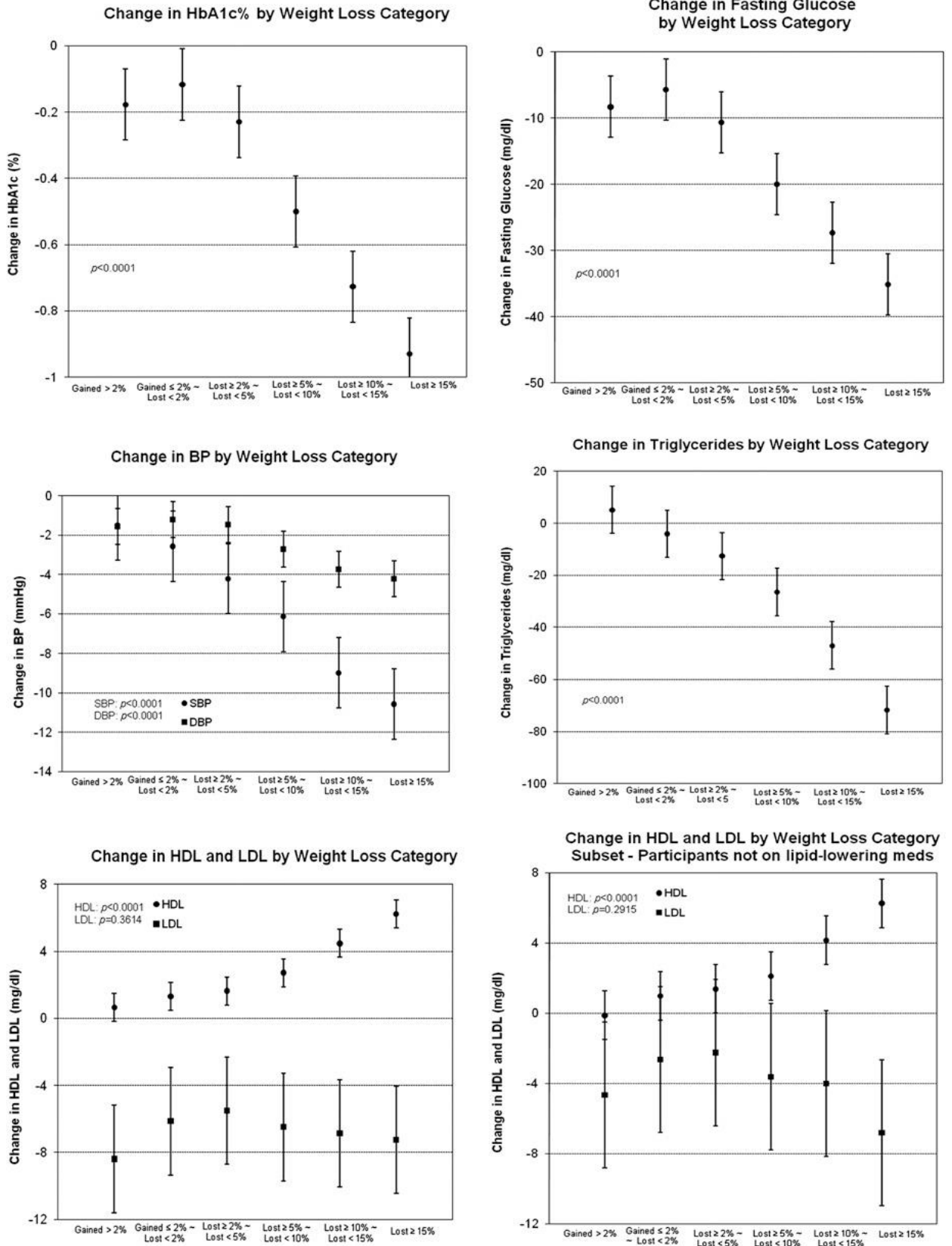
The amount of weight loss for clinical benefits, such as improvements in glycaemia, blood pressure, triglycerides and HDL cholesterol, is thought to be 5-10% of initial body weight⁶⁴⁻⁶⁷. A 5% weight loss has also been associated with an improvement in self-reported disability in patients that have been diagnosed with knee osteoarthritis⁶⁸.

An observational study of 5145 participants taking part in the Look Ahead weight loss study (40.5% male) found that greater weight loss resulted in greater clinical benefits⁶⁷. Figure 6 is taken from the Look Ahead paper and shows that in all markers of health there seems to be a linear relationship with the amount of weight loss. The greater the amount of weight loss the greater the clinical benefits for health. The Diabetes Prevention Programme has shown that an intensive programme of lifestyle intervention that aimed to achieve and maintain a weight loss of at least 7% of initial body weight reduces the incidence of diabetes in persons that are at high risk⁶⁹. A ten-year follow-up of those in the Diabetes Prevention Programme showed a

continued reduction in incidence of diabetes, even though some weight was regained ⁷⁰. Thus reducing weight in high risk individuals can help prevent the development of diabetes.

Although some weight regain may not affect clinical outcomes such as diabetes incidence, it is not clear how much weight loss needs to be maintained for other clinical benefits. However the number of years being classified as obese is associated with early mortality, ¹⁸ therefore maintenance of weight loss is important, especially as the prevalence of obesity has increased in younger age groups ⁷¹. It is plausible that for musculoskeletal problems weight loss needs to be maintained as there is less pressure on the body's joints. Modest weight loss results in clinical health benefits and at least a 5% weight loss should be recommended for individuals. They should further be encouraged to maintain this weight loss, to reduce the likelihood of early mortality.

Figure 6: Change in risk factors by weight loss category in the Look Ahead study⁶⁷

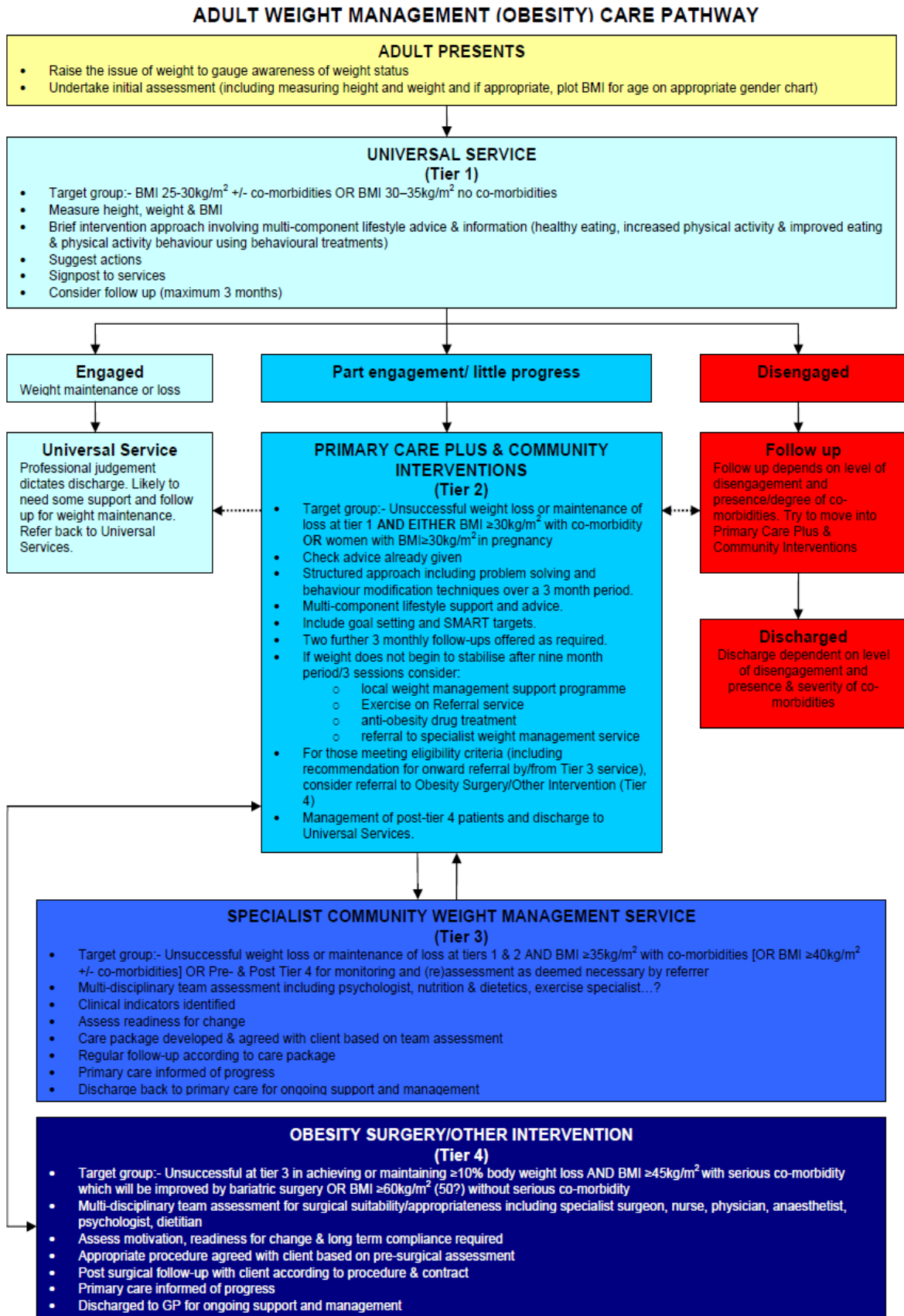


2.6.2 Current weight management guidelines in the UK

In the UK the clinical and public health guidance recognises the multifaceted approach needed to help reduce the prevalence of obesity ⁷². An example of the weight management care pathway for adults is illustrated in Figure 7. The pathway provides guidance of what services should be offered at different levels of obesity and risk. It also recognises that patients should receive Tier 1 services before moving to Tier 2 services, if Tier 1 is not effective. This is important due to the increasing costs associated as patients move through the pathway.

The focus of this thesis is on interventions suitable for Tier 1 and Tier 2. In the UK as part of the quality and outcomes framework (QOF) General Practitioners (GP's) receive payment for recording patients with a BMI ≥ 30 kg/m² ⁷³. This also means that practices could pro-actively target patients that would benefit from weight loss, however this is not a requirement of the QOF payment scheme and is not actively done. Primary care physicians potentially have a big role in addressing obesity in their patients, but this is a role they exercise uncommonly ⁷⁴⁻ ⁷⁶. One key reason is that primary care physicians may not believe that weight management interventions are effective ⁷⁷. Evidence from observational studies suggests that it may be helpful if they were to raise the topic of excess body weight as it may be enough to motivate some patients to lose weight ^{78,79}. However no data from RCTs exist to support that notion. A further issue is that there is a lack of available services for primary care health professionals to refer patients to.

Figure 7: An example of an adult obesity care pathway ⁸⁰



It is recommended that primary care health professionals should discuss the range of weight management options with, and continue to monitor their patients ⁷². Health professionals should take appropriate measurements and then conduct an assessment that covers a range of topics, as documented in Box 1 ⁷². However, a typical primary care consultation is only 10 minutes and within this timescale it is likely to be impractical to even raise the issue and discuss all of these items. It also illustrates some of the difficulties primary care health professionals' face when trying to help people manage their weight especially, when other barriers to intervening are fear of offending patients and lack of confidence of what to say ¹⁰.

Box 1: Factors to be assessed when treating obesity ⁷²

- Presenting symptoms and underlying causes of overweight and obesity
- Eating behaviour
- Co morbidities (such as type 2 diabetes, hypertension, CVD, osteoarthritis, dyslipidaemia and sleep apnoea) and risk factors using the following tests – lipid profile, blood glucose and blood pressure measurement
- Lifestyle – diet and physical activity
- Psychosocial distress and lifestyle, environmental, social and family factors – including family history of overweight and obesity and co morbidities.
- Willingness and motivation to change
- Potential weight loss to improve health
- Psychological problems
- Medical problems and medication

2.6.3 Behavioural weight management interventions in primary care

Behavioural treatment is an approach used to help individuals identify changes they can make to manage their weight, and gives them the strategies to do so ⁸¹. The research reviewed here may not have been previously utilised in primary care, however there is the potential to refer patients to behavioural weight management programmes or implement strategies within primary care and thus are included here.

A comprehensive meta-analysis of RCTs assessed the effects of multi-component behavioural weight management programmes in overweight and obese adults compared to a minimal control group⁸². Thirty studies were included with 44 interventions. Of the studies, 15 were conducted in the USA, 69% of participants were females and the mean age was 49 years⁸². Results inferred that 12 to 18 months after baseline the mean difference between control and intervention groups was -2.6 kg (95% CI -2.8 to -2.4), significantly favouring the intervention group. That is participants who attended a behaviour weight management programme lost on average 2.6 kg more than someone in the control group, 12-18 months after starting the programme. It was also found that commercial weight management programmes resulted in a mean difference of -2.2 kg (95% CI -2.9 to -1.5) compared to primary care interventions where on average participants lost 0.5 kg (95% CI -1.3 to 0.4)⁸². This suggests that commercial weight management programmes result in greater weight loss and are thus more effective, than primary care led services.

Two large observational studies have provided data about two commercial programmes (Slimming World and Weight Watchers). Participants were referred to the programmes by health professionals^{83,84}. Both had similar starting BMIs (35.1 and 36.8) and the majority of participants were female. At the end of the 12 week programmes respectively, both had similar attendance rates (54 % and 58%). The authors reported weight change differently but the mean weight change for Slimming World participants was -4.0 kg (SD 3.7) and the median weight change for Weight Watchers was -3.6 kg (IQR -6.4 to -1.0)^{83,84}. Given that these were uncontrolled studies and control groups also generally lose weight, then, these findings are similar to those in the systematic review⁸².

An observational study has compared Weight Watchers, Rosemary Conley and Slimming World programmes. Dixon and colleagues⁸⁵ reported that participants (n=1047) attending Weight Watchers lost significantly more weight than those participating in Rosemary Conley (+0.24 kg) and Slimming World (+1.15 kg) at the end of the three month programmes. These differences were significant suggesting that some commercial weight management programmes may be more effective than others, but these data report weight loss in the first three months only. The most likely explanation of Dixon and colleagues' findings is attendance. Only 36% of people attending Slimming World completed the course of treatment compared to 56% for Weight Watchers and 45% for Rosemary Conley. Greater attendance has been shown to be associated with greater weight loss^{83,86}.

The Counter Weight programme is a model of an in house primary care weight management programme. Practice nurses and GP's receive training about how to deliver the programme⁸⁷. It is a structured behavioural programme to help patients lose weight and patients meet with practice nurses on a one to one basis (10- 30 minutes) or have group sessions (60 minutes)⁸⁷. A prospective evaluation found that at 12 months follow-up patients had lost 3.0 kg (95% CI 2.4 to 3.5) and at 24 months -2.3 kg (95% CI -3.2 to -1.4). However this is likely to overestimate weight loss as the analysis only considered those that were followed-up. These participants are likely to be the most motivated patients and most successful at weight loss. As there was no control group the weight loss is likely to be inflated as evidence suggests the control group would lose weight if they were given only advice⁸⁸. Additionally, an RCT of a structured one to one behavioural weight management programme in primary care found no difference between the control and intervention groups at 12 months⁸⁹.

The two interventions mentioned above in primary care have been relatively complex and time consuming to deliver. Lally and colleagues evaluated the efficacy of a simple weight loss intervention based on the principles of habit formation using an RCT design⁹⁰. Both intervention groups received the same leaflet consisting of seven simple behaviours associated with negative energy balance, two behaviours to improve awareness of food intake and one to promote routines. There was also a delayed intervention control group. The intervention groups only differed in frequency of weighing; in one group participants were weighed weekly and the other group they were weighed monthly for six months. At eight weeks (intention to treat [ITT] analysis) the weekly weighed group lost 1.5 kg (SD 1.5) and the monthly weighed group lost 2.0 kg (SD 2.1); both significantly more than the control group (-0.4 kg SD 1.5). However there was no significant difference between the intervention groups and therefore the weekly weigh ins were not the active treatment component⁹⁰. Participants (intervention groups only and last observed weight carried forwards [LOCF]) who provided follow-up data at six months continued to lose weight with a mean weight loss of 2.6 kg (SD 3.2) and 54% lost 5% or more of their initial body weight. However drop outs were high at six month follow-up (59%).

2.6.4 Summary

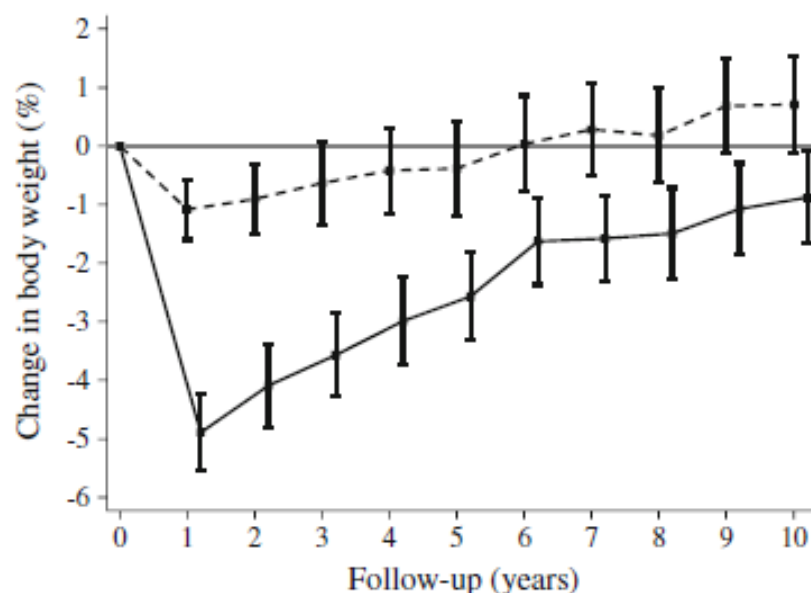
Behavioural weight management programmes can result in significant weight loss and it is probable that commercial programmes are more effective than primary care-based programmes. However commercial weight management programmes have not been compared directly to each other and therefore we cannot be sure whether they differ in weight loss. Tier one of the weight management care pathway suggests offering brief advice, therefore finding effective techniques would be beneficial. A review of behavioural weight management

practices that primary care providers could use within consultations concluded that self-monitoring, portion control, increasing sleep, limiting restaurant eating and TV viewing were effective strategies for weight loss ⁹¹. We need to identify effective interventions that can be utilised in primary care. Not all interventions are effective for all people, therefore if we have a paucity of interventions this would be important for public health.

2.6.5 Weight loss maintenance

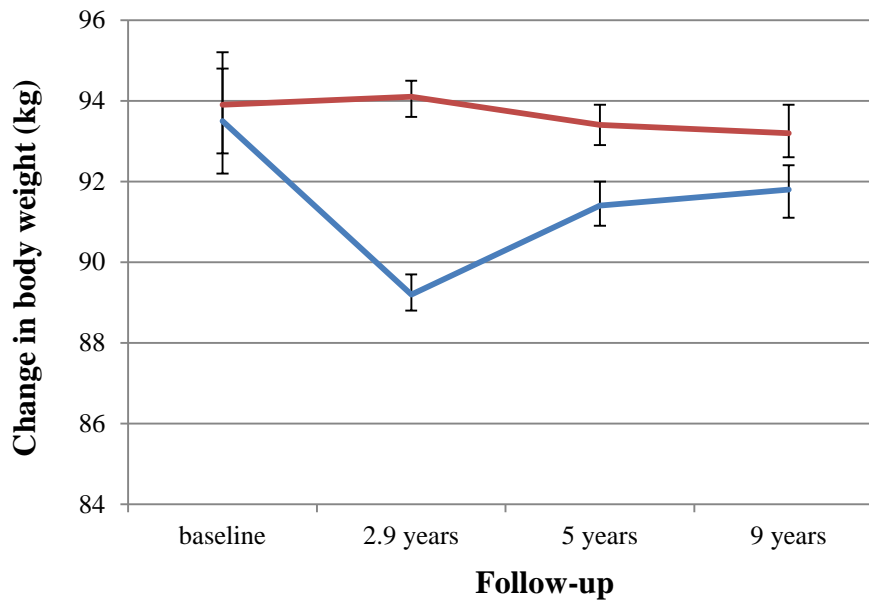
The comprehensive review of behavioural weight management programmes further assessed weight regain after receiving a weight loss programme ⁸². Only 11 studies had follow-up data after programme end (approximately 4874 participants). The intervention groups regained 0.047 kg (95% CI 0.029 to 0.066) more per month compared to the comparator groups. The Finnish Diabetes Prevention Study and the Diabetes Prevention Programme both show that participants generally regain the amount of weight lost as shown in Figure 8 and Figure 9.

Figure 8: Weight regain in the Finnish Diabetes Prevention study ⁹²



*Control group (dashed line) and intervention group (solid line)

Figure 9: Weight regain in the Diabetes Prevention Programme



* Intervention (blue line) and the control group (red line)

Maintenance of weight loss is problematic^{70,92} but some people are able to maintain their weight loss. The National Weight Control Registry is a cohort of participants that have successfully lost ≥ 13.6 kg of weight and maintained it for a minimum of one year. Those who maintain weight loss report taking part in high levels of physical activity, eating breakfast, consuming low-energy/ low fat diets, demonstrate a high level of dietary restraint and weigh themselves regularly⁶⁶. These participants were recently followed-up 10 years after being enrolled in the National Weight Control Registry. Participants still had considerable weight losses at ten years, although some weight had been regained (mean weight loss 31.3 kg [95% CI 30.8 to 31.9] at baseline vs. 23.1 kg [95% CI 22.3 to 23.9] at ten years follow-up)⁹³. Those who lost a large amount of weight initially sustained greater weight loss. Decreases in dietary restraint, leisure time physical activity, frequency of self-weighing and increases in percentage of fat and disinhibition were associated with greater weight regain⁹³.

Systematic reviews of weight management have found similar results; self-monitoring, opportunities for social comparison, peer/social support and maintaining contact with patients can positively reduce weight regain⁹⁴⁻⁹⁷. A review of RCTs of weight loss maintenance interventions included 42 studies and almost half were interventions after a very low calorie diet⁹⁸. Interventions (n=10) including more treatment components seemed to be more effective. Although this is in contrast to the findings of Michie and colleagues who found that adding more techniques does not necessarily improve effectiveness for promoting healthy eating and increasing physical activity⁹⁹. The findings may differ as there are perhaps different techniques used for weight loss and weight loss maintenance¹⁰⁰. It is plausible that the strategies participants learnt in their weight loss programme could interact with the weight loss maintenance intervention. As half of the studies were interventions after a very low calorie diet, this may need to be taken into account. There has also been a lack of weight loss maintenance interventions in a primary care setting and thus further research needs to investigate how primary care can help patients maintain weight loss.

2.6.6 Behaviour change techniques

Identifying the active components of an effective complex intervention is important so that these can be used in the limited time of a primary care consultation. Multi component interventions that are intensive can be costly and due to the limited time in a primary care-consultation these may not be implemented. It is also important to build interventions based on components that are known to be effective which are compatible with a primary care setting. Additionally, not all people want to go to behavioural weight management programmes therefore health care professionals need to offer effective alternative strategies.

Behaviour change techniques are ‘active ingredients’ in an intervention; they are designed to change behaviour and have to be observable, replicable and irreducible components of an intervention ¹⁰¹. Michie and colleagues used a meta-regression to identify effective behavioural change techniques for increasing healthy eating and physical activity in general populations ⁹⁹. Twenty-six behaviour change techniques were examined and on average 6 (SD 3.1) were used per intervention. Those interventions that contained multiple behaviour change techniques rather than just providing information resulted in an effect size of 0.31 (95% CI 0.26 to 0.36). Sensitivity analysis was undertaken to examine heterogeneity and ‘prompt self-monitoring of behaviour’ explained the greatest amount of variance (13%). Combining self-monitoring with the techniques in Box 2 resulted in an increased effect size of 0.42 (95% CI 0.30 to 0.54).

Box 2: Behavioural change techniques associated with increased effectiveness when used in conjunction with self-monitoring

1. Prompt intention formation
2. Prompt specific goal setting
3. Prompt review of behavioural goals
4. Provide feedback of performance

There were similar findings from a systematic review of behavioural interventions for obese adults with obesity-related co-morbidities ¹⁰². Three techniques showed significant moderator effects of weight change: provision of instructions (26.2 % of variance), prompt self-monitoring of behaviour (39.9% of variance), and relapse prevention (24.3% of the variance). Additionally a meta-regression of behavioural techniques associated with alcohol reduction

found that self-monitoring was associated with improved outcomes¹⁰³. Together, these findings suggest that self-monitoring may be an effective behaviour change technique within a behavioural modification intervention for weight management.

2.7 Self-monitoring of behaviour

2.7.1 Self-regulation theory

The ability to self-regulate dietary intake and expenditure and thus weight in an obesogenic environment may help people to manage their weight. Self-regulation theory is centred on the notion that individuals have the ultimate responsibility for their behaviour. For health outcomes this is about a process of conscious personal management which involves monitoring one's behaviour and evaluating it against set goals⁶¹. The aim of self-monitoring is to increase self-awareness and this heightened consciousness may lead to the individual making improvements to their lifestyle⁶¹. It can provide positive reinforcement for weight management and individuals are able to identify lapses in their progress and adjust their behaviour accordingly.

2.7.2 Self-monitoring of diet and physical activity

A systematic review reported the effect of self-monitoring of diet, physical activity and weight on weight loss in behavioural treatment studies (n=22 studies: 15 diet, one physical activity, six weight)⁹⁴. This section solely focuses on self-monitoring of diet and physical activity. Significant associations were found between self-monitoring of diet and weight loss. The only study of physical activity self-monitoring was associated with significantly greater weight loss. However no conclusions could be deduced due to the lack of studies. Adherence to self-monitoring was rarely reported and it is unknown how this changes over time. Most studies used descriptive designs with only six RCT's included. Studies rarely used an

objective measure of the self-monitoring strategy and previous research has demonstrated self-reported data can be biased ¹⁰⁴.

2.7.3 Self-weighing

Self-weighing may be an effective strategy for weight management as it allows individuals to identify changes in their weight and take actions to change their diet or increase their physical activity ^{105,106}. It is also a simple strategy primary care health professionals can give to their patients in the form of brief advice for weight management. Self-weighing has been suggested to be effective in three ways ¹⁰⁷:

1. Feedback – by self-weighing individuals are receiving information about how much they weigh and can evaluate against set goals.
2. Positive/negative reinforcement – individuals can receive positive reinforcement about healthy behaviours promoting weight loss, but also negative reinforcement of unhealthy behaviours that will mean they gain weight.
3. Priming – living in an obesogenic environment, self-weighing may make individuals more conscious about the environment ¹⁰⁸.

2.7.3.1 Evidence for self-weighing

The most recent systematic review of self-weighing (8 observational studies and 4 RCTs) reported that regular (at least once per week) self-weighing can facilitate weight management ⁹⁶. The National Weight Control Registry has found that self-monitoring of weight is a key component of successful weight loss maintenance ¹⁰⁵. Using data from the Health Works Trial, Van Wormer and colleagues ¹⁰⁹ published a prospective cohort study of 1222 adults (mean age 44.2, 61% female, 69% overweight or obese) to examine self-weighing and prevention of

weight gain over two years. On average weight gain was 0.65 kg (SD 6.1) between baseline and 24 months follow-up. Chapter 6 of this thesis presents a systematic review of studies of self-weighing using experimental designs, therefore the critical analysis of evidence will not be repeated here. The prescription of self-weighing that is most effective for weight management has not been established ⁹⁶. There are benefits of both daily and weekly weighing and these are described in Table 2.

Table 2: Pros and cons of daily versus weekly weighing

Daily	Weekly
Receive both positive and negative feedback immediately	Delayed feedback and therefore may not be able to reinforce positive/negative behaviour
May hide actual weight loss due to fluid changes	Closer to real weight change as more time to see difference.
May become obsessive	Less obsessive as not so intense
More likely to become a habit	Forget to do as not so often

The Health Works Trial researchers conducted a secondary analysis and found obese participants who weighed themselves daily lost on average 3.5 kg (SE 1.2) compared with a 1.0 kg (SE 1.0) loss if they weighed themselves weekly ¹⁰⁶. The intervention aimed to restructure the environment and therefore guidance about frequency of self-weighing was not given. Furthermore Milsom and colleagues ¹¹⁰ retrospectively investigated the weight management practices of 110 women 3.5 years after completing a weight loss intervention. Participants, who were successful at maintaining a weight loss of $\geq 5\%$ of initial weight, weighed themselves significantly more often and also reported engaging in more days of record keeping. Secondary analysis of a trial of a lifestyle intervention that instructed both groups to weigh daily found no significant difference in weight change at six months between

those who weighed daily and those who weighed less than daily ¹¹¹. However at 12 and 18 months there was a significant difference in weight change (-13.8 kg \pm 8.6 vs. -9.4 kg \pm 7.4 and -13.4 kg \pm 9.4 vs. -7.4 kg \pm 7.8) in favour of those that weighed daily.

2.7.3.2 Self-weighing isolated and as part of a multi-component intervention

Only two of the studies of the systematic review of self-weighing by VanWormer and colleagues ⁹⁶ were RCTs that had specifically isolated self-weighing as an intervention to promote weight loss, relative to comparators who did not receive self-weighing advice or support ^{112,113}. These trials were small (n=23 and 89) and contained other methodological concerns such as short follow-up and high attrition. These studies also reported conflicting results, with one study ¹¹² reporting no benefits to regular self-weighing for weight loss and Fujimoto and colleagues ¹¹³ reporting positive results for weight loss maintenance. The effect of isolating self-weighing for weight loss is not clear, although self-weighing seems to be effective as part of multi-component interventions ^{114,115}.

2.7.3.3 Adverse effects of self-weighing

It has been suggested that frequent weighing and in particular daily weighing may result in adverse psychological health outcomes ^{116,117}. A small study of normal weight women (n=30) were allocated to daily weighing for two weeks or weighing at the beginning and end of a two week period ¹¹⁸. Those in the weighing group had significant increases in anxiety and depression scores compared to the control group. However this was a very small study, short follow-up and involved females of normal weight aged 16 to 20 years. The results may differ for obese populations who need to regulate their weight.

In contrast, participants in the Stop Regain Trial (weight loss maintenance trial) who increased their frequency of self-weighing had an increase in dietary restraint scores (0.79 95% CI 0.49 to 1.08, $p < 0.001$), decreased disinhibition (-0.37 95% CI -0.61 to -0.13, $p = 0.003$) and decrease in depressive scores (-0.7 95% CI -1.13 to -0.27, $p = 0.002$). Participants weighing daily at 18 months were less likely to report four or more binge episodes per month than those who weighed less often (8.3% vs 16.8%)¹¹⁹. The authors also analysed those who self-weighed less than daily weighing at baseline and weighed themselves at least daily at 18 months and reported significant decreases in disinhibition ($p = 0.04$). Overall there was no evidence that self-weighing resulted in negative psychological consequences. In two other trials there were no significant associations of self-weighing frequency and body satisfaction at six months follow-up compared to control groups^{120,121}.

In a sensitivity analysis Steinberg and colleagues examined those in the intervention group (instructed to weigh daily) who did not lose weight and found no significant changes in body dissatisfaction or depressive symptoms. This provides some evidence that daily weighing does not lead to adverse outcomes even when there is no weight loss¹²¹. There were similar findings by Gokee LaRose and colleagues of 178 participants enrolled in a lifestyle intervention (53% female, mean age 52 years, mean BMI 35 kg/m²) that asked participants to weigh themselves daily¹²². There was no relationship between change of frequency of self-weighing and disordered eating. Those weighing daily achieved better weight losses ($p = 0.003$). Collectively research suggests there are no adverse outcomes from daily self-weighing and perhaps improvements in some measures. However more research is needed in other populations as the participants here were generally white, female and highly educated.

In conclusion, there is some evidence to suggest that self-weighing is an effective strategy for weight management but there are still unanswered questions. Firstly it is unclear whether regular (at least once per week) self-weighing is effective as an isolated weight loss strategy or what the contribution is to multi-component interventions. The systematic review in chapter six investigates the effectiveness of regular self-weighing for weight management in detail and will try and answer these questions.

2.8 Summary of the evidence

The prevalence of obesity is high and there are many negative health consequences of obesity as well as economic costs. The causes of obesity are complex and often interrelated. Primary care provides an opportunity where people that need advice or help to manage their weight can be identified. Primary care is typically the first contact patients will have with NHS services, and by offering treatment within this setting there is the potential to reach more people.

Behavioural weight management programmes such as commercial weight management programmes are effective for weight loss and health care professionals can refer patients to these services. However there has been a lack of previous research about whether these programmes differ in effectiveness and whether one should be recommended over another. Additionally, not all people choose to attend these types of programmes and therefore health professionals need to be able to offer patients brief effective techniques. One such technique that has shown promise in the literature is self-weighing; however there is a lack of research that has investigated isolating the effect of self-weighing for weight management, particularly in a primary care population. Weight loss also needs to be sustained for longer-term health benefits and therefore self-weighing may be one way to help people to maintain weight loss.

There has only been one previous trial that focused on self-weighing for weight loss maintenance and this was multi-component and found significant differences in favour of one intervention group at 18 months follow-up¹¹⁴. Thus the aim of this thesis is to investigate behavioural weight management practices that can be used in primary care.

2.8.1 Objectives

1. To examine if four behavioural weight management programmes (Rosemary Conley, Slimming World, Weight Watchers and an NHS group based programme) differ in weight loss using a noninferiority analysis at three and 12 months follow-up. This is presented in chapter 3.
2. To investigate the isolated effect of self-weighing for weight loss using a randomised controlled trial design. This is presented in chapter 4.
3. To examine the efficacy of an intervention focused on self-weighing for weight loss maintenance using a quasi-randomised controlled trial design. This is presented in chapter 5.
4. To summarise the evidence of self-weighing for weight loss, weight maintenance and weight loss maintenance including the randomised controlled trial presented in chapter 4. This study is a systematic review and meta-analysis and can be found in chapter 6.

CHAPTER 3

3.0 WHICH WEIGHT LOSS PROGRAMMES ARE AS EFFECTIVE AS WEIGHT WATCHERS: A PROSPECTIVE COHORT NONINFERIORITY ANALYSIS.

This chapter is based on the following published paper: Madigan, CD, Daley AJ, Lewis AL, Jolly K, Aveyard P. Which weight loss programmes are as effective as Weight Watchers: noninferiority analysis. *British Journal of General Practice* (2014), 64: e128-136. ¹²³

Acknowledgements: All authors planned the study. I conducted the statistical analyses with support from PA. I wrote the first draft of the paper with support from AD and PA, with additional input from KJ and ALL. I wrote the chapter and added additional information.

As shown in chapter 2, there is a need to find weight management interventions that can be used in primary care. Behavioural weight management programmes, particularly commercial programmes are effective but it is not clear whether one should be commissioned over another. This chapter will investigate this.

3.1 Introduction

As documented in chapter 2 there has been a sharp increase in the prevalence of obesity resulting in more people being classified as obese and therefore at higher risk of disease ^{7,12,13}. Behavioural interventions to support weight loss that target physical activity and diet are part of the public health approach to prevent ill health ⁷². Two randomised controlled trials (RCTs) provide evidence of the effectiveness of primary care referrals to commercial weight loss programmes ^{86,124}. Participants attending commercial programmes that are widely available in the UK (Weight Watchers, Rosemary Conley Diet and Fitness Clubs and Slimming World) achieved significantly higher weight loss than those receiving usual care or primary care

based programmes; the content of these programmes can be found in Box 3. GP's can refer patients to these programmes and this method was utilised in both trials^{86,124}.

Box 3: A brief overview of the content of the behavioural weight management programmes¹²⁵

Weight Watchers is group-based, the participant was able to join at any time. There is one-to-one support for new members and during weighing. This is followed by a group talk from the leader with discussion. Meetings took place in community venues for 1 hour duration. Core programme material delivered over 5 weeks included: food points system (based on age, gender, 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 kcals deficit/day leading to 0.5 to 1kg loss per week. Physical activity is encouraged, with the objective to gradually build up to 10,000 steps daily. Predominant behaviour change strategies used included: Stages of Change, food and activity diaries, goal setting and evaluation of progress. Rewards are given for every 3.2 kg (7lbs) lost, at 5% and 10% of body weight.

Slimming World is group-based, the participant was able to join at any time. Meetings took place in community venues for 1 1/2 hours duration. Also included is access to website, magazines and 1-2-1 telephone support from consultant or other members. Members are encouraged to eat mainly low energy dense foods 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 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; group praise for weight loss, new decisions and continued commitment even in absence of weight loss. Awards for 3.2 kg (7lbs) lost and loss of 10% of body weight. Individual support if needed using self-monitoring of food and emotions, for and against evaluations, visualisation techniques, and personal eating plans.

Rosemary Conley is group-based, the participant was able to join at any time. Meetings took place in community venues for 1 1/2 hours duration. There is one-to-one support during weighing and to establish a calorie allowance. Additional support is available via email and telephone. Goals are staged: either 1-1.5kgs per week with goal of 1 stone loss or 0.5-1kg per week with 3.2kg (7lb) initial goal. Sessions include 45 minutes optional exercise class. Extra exercise sessions may be offered for additional fee. The theoretical background is based on role modelling, group support and uses visualisation and reframing to support behaviour change. Predominant behaviour change strategies used include: rewards for slimmer's who maintain weight or lose, slimmer of the week and certificates for 3.2 and 6.35 kg milestones.

The NHS Programme was an NHS group-based programme run in community venues by support workers trained by the dietetics service. This provided six weekly 2-hour sessions, with follow-up sessions at 9 and 12 weeks. All participants joined together in week one of the programme. Its particular focus was on long-term changes in eating behaviours patterns, achieving a balanced diet and increasing physical activity within daily life and it used an interactive style. Topics covered included: managing behaviour around food and relapse prevention; the eatwell plate; nutrition information; planning strategies to deal with lapses into previous dietary behaviours interactive visual aids to show fat and sugar content of foods and recipes adaptation. Theoretical background was based on the cycle of change (Prochaska and Di Clemente). Discussion of the benefits of physical activity, setting goals and finding activities to fit into life. Predominant behaviour change strategies used include: goal setting; stages of change and self-monitoring via food diary.

The two RCTs mentioned above as well as a third RCT compared Weight Watchers to a minimal intervention control and each showed significant weight loss in participants attending Weight Watchers, with an average difference of approximately -2.5 kg (-3.1 to -1.9 kg)⁸².

However there are no RCTs showing individually Rosemary Conley or Slimming World are

effective at 12 months. One RCT compared Rosemary Conley, Slimming World, Weight Watchers and an NHS group programme to a comparator group but was not powered to compare each programme¹²⁴. This trial also showed only Weight Watchers had significantly greater weight loss than the comparator at 12 months. There was no evidence of longer-term effectiveness of Rosemary Conley and Slimming World, yet confidence intervals suggest the effect could be similar to Weight Watchers.

There is also observational data that Weight Watchers may be more effective than other widely used UK-based weight loss programmes. Dixon and colleagues⁸⁵ reported 1047 participants attending Weight Watchers lost significantly more weight than those participating in Rosemary Conley (+0.24 kg) and Slimming World (+1.15 kg) at the end of three month programmes. These differences were significant suggesting some commercial weight loss programmes may be more effective than others, but these data report weight loss in the first three months only. Assessment of longer term outcomes would also be valuable.

It may be more important to offer a range of services to accommodate people's preferences as this may encourage uptake. However, only one of the widely available commercial weight loss programmes (Weight Watchers) has been proven to be effective; whilst the others may be effective, there is insufficient evidence to be sure. Therefore, this study compares the performance of the other programmes (Rosemary Conley, Slimming World and an NHS group programme) to Weight Watchers using a noninferiority analysis. If the other widely available programmes are not inferior to Weight Watchers then that is reasonable evidence they are also effective.

3.2 Participants and methods

3.2.1 Study design

A prospective cohort study using anonymised routinely collected data from the Lighten Up service database, a weight management service commissioned by South Birmingham Primary Care Trust (SBPCT).

3.2.2 Setting and recruitment of participants

Eligible patients were invited to take part in a weight loss programme by letter from their general practitioner (GP) or referral from a health professional. GPs searched their computerised lists for patients of ≥ 18 years with a raised BMI recorded in the previous 15 months. Raised BMI was defined as South Asians with no comorbidities (≥ 25 kg/m²) or with comorbidities (≥ 23 kg/m²) and all ethnic groups (except South Asians) with no comorbidities (≥ 30 kg/m²) or with comorbidities (≥ 28 kg/m²). These BMI thresholds made patients eligible for primary care weight management services. There is evidence to suggest that Asian populations have higher adiposity at lower BMIs but a review of the evidence by NICE failed to reach a conclusion as to what cut-off for Asians would be equivalent to a BMI of 30 kg/m² in non-Asians ⁶. However, commissioners needed to set a threshold for eligibility and therefore chose the cut off points described above ⁷². GPs excluded patients who had a medical contra-indication for a weight loss programme before a letter of invitation was posted. Interested patients telephoned a co-ordinating centre, free of charge, where the programme was explained. The telephone co-ordinating centre had a database of times, days and venues of the weight loss programmes in the area. Patients were excluded if they were unable to understand English or were pregnant.

3.2.3 Allocation

For this study, participants entered the service between May 2009 and March 2010 and the service was available to all general practices within SBPCT. Participants chose which weight loss programme to attend.

3.2.4 Measurements

The outcome was change in body weight between baseline and three months (programme end) and change in body weight between baseline and 12 months. The weight loss provider weighed participants at three months and self-reported weight was used when an objective measure could not be obtained. At 12 months participants self-reported their weight.

3.2.5 Demographic and baseline information

At baseline participants reported their age, gender, ethnicity, postcode and occupation to the telephone co-ordinating centre staff. Postcode was used to derive the Index of multiple deprivation score (IMD), which is an area-based measure of socio-economic status, which were categorised into quartiles ¹²⁶. Height was collected at baseline and BMI was calculated at baseline, three and 12 months.

3.2.6 Weight loss interventions

Participants were offered a choice of four weight loss programmes: Rosemary Conley, Slimming World, Weight Watchers and an NHS group weight loss programme (full descriptions in Box 3). Participants were able to attend one of these programmes using vouchers paid for by the NHS for three months and attended alongside people who paid to attend the programmes. The exception to this was the NHS group programme. In the NHS

programme attendees were only those that had been referred from primary care therefore sometimes the start of the group session was delayed because of waiting for sufficient referrals.

On completion of their 12 week weight loss programme the co-ordinating centre telephoned participants to offer a three month weight loss maintenance intervention including a weight record card, information about weight management and a phone call three-months later to encourage regular self-weighing. Participants without weighing scales were given a voucher to obtain some for free.

3.2.7 Data analyses

Baseline weight was used for missing weights at follow-up and all analyses were conducted using ITT. Baseline differences were checked between the groups attending each programme by comparing frequency distributions of categorical variables and means of continuous variables. Using linear regression analysis the mean differences and confidence intervals were determined between Weight Watchers, which is known to be effective, and the other weight loss programmes. Between programme differences in weight change were reported unadjusted and adjusted for age, gender, baseline BMI, ethnicity and uptake of weight maintenance intervention (12 months analysis only). Continuous variables were mean centred and all categorical variables divided into binary variables. Deprivation was divided into two groups (high and low by quartiles) and for ethnicity participants were classified as white or non-white.

3.2.8 Noninferiority analyses

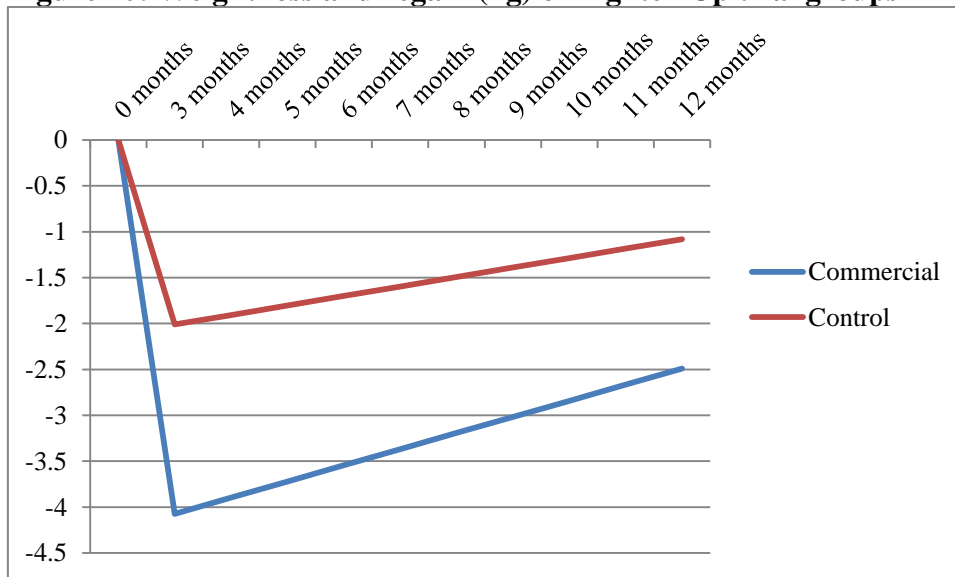
The aim of a non-inferiority analysis is to choose a margin where a treatment is not going to be worse than another treatment (i.e. no difference in weight loss) ¹²⁷. Health benefits from weight loss appear roughly proportional to weight lost, so it is not possible to choose a margin that divides unbeneficial weight loss from useful weight loss. For this study the noninferiority margin was set at 1.0 kg at three months follow-up as it was believed this might be the kind of difference that patients and commissioners would choose to commission one service over another, whereas a service producing differences of only hundreds of grams may be chosen on other characteristics than effectiveness such as cost and content. It was recognised that in weight loss studies the difference in weight between treatments decrease as time passes because most participants regain weight and therefore mean weight loss curves tend to converge. This was accounted for by reducing the noninferiority margin to 0.7 kg at 12 month follow-up and was based on previous evidence of weight regain ¹²⁴.

In the Lighten Up trial participants were randomised to commercially provided weight loss interventions or a comparator group and weight loss was assessed at three and 12 months (Table 3) ¹²⁴. Figure 10 indicates the group who received the commercial programmes lost more weight initially but gained it faster than the comparator group that lost less weight. This is because they have more weight to regain. If these lines were projected forward they will meet at some point in the future.

Table 3: Weight loss at three and 12 months in the Lighten Up trial ¹²⁴

	Commercial interventions	Control
3 months	-4.1 kg	-2.0 kg
12 months	-2.5 kg	-1.1 kg

Figure 10: Weight loss and regain (kg) of Lighten Up trial groups ¹²⁴



In a noninferiority analysis a band is chosen within which we say we are indifferent to differences in effectiveness. If the margin within which we declare we are indifferent were constant with time noninferiority would be declared for all treatments because the weight loss curves might become close or meet. This would ignore the evidence that the risk from excess adiposity appears proportional to the years spent obese and that weight loss for a period is a worthwhile goal ¹⁸.

In the Lighten Up trial the difference at 12 months was 70% of that at three months, which is why in this analysis a noninferiority margin of 1.0 kg was used at three months and 0.7 kg at

12 months. A difference of 1.0 kg at three months is equivalent to a difference of 0.7 kg at 12 months.

Following the CONSORT statement, if the confidence intervals for the point estimate for the difference in weight between Weight Watchers and each of the other weight loss services were inside the margins, the services would be declared not inferior to Weight Watchers¹²⁷.

3.3 Results

Follow-up rates at three months for the weight loss programmes were 74.5% for NHS group programme, 69.9% for Rosemary Conley, 81.4% for Slimming World and 77.6% for Weight Watchers (Figure 11). At 12 months follow-up rates were: 80.2% NHS group, 60.7% Rosemary Conley, 71.8% Slimming World and 63.1% Weight Watchers. Forty five percent of weights were self-reported at three months.

3.3.1 Baseline characteristics

The percentage of participants that selected each programme was: 6.4% NHS group, 24% Rosemary Conley, 28% Slimming World and 41.5% Weight Watchers (Figure 11).

Participant's mean age was 49.9 years, 83.9% were white, mean BMI was 35.1 kg/m² and 86.6% were classified in the two IMD quartiles with greatest deprivation. Only a small percentage of men attended each programme (11.5 to 26.4%) but there were similar proportions to other weight management trials^{128,129}. Deprivation, baseline BMI and proportion receiving the weight maintenance intervention was similar across the programmes (Table 4).

Figure 11: Participant inclusion flow diagram

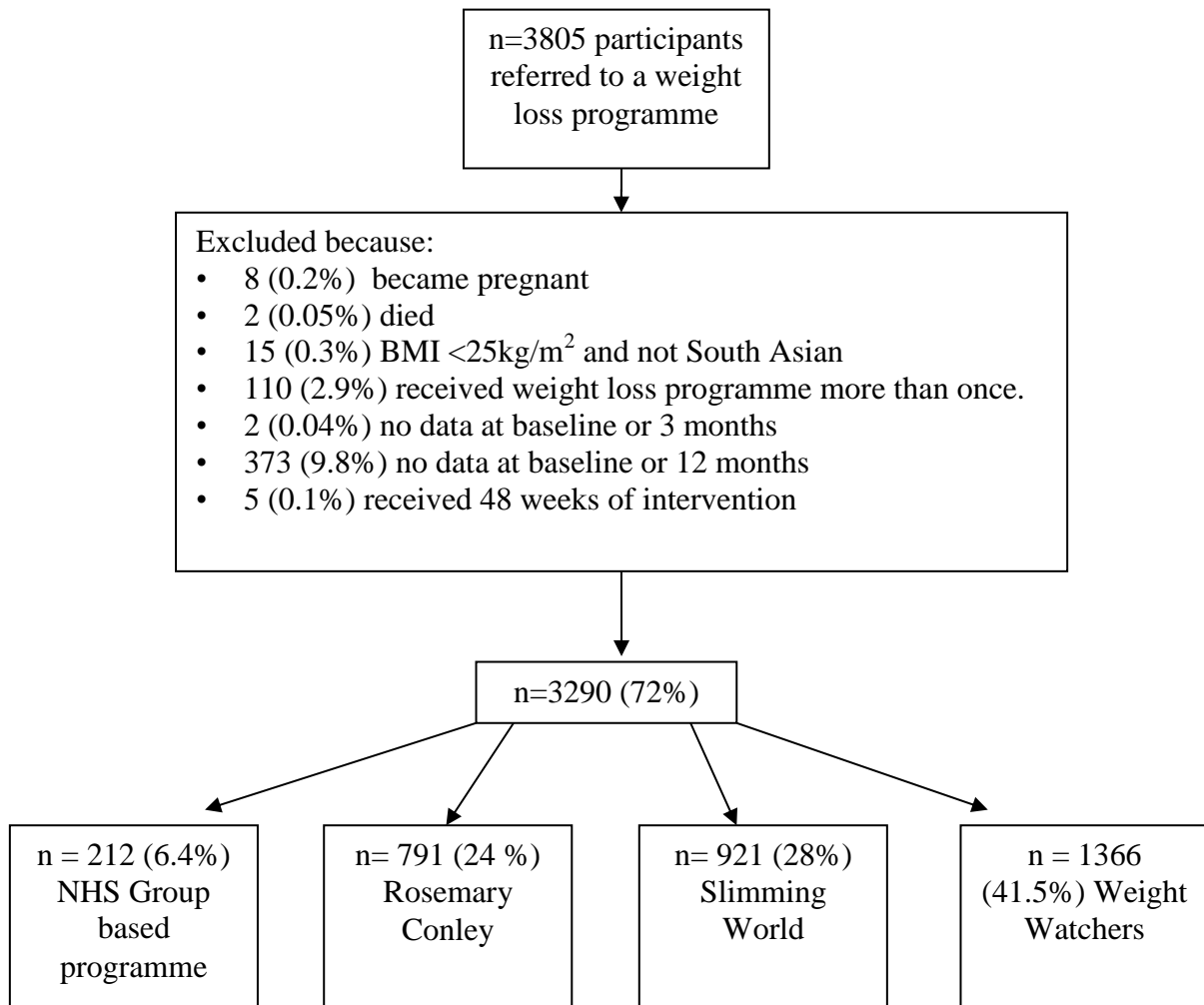


Table 4: Characteristics of participants at baseline according to weight loss programme
(Values are numbers [percentages] unless stated otherwise)

Characteristics	All participants (n=3290)	Weight Watchers (n=1366)	Slimming World (n=921)	Rosemary Conley (n=791)	NHS group programme (n=212)
Male	436 (13.3)	166 (12.2)	123 (13.4)	91 (11.5)	56 (26.4)
Mean (SD) age (years)	49.9 (14.9)	48.9 (15.2)	49.6 (14.5)	50.1 (14.4)	57.7 (14.4)
Ethnic group					
White	2761 (83.9)	1179 (86.3)	827 (89.8)	583 (73.7)	172 (81.1)
Non white	529 (16.1)	187 (13.7)	94 (10.2)	208 (26.3)	40 (18.9)
Deprivation					
High	2850 (86.6)	1179 (86.3)	805 (87.4)	688 (87.0)	178 (84.0)
Low	440 (13.4)	187 (13.7)	116 (12.6)	103 (13.0)	34 (16.0)
Mean (SD) starting BMI (kg/m²)	35.1 (5.7)	35.2 (5.8)	35.7 (6.1)	34.3 (5.1)	34.5 (5.5)
Starting BMI <30 kg/m ²	548 (16.7)	229 (16.8)	130 (14.1)	149 (18.8)	40 (18.9)
Starting BMI 30-39 kg/m ²	2210 (67.2)	906 (66.3)	613 (66.6)	549 (69.4)	142 (67.0)
Starting BMI ≥40 kg/m ²	532 (16.2)	231 (16.9)	178 (19.3)	93 (11.8)	30 (14.2)
Maintenance intervention	892 (27.1)	381 (27.9)	277 (30.1)	185 (23.4)	49 (23.1)

3.3.2 Noninferiority analyses

The results of the regression analysis are shown in Table 5. Participants attending Weight Watchers lost on average 4.2 kg (SD 4.1) at three months, reducing to 3.7 kg (SD 6.4) at 12 months. Using adjusted data, participants attending the NHS group programme lost 2.6 kg

less than Weight Watchers at three months and Rosemary Conley and Slimming World lost 0.7 and 0.3 kg less respectively. At 12 months this pattern differed; Rosemary Conley lost 0.2 kg less and the NHS programme 1.2 kg less than Weight Watchers, however Slimming World lost 0.7 kg more than Weight Watchers.

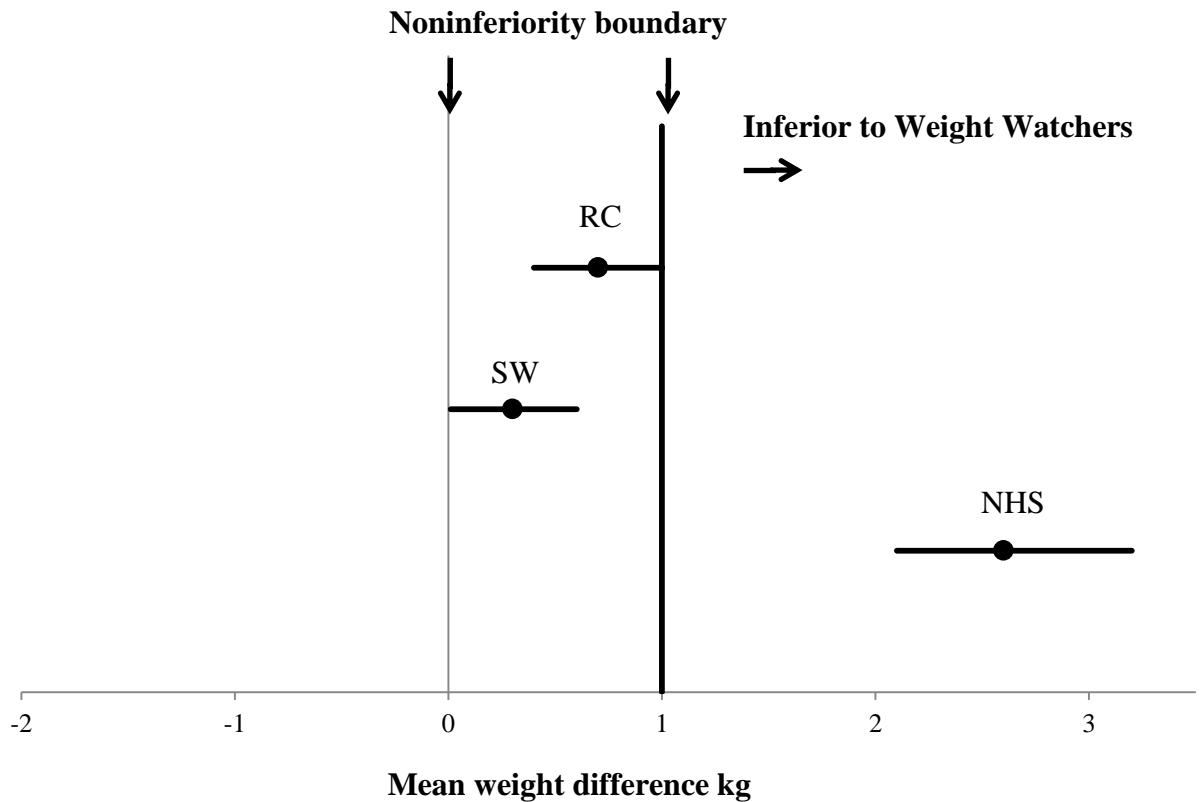
Table 5: Mean weight differences compared to Weight Watchers at three and 12 months

	Unadjusted mean weight difference at three months kg(95% CI)	Adjusted mean weight difference at three months kg(95% CI)	Unadjusted mean weight difference at 12 months kg (95% CI)	Adjusted mean weight difference at 12 months kg (95% CI)
Weight Watchers (constant)	0.0	0.0	0.0	0.0
NHS Size Down	2.6 (2.0 to 3.1)	2.6 (2.1 to 3.2)	1.2 (0.3 to 2.1)	1.2 (0.3 to 2.1)
Rosemary Conley	0.9 (0.6 to 1.2)	0.7 (0.4 to 1.0)	0.6 (0.0 to 1.1)	0.2 (-0.4 to 0.7)
Slimming World	0.2 (-0.1 to 0.5)	0.3 (0.01 to 0.6)	-0.8 (-1.4 to -0.3)	-0.7 (-1.2 to -0.2)

Figure 12 shows the noninferiority plot of adjusted mean differences and 95% CI for the difference between each weight loss programme and Weight Watchers. A mean weight difference of zero would indicate participants in the other programmes lost the same as Weight Watchers. The point estimates and confidence intervals for weight loss at three months for Rosemary Conley and Slimming World are to the left of the noninferiority line, indicating they are noninferior by the pre-specified margin of 1.0 kg. However, both estimates and confidence intervals are to the right of the zero line, indicating that participants attending Weight Watchers lost slightly more weight than participants attending Slimming World and

Rosemary Conley. The NHS group programme was to the right of noninferiority line, indicating it is inferior to Weight Watchers.

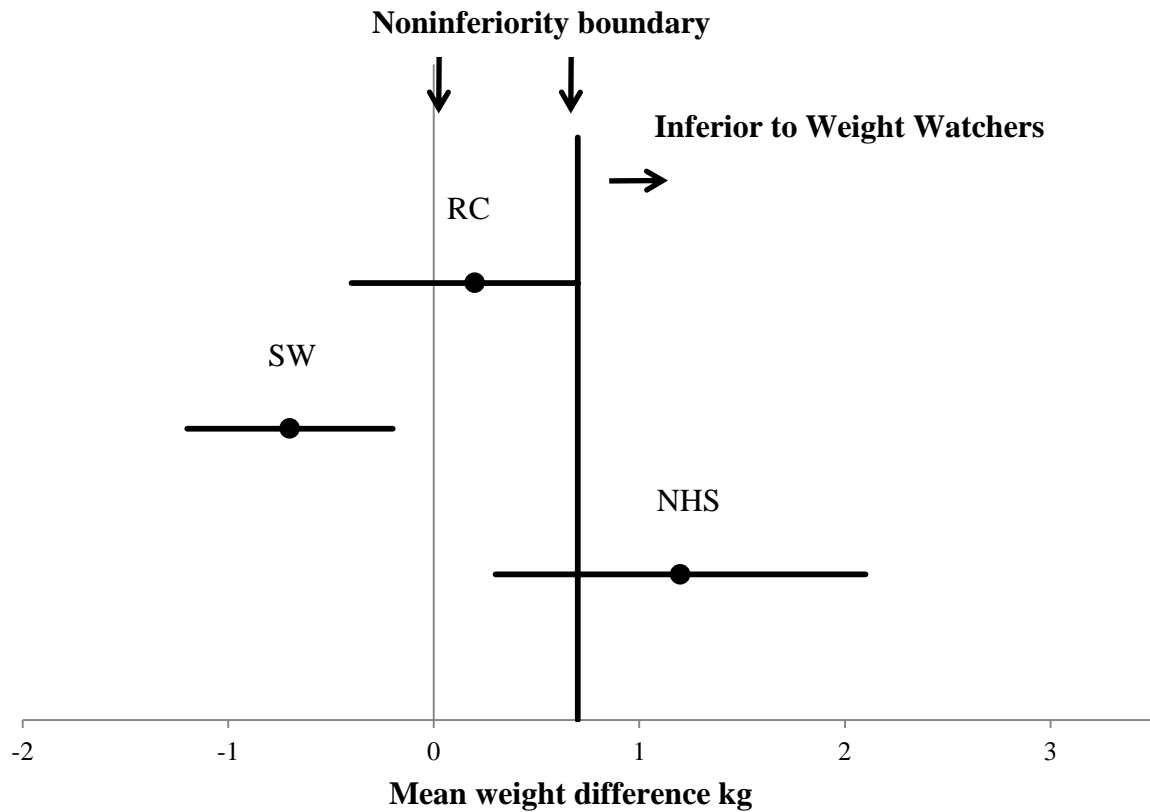
Figure 12: Noninferiority plot: adjusted mean difference in weight change at three months



NHS = NHS group based programme, RC= Rosemary Conley, SW = Slimming World

The pattern for the adjusted differences from Weight Watchers at 12 months was different (Figure 13). Participants attending Slimming World showed greater weight loss than Weight Watchers attendees, however Rosemary Conley was noninferior to Weight Watchers. The point estimate for the difference between Weight Watchers and the NHS group was smaller at 12 months than three months and confidence intervals overlapped the noninferiority margin, giving an inconclusive result.

Figure 13: Noninferiority plot: adjusted mean difference in weight change at 12 months



NHS = NHS group based programme, RC= Rosemary Conley, SW = Slimming World

3.4 Discussion

Weight Watchers is the only behavioural weight loss programme available in the UK currently shown to be effective in clinical trials ^{82,86,124,128}. In this observational study, the weight loss in participants attending Rosemary Conley and Slimming World was similar to that in users of Weight Watchers, giving evidence that these programmes are noninferior. Slimming World may have greater weight loss at 12 months, though the difference was small. The NHS group programme was inferior to Weight Watchers at three months but these data were inconclusive at 12 months.

3.4.1 Findings in relation to other research

The single trial ¹²⁴ that randomised participants to all four interventions produced inconclusive results on whether the NHS group, Slimming World, or Rosemary Conley were more effective than no support, while producing clear evidence of the effectiveness of Weight Watchers (at 12 months), which has also been subject to two other clinical trials. The trial also showed that commercial programmes considered together were effective ¹²⁴. The same noninferiority analyses that was conducted here were also conducted on the Lighten Up trial data. All programmes were defined as inconclusive due to small numbers and therefore a lack of power ¹²⁴. This left open the possibility that there are substantial differences in effectiveness between programmes. There are, however, observational data such as the study reported here that shed light on the effectiveness of these programmes.

Dixon and colleagues ⁸⁵ found that participants using Weight Watchers or Rosemary Conley lost statistically significantly more weight than participants using Slimming World at the end of three-month programmes. The approach reported here was different. The view here is that it is better to have a range of services available, even if there are minor differences in weight loss, providing all are effective ¹³⁰, and so a noninferiority approach was adopted in this analysis. The pattern of results is somewhat different from Dixon and colleagues study. While at three months Weight Watchers looked more effective than Slimming World and Rosemary Conley, the data presented here suggest the differences were very small and inside the noninferiority margin. The results here were based on a substantially larger, ethnically and socio-economic diverse sample. Baseline weight observed carried forwards (BOCF) was used to impute weight that was missing, which implies zero weight change at follow-up whereas Dixon and colleagues used LOCF. There is no reason to assume that the different imputation methods should lead to substantial differences between treatments, though it would affect the

estimate of the amount of weight lost perhaps resulting in greater weight losses compared with the findings here.

The most likely explanation for Dixon and colleagues findings is attendance. Only 36% of people attending Slimming World completed the course of treatment compared with 56% for Weight Watchers and 45% for Rosemary Conley; attendance has been shown to be associated with greater weight loss ⁸⁶. The study by Dixon and colleagues used only data collected by the services themselves (i.e. only people that continued to attend had weight data). Even if people who attended for a while then dropped out of treatment but continued using the methods they were taught and continued to lose weight, the LOCF method would impute a lower weight loss than might have been the case at three months. In the study reported here, participants were telephoned who had dropped out of treatment to obtain their weight therefore rates of follow-up in this study were higher.

The finding that the NHS group programme was inferior to Weight Watchers is in line with data reported from the Lighten Up trial and there is evidence that other configurations of services provided by NHS personnel are ineffective ¹²⁴. Commercial programmes are also substantially cheaper ¹²⁴.

3.4.2 Strengths and limitations

The main strength of this study is the large sample size that allowed precise estimates of treatment effect and therefore had the power to estimate whether or not treatments were noninferior. Noninferiority analyses typically require larger sample sizes than traditional superiority analyses. The major weakness is that this is a non-randomised comparison and therefore could be subject to more biases and confounding than a corresponding RCT.

However, participant characteristics appeared well balanced and there was no substantial difference between the unadjusted and adjusted analyses. It is doubtful that a trial of this size would ever be commissioned to investigate this question, given its inevitable cost.

The analytical approach was conservative using BOCF for people whose weight was unavailable at follow-up and this may have underestimated the impact weight loss programmes have on weight loss, though it may overestimate if participants who were not followed up had in fact gained weight. Participants self-reported their weight at 12 months which may have led to under reporting of weight, but this would be true for all programmes. The rate of self-reporting and loss to follow-up was similar across all programmes therefore this is unlikely to have biased the findings.

The noninferiority margin was pre-specified at 1 kg as this was considered to be the minimum difference that would be important when deciding upon which weight loss programmes to commission, although it is accepted this might be seen as somewhat arbitrary. Readers can select a different margin and apply it to Figure 12 and Figure 13.

3.5 Conclusion

Whilst Slimming World was superior to Weight Watchers at 12 months, in practical terms this difference was small. I would advocate that public health authorities commission all three commercial weight loss programmes since all result in similar amounts of weight loss and the choice is likely to extend the take-up of these programmes. Commissioners may also use this evidence to be confident that one programme is not necessarily better than another and can commission on other factors such as costs and the suitability for the target population.

CHAPTER 4

4.0 A RANDOMISED CONTROLLED TRIAL OF THE EFFECTIVENESS OF SELF-WEIGHING AS AN ISOLATED WEIGHT LOSS INTERVENTION (SCALE DOWN)

Madigan CD, Jolly K, Lewis AL, Aveyard P, Daley AJ. (submitted) A randomised controlled trial of the effectiveness of self-weighing as an isolated weight loss intervention.

Acknowledgements: All authors planned the study. I coordinated and delivered the trial. I conducted the statistical analyses with support from PA. I, AD and PA drafted the paper with additional input from KJ and AL. I wrote the chapter and included additional information.

In chapter 3, commercial weight management programmes were found to result in similar weight losses, however not all people like to use these types of programmes. Finding interventions that are easy to implement in primary care and are low cost is important for public health. Self-weighing may be one such practice. This chapter investigates self-weighing as a practice for weight loss. A copy of ethical approval can be found in appendix 8 and the trial registration number is ISCRTN05815264.

4.1 Introduction

Primary care physicians potentially have a significant role in addressing obesity in their patients, but this is a role they exercise uncommonly^{74,75}. One key reason is that physicians do not believe that such interventions are effective⁷⁷. Evidence from observational studies suggests that it may be helpful if they were to raise the topic of excess body weight⁷⁹. It is possible that simply recommending weight loss may be sufficient to motivate some people to

attempt weight loss and succeed, however brief interventions (offering insight in to how to lose weight) may be more effective.

It is known that referral to multi-component weight management programmes are effective for weight loss, however not all people are willing to attend these programmes^{86,124,131,132}.

Offering brief interventions in a primary care setting may reach more people and be cheaper for health services. One promising strategy is to suggest to patients that they weigh themselves daily and record their weight. People participating in complex weight management behavioural programmes often report that it is the regular weighing that is critical to their success¹³³.

A meta-regression of interventions for reducing problem drinking found that encouraging participants to record their daily consumption of alcohol appeared to explain most of the variation in effectiveness of brief interventions¹⁰³. There is also evidence that self-monitoring is an effective technique for healthy eating and increasing physical activity⁹⁹. Multi-component RCTs that focused on self-weighing resulted in significant weight loss compared to a control group that did not self-weigh^{107,115}. There have been only two RCTs that have isolated the effect of self-weighing and these found no significant differences at programme end, although they were small and had high attrition^{112,113}.

For self-weighing to be effective, people have to be able to reflect on how their behaviour has affected their weight, make plans to change that behaviour, and enact those plans. It is possible, then, that self-weighing may need to be added to incrementally to build an effective yet simple to deliver brief intervention for primary care use. The aim of this trial was to start intervention building. This was examined in an explanatory trial to test whether this could work before testing it as an opportunistic brief intervention. This involved giving extra

support to participants to ensure they did weigh themselves regularly. It also involved creating a 'sham' weight loss treatment for the control group that aimed to motivate their continued weight loss attempt and adherence to follow-up.

4.2 Patients and methods

4.2.1 Design

Two arm individually RCT with blinding of the participants and those conducting follow-up. Participants were allocated to the intervention group of daily self-weighing or control group.

4.2.2 Participants

Two family practices within Birmingham, England agreed to participate. A total of 1914 patients with a raised BMI (≥ 30 kg/m²) recorded within their primary care medical notes in the past 15 months were invited to take part, by letter from their GP. Interested patients completed a screening questionnaire by telephone or sent this back by post. Eligible patients were given an appointment at their GP practice to discuss the trial in more detail, confirm eligibility and take written informed consent. Participants were not explicitly told this was a study about self-weighing rather that it was about two different approaches to weight management (See Appendix 2).

4.2.3 Inclusion criteria

Participants were aged ≥ 18 years with a raised BMI of ≥ 30 kg/m² and considered suitable to participate by their GP.

4.2.4 Exclusion criteria

Participants were excluded if they: were pregnant or intending to become pregnant within the study time period; could not understand or speak English sufficiently to undertake the tasks of the study; were currently attending a weight management programme (including pharmacotherapy or bariatric surgery) or had taken part in a formal weight management programme in the previous three months. They were also excluded if they currently reported weighing themselves at least once per week. These exclusions were chosen as the intervention was very simple. If participants were already weighing themselves or taking part in a weight management programme, they were already engaged with what the intervention was asking them to do and therefore no effect may have been found.

4.2.5 Settings

Both groups received weight management consultations at their GP practice by a researcher. Three month follow-up took place either at the GP practice or at the participant's home.

4.2.6 Components across both groups

I wanted to isolate the effect of self-weighing, but sought to minimise follow-up bias by giving the control group a plausible but ineffective intervention that was similar to a consultation that a family practice nurse might deliver. This type of intervention in a more intensive form has shown to be ineffective¹²⁴. Both groups received this same intervention which consisted of two visits. At visit one participants received a 45 minute consultation to discuss weight management tips (components can be found in Table 6), a booklet titled 'Your Weight, Your Health' and a basic four-day food diary that was to be completed before the next visit, seven days later (visit 2) (Appendix 4)¹³⁴. At visit two participants discussed the

completed food diary with the weight management practitioner. Participants were advised they should aim to lose 0.5 kg of body weight per week in line with NICE guidance in England⁷².

4.2.7 Intervention group

At visit one, participants were given weighing scales and instructed to weigh themselves daily and record their weight on the record card provided (Appendix 3). On the record card at the end of each week there was a box participants could use to calculate their average weight for the week to compare to their target weight loss. Daily weighing was chosen over weekly weighing as the most effective dose response is unknown and it is more likely to become a habit if completed daily^{96 135}.

As this was an explanatory trial a range of behavioural techniques were used to help participants weigh themselves daily and are described in detail in Table 6. These techniques have been categorised based on the CALO-RE behavioural change taxonomy which is specific to changing diet and physical activity behaviours¹³⁶. Briefly, the main technique used was self-monitoring of behaviours through self-weighing. The benefits of self-weighing for weight loss were discussed and participants were instructed to aim for a weight loss of 0.5 kg per week, and to review their average weight loss against this target. Participants were told to weigh themselves at the same time every day to help self-weighing become a habit. They were also instructed to put the scales in a place which would help them remember to weigh themselves. Brief weekly text messages were sent to participants at times participants suggested were appropriate for them to prompt them to weigh themselves (see Box 4 for content of text messages).

At visit two the frequency of participants' self-weighing over the previous week was discussed and those not weighing themselves daily were further encouraged to do so and given ideas/strategies of how they might overcome barriers.

Table 6: Behavioural change techniques used in the intervention based on CALO-RE taxonomy ⁹⁵

Behavioural technique	Definition
Intervention only	
Prompt self-monitoring of behavioural outcome	Participants were instructed to weigh themselves daily and record it on the weight record card provided.
Prompt review of outcome goals	Participants were instructed to work out their average weight for the week and review their progress against losing 0.5 kg per week.
Provide information on the consequences of behaviour in general	The benefits of self-weighing for weight management were discussed with participants.
Environmental restructuring	Participants were asked to put the scales in a place that would help them remember to weigh themselves.
Provide information on where and when to perform the behaviour	Participants were asked to weigh themselves at the same time each day.
Use follow-up prompts	Participants were sent text messages once per week at a time which would help participants to remember to weigh themselves.
Barrier identification/problem solving	At visit two participants were asked if there were any barriers and discussed how to overcome these barriers.
Behavioural techniques given to both groups	
Provide information about behaviour health link	The consequences of an unhealthy weight were discussed.
Provided general encouragement	Praised participants in week two for making changes to their diet and activity.
Goal setting (outcome)	Participants were instructed to lose 0.5 kg per week.
Prompt self-monitoring of behaviour	Participants were asked to complete a 4 day food diary.

Box 4: Text message content

1. Have you remembered to weigh yourself today?
2. Have you hopped on the scales?
3. Don't forget to weigh yourself daily?
4. I hope the daily weighing is going well?

4.2.8 Control group

Self-weighing was not discussed at either consultation and participants were not sent text messages.

4.2.9 Outcomes

The primary outcome was change in weight from baseline to three months. Secondary outcomes were physical activity and weight management strategies; these were measured as it was hypothesised the behaviour of self-weighing should prompt a change in energy intake or expenditure based on the review of daily weight. Diet was not measured as it would have been too onerous for participants and by measuring diet participants would be self-monitoring what they ate, and thus an additional strategy to self-weighing.

Self-weighing frequency was measured objectively in the intervention group using weighing scales (USB Scale, ION health). The scales recorded and stored the weight of participants every time it was used and this data was downloaded by the researchers at follow-up. Self-weighing was also self-reported by both groups at baseline and three months by asking a single question: 'how often do you usually weigh yourself.' Intervention group participants were asked to record their weight daily on a record card as a secondary measure of self-weighing frequency.

At baseline, participants reported socio-demographic data including: age, gender, ethnicity, postcode (converted to IMD), occupation, medication and long-term health conditions ¹²⁶. Height was measured at baseline to the nearest centimetre and weight (kg) measured at baseline and follow-up on validated scales (SECA 875). If an objective measure of weight at follow-up could not be obtained self-reported weight was used. At baseline and follow-up, participants completed a questionnaire about weight management strategies they had used in the past month (adapted from a questionnaire previously used) and the international physical activity questionnaire (IPAQ-short) ^{100, 137}. To identify any adverse effects participants in the intervention group were asked on a Likert scale (1-9) if self-weighing affected their mood or made them change the way they felt about their body (a score of five being no difference). There was an open question where participants could provide comments about self-weighing. Both groups were asked general questions about participating in the study and there was another open question where participants provided further comments.

4.2.10 Sample size

Based on the assumption that the intervention group would lose 1.0 kg (SD 2.0 kg) more than the control group at follow-up with 80% power and 5% type I error, 180 participants were required (including 30% loss to follow-up at three months). A 1.0 kg difference was chosen as it was considered a plausible difference for a low intensity intervention. The SD was taken from a similar study of a low intensity primary care weight loss intervention ⁹⁰.

4.2.11 Allocation and randomisation

Participants attended their family practice for the consultation and were randomised after eligibility assessment and consent was taken. An independent statistician prepared random

block sizes of between two and eight to ensure balance of trial arms. The weight management practitioners took written informed consent from patients and then, using opaque sealed envelopes, randomly allocated participants to their treatment group. An independent researcher checked the randomisation sequence weekly.

4.2.12 Blinding

Participants were blinded to group allocation, i.e. neither group was told that this was really a trial about self-weighing; there was no mention of self-weighing in the information sheet (Appendix 3). Participants' weight at three months was measured by independent researchers.

4.2.13 Data analysis

Continuous variables are shown as means and standard deviations or medians, and categorical variables as numbers and percentages. Descriptive data of age, gender and IMD were compared between those invited to take part and those who were randomised. The primary analysis was conducted unadjusted using ITT, and participants with missing weight data were assumed to have their baseline weight (i.e. no weight loss). Within group t-tests were used to examine if each group had lost a significant amount of weight between baseline and three months. The difference in weight change between the groups was analysed using linear regression. A sensitivity analysis was used to adjust for demographics. Age and baseline weight were centred, ethnicity categorised as white and non-white and the presence of a long term health condition categorised as yes or no.

In a post hoc analysis, adherence to self-weighing and weight loss was analysed by comparing those who had weighed themselves 45 times or more (i.e. 50% adherence or more) with those who had weighed themselves less than 45 times using an independent sample t-test (objective

self-weighing data and self-report data). A 50% cut off was chosen as it equates to participants weighing at least three times per week and therefore participants would have received regular feedback about their weight. For those that did not have weight data it was assumed that they did not weigh themselves (both objective and self-reported). The agreement was examined between objective self-weighing data and self-reported data (from the weight record card) using a Bland Altman plot (missing frequency data omitted).

A regression analysis was used to examine the mean change in weight and self-weighing as continuous variable adjusting for ethnicity, age and gender (using objective and self-reported frequency data). These data were illustrated using a scatter plot and line of best fit. Those participants in the intervention group that calculated their average weight on their record chart across the week were added together as another means of exploring engagement with the intervention.

Independent sample t-tests were used to examine differences between the group's physical activity levels and change in hours spent sitting. Physical activity data were converted to MET minutes per week; one MET minute is defined as the resting metabolic rate when sitting at rest¹³⁸. The mean change in weight management strategies used was analysed using independent t-tests.

Comments about the study were collated and categorised into participants praising the study, reporting no effect, giving reasons why they hadn't lost weight and improvements to the study. Comments about self-weighing were collated and presented in a table.

4.3 Results

Participants were recruited between August and November 2012. In total 355 (18.5%) invited patients were assessed for eligibility (see Figure 14). These were comparable in age, gender and IMD to those invited to take part by their family practices (Table 7). One hundred and seventy-two patients were excluded (see Figure 14) and 183 participants were randomised. Participants in both groups were similar on all baseline characteristics, although marginally more of the intervention group reported they had a long-term health condition, consequently the number of people taking medication was higher in this group (Table 7). Follow-up rates were high at three months in both groups; 92.4% intervention group and 85.7% in the control group.

Figure 14: CONSORT flow diagram

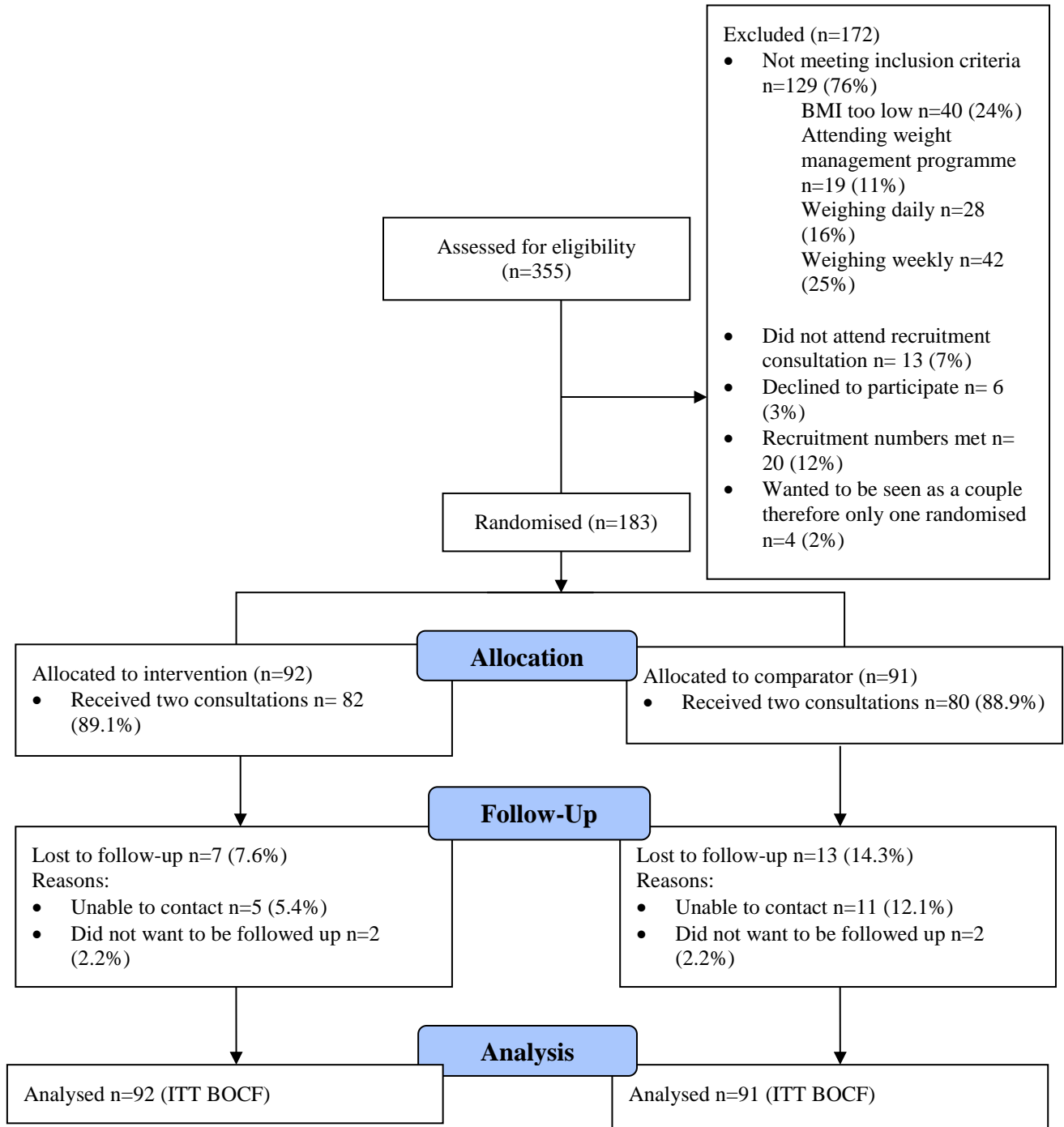


Table 7: Baseline characteristics of participants

	Patients Invited n=1914	Control n=91	Intervention n=92
Age mean (SD)	52.3 (16.8)	53.3 (14.6)	53.9 (14.9)
Male n (%)	766 (40)	33 (36.3)	34 (37.0)
Baseline BMI mean (SD)	n/a	36.2 (4.8)	35.8 (4.3)
White participants n (%)	n/a	59 (64.8)	60 (65.2)
Long-term health condition n = (%)	n/a	39 (42.9)	50 (54.3)
Taking medication n (%)	n/a	61 (67.0)	69 (75.0)
Deprivation*n (%)	n/a		
1 Most deprived	1494 (78)	68 (76.4)	70 (77.8)
2	383 (20)	15 (16.9)	17 (18.9)
3	30 (0.02)	6 (6.7)	2 (2.2)
4 Least deprived	7 (0.004)	0	1 (1.1)
Physical activity per week, MET minutes median (IQR)	n/a	744 (99 to 1740)	605 (177 to 2079)

*Missing data for four participants, two in each group, all other variables n=183 Only IMD, gender and age data available for participants invited.

4.3.1 Primary outcome

The intervention group lost on average 0.5 kg (95% CI 0.3 to 1.3) more than the control group (non-significant, Table 8) and adjusting for covariates did not alter the results. Both groups lost significant amounts of weight from baseline to three months; weight change in the control group was -1.2 kg (95% CI -1.7 to -0.7) and the intervention group -1.7 kg (95% CI -2.3 to -1.1) (Table 8).

Table 8: Analyses of weight change between baseline and three months

	Mean weight change		Mean difference between groups	
	Control n=91	Intervention n=92	Unadjusted n=183	Adjusted n=183
All participants followed up kg (95% CI)	-1.4 (-2.0 to -0.8)*	-1.8 (-2.5 to -1.1)*	-0.4 (-1.3 to 0.5) p=0.4	-0.5 (-1.4 to 0.4) p=0.27
BOCF weight kg (95% CI)	-1.2 (-1.7 to -0.7)*	-1.7 (-2.3 to -1.1)*	-0.5 (-1.3 to 0.3) p=0.24	-0.5 (-1.3 to 0.3) p=0.20

Significance level *p <0.01

4.3.2 Adherence to self-weighing

Due to the exclusion criteria at baseline no participants reported weighing themselves daily or weekly, however using the single question about self-weighing at three months, 73.1% (n=57 of 78 responses) of the intervention group reported weighing themselves at least once per week and of that, 60% (n=47) weighed daily. Some of the control group also started to weigh themselves regularly with 19.4% (n=14 of 72 responses) reporting weighing themselves at least once a week and of that 11.1% (n=8) weighed daily at follow-up. Based solely on the weight record cards, 21 (41% of the intervention group only) participants calculated their average weight loss for the week at any time point.

An objective measure (at least one weight recorded) of self-weighing was obtained for 54/92 participants in the intervention group and the median number of days participants weighed themselves was 16.5 (range 1 to 89) over the three months. Fifty one participants who returned the weight record cards reported weighing themselves a median of 73 days (range 10

to 84). The Bland Altman plot showed that on average participants (n=34 who had both record cards and objective weighing scales data) recorded a weight on the scales on average -31 times less during the intervention than they recorded on the record card (95% limits of agreement -83.3 to 21.3). The limits of agreement reflect the range of disagreements between the two measures.

It was explored if frequency of self-weighing was associated with greater weight loss in the intervention group only. When the group was divided into those who weighed themselves more than half the days (≥ 45 days) and half or fewer, there was evidence using objective frequency data of a difference of 2.0 kg (95% CI -3.5 to -0.4) but not using self-reported frequency data (0.8 kg, 95% CI -2.1 to 0.5). Regression models were fitted of weight loss on frequency of self-weighing using linear and quadratic terms but as the quadratic term did not improve the fit it was omitted. There was no evidence that frequency of self-weighing using continuous data measured objectively (-0.02 95% CI -0.06 to 0.02) or self-reported (-0.02 95% CI -0.03 to 0.02) was associated with greater weight loss (Figures 15 and 16).

Figure 15: Frequency of self-weighing and weight change with a line of best fit using an objective measure

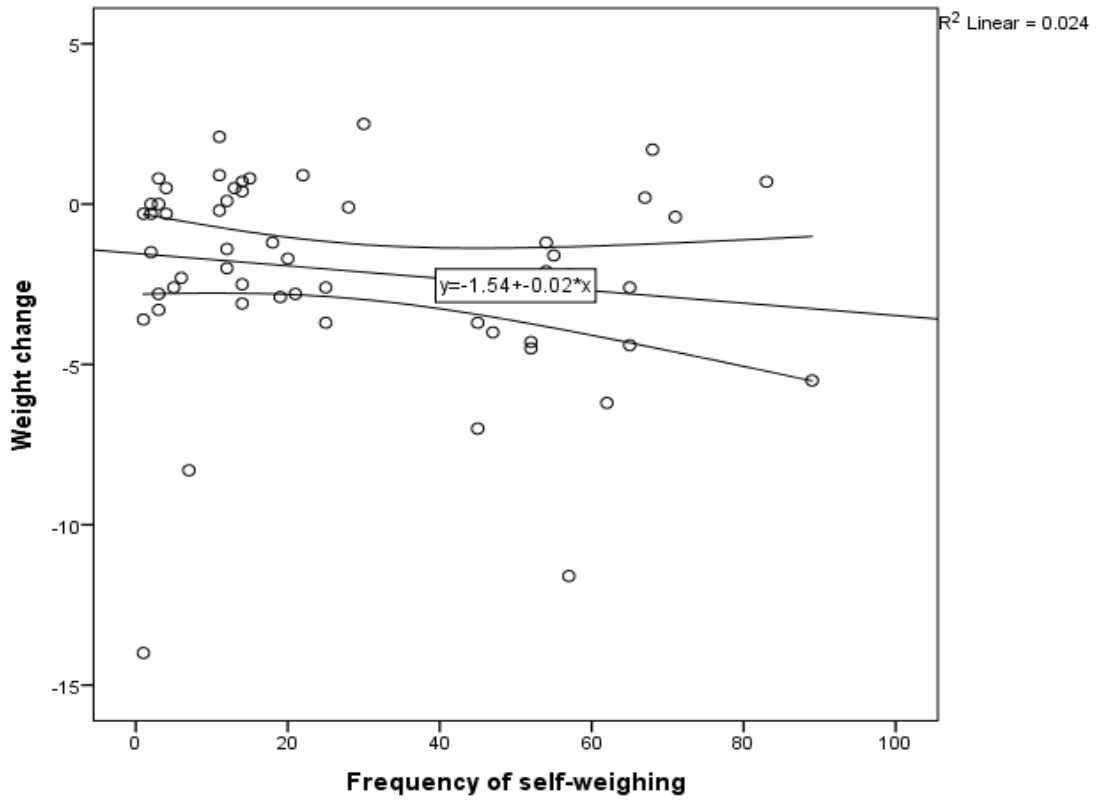
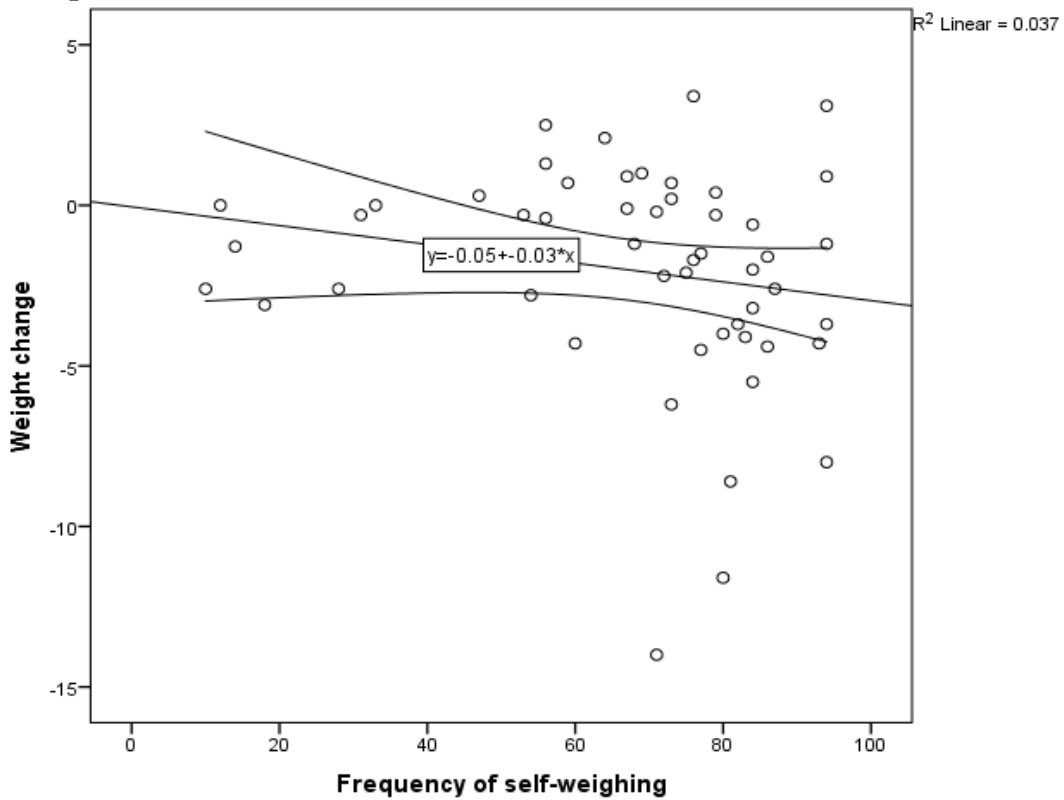


Figure 16: Frequency of self-weighing and weight change with a line of best fit using self-reported measures



4.3.3 Implementation of self-weighing

Most participants (n=44) reported that self-weighing was “fine” and they “didn’t mind doing it”, 18 participants found it to be a positive experience and nine found it to be problematic. Some of the participants that reported it to be problematic suggested it was due to their weight fluctuating even when they had tried really hard, and therefore felt demoralised. Some participants suggested that they would continue to weigh themselves but not every day as they thought it was too much and may become ‘obsessive’. However other participants reported that they would carry on weighing themselves regularly and that it had become part of a routine and kept them on track to achieve targets (Appendix 6 and 7).

4.3.4 Weight management strategies

It was examined whether self-weighing prompted participants to use weight control strategies more frequently. There was limited evidence that it did, only the reported number of days keeping a record of what participants ate and drank increased significantly in the intervention group, compared to the control group (mean difference 4.8 days 95% CI 1.3 to 8.2). The control group significantly increased the number of days they limited the amount of sugar they consumed compared to the intervention group (mean difference 6.1 days 95% CI 0.6 to 11.5) (Table 9).

Table 9: Mean number of weight loss strategies used at baseline and three months

How often in the past month have you....	Mean change in control group (SD)	Mean change in intervention group (SD)	Mean changes between control and intervention (95%CI) days per month
Planned your meals ahead of time?	2.3 (16.1)	0.8 (15.3)	-1.6 (-6.6, 3.5)
Tried to slow down your pace of eating?	4.7 (14.6)	7.4 (14.2)	2.6 (-2.0, 7.3)
Kept a record of what you eat and drink?	0.6 (10.6)	5.3 (10.7)	4.8 (1.3, 8.2) p = 0.007
Controlled your portions?	2.9 (13.7)	0.1 (15.3)	-2.8 (-7.5, 1.9)
Kept a goal for the amount of calories you eat per day?	1.5 (10.7)	2.4 (11.2)	0.8 (-2.7, -1.8)
Read nutrition labels?	-1.1 (16.1)	-0.2 (13.8)	0.9 (-3.9, 2.4)
Follow a consistent exercise routine?	1.0 (12.6)	-0.7 (12.8)	-1.8 (-5.9, 2.3)
Tried to limit eating out at restaurants?	2.2 (18.6)	-0.4 (17.5)	-2.6 (-8.4, 3.2)
Eaten breakfast?	2.1 (11.0)	0.6 (11.8)	-1.5 (-5.1, 2.2)
Chosen lower-calorie options of particular foods?	-0.8 (16.1)	1.8 (18.4)	2.6 (-3.0, 8.1)
Tried to avoid eating late at night?	1.4 (15.5)	0.8 (14.5)	-0.7 (-5.5, 4.2)
Tried to avoid doing other activities (e.g. watching TV) whilst eating?	3.5 (15.2)	2.7 (14.8)	-0.9 (-5.7, 1.7)
Do exercises that you enjoy?	0.3 (11.9)	-1.7 (11.1)	-2.0 (-5.7, 1.7)
Limited the amount of sugar you eat or drink?	3.3 (16.1)	-2.8 (17.7)	-6.1 (-11.5, -0.6) p = 0.029
Kept a goal for the amount of fruit and vegetables you eat per day?	-2.7 (16.7)	-0.3 (16.7)	2.3 (-3.1, 7.7)
Kept a goal for the grams of fat you eat per day?	1.9 (2.7)	3.8 (12.3)	2.0 (-2.1, 6.0)

4.3.5 Physical activity

Overall self-reported physical activity levels were relatively high at baseline in both the control (744 median met minutes per week IQR 99 to 1740) and intervention (605 met minutes per week IQR 177 to 2079) groups. Both groups increased their self-reported physical activity between baseline and three months (Table 10). However there was no evidence of a significant difference in the change between the groups (mean difference intervention vs. control -145 met minutes per week 95% CI -636 to 347). There was no significant changes in the hours spent sitting between the groups at follow-up either (mean difference -0.9 95% CI -2.6 to 0.8).

Table 10: Change in physical activity levels between baseline and three months

	Mean change (SD)		Mean difference between groups	
	Control n=91	Intervention n=92	Unadjusted n=183	Adjusted n=183
Physical activity met minutes per week	127 (1514)	-18 (1839)	-145 (-636 to 347)	-133 (-569 to 596)
Sitting time Hours per day	-0.06 (3.5)	0.5 (3.6)	0.6 (-0.4 to 1.6)	0.7 (-0.3 to 1.8)

4.3.6 Adverse Events

There were no serious adverse events related to the trial for either group. Participants in the intervention group (n=74) provided data about self-weighing and mood, the mean mood score was 5.0 (2.4) which represents no difference to mood during the study. Self-weighing did not affect the way participants felt about their body, mean score 4.7 (2.4). A score of five is equal to no difference.

4.3.7 Feedback from participants

Participants in both groups found the consultations and food diaries useful (scoring 8.3/10 in control group and 8.9/10 in the intervention group). Overall the study was well received with positive feedback for all questions asked (see Table 11). Participants also provided further comments, with 30 praising the study, five explaining that there was no effect, 16 giving reasons why they did not lose weight and 17 suggesting improvements to the study (Appendix 6). Seven participants reported that their health was a factor in them not losing weight; three reported it was due to Christmas time and three reported it was due to their job, the remainder reported other reasons. One of the main aspects participants stated that would improve the study was regular consultations as participants suggested they would like to be accountable to someone and have that support to stay motivated to lose weight.

Table 11: Participants ratings about the study and the weight management practitioners

Questions about the study	Control	Intervention
On a scale of 1 to 10 how useful were the consultations you received? 10=very useful	8.3 (2.3)	8.9 (1.6)
On a scale of 1 to 10 how useful was the food diary you were asked to complete? 10=very useful	7.5 (3.3)	7.5 (3.2)
A clear explanation about what will happen to me during the study (4=right amount, 7=too much, 1=none)	4.1 (0.6)	4.2 (0.7)
How weight loss may benefit my health (4=right amount, 7=too much, 1=none)	4.4 (0.8)	4.3 (1.0)
What steps to take to manage your weight (4=right amount, 7=too much, 1=none)	4.3 (0.9)	4.2 (0.9)
Provided me with the knowledge about weight management that I needed (1=not well at all, 4=quite well, 7=very well)	5.8 (1.4)	5.8 (1.4)
Helped me feel more confident about weight management (1=not well at all, 4=quite well, 7=very well)	5.5 (1.5)	5.9 (1.3)
Communicated with me on a level I could understand (1=not well at all, 4=quite well, 7=very well)	6.1 (1.3)	6.0 (1.3)
Put me at ease (1=not well at all, 4=quite well, 7=very well)	6.2 (1.2)	6.1 (1.2)

4.4 Discussion

Advice and support to encourage daily weighing did not lead to greater weight loss than was received by participants who received no such instruction. Interpretation of this result is complicated. If the self-report data are to be believed, most people in the intervention group weighed themselves nearly every day. If the objective data are correct, only a fifth weighed themselves on most days, which itself could explain why the intervention had limited effects on behaviours that facilitate weight loss. However regardless of whether participants did or did not weigh themselves daily, there is no evidence instructing participants to do so results in greater weight loss than a control group.

4.4.1 Strengths and limitations

Obesity is associated with deprivation and 92% of participants were classified in the top two deprivation quartiles in the UK. Participants were representative of the family practices recruited in age, gender and IMD. The proactive approach to recruit people who were obese resulted in recruiting men, people with socio-economic disadvantage and people from minority ethnic groups, which shows that such people who are often under-represented in weight loss trials do want support.

There were few exclusion criteria's which led to recruitment of a population that had a range of long-term health conditions, and could be inferred this intervention may not be effective for these people. Participants may have been unable to make changes from this brief intervention due to their health conditions and perhaps required more support. The study did not measure any psychological outcomes such as dietary restraint, disinhibition and weight locus of control which have been shown to be associated with self-weighing, future studies should include these to better understand the mechanisms of effect for self-weighing for weight loss

107 .

A study strength was that I was able to investigate self-weighing as an isolated strategy by utilising an approach in which both groups received a minimal "sham" intervention that is known to be ineffective¹²⁴. This ensured that there were good follow-up rates in the control group and therefore reduced bias. Self-reported weight (n=15) was used when an objective measure could not be obtained, however a sensitivity analysis showed that removing self-reported data from analyses did not significantly change the results. The study was short in duration and there was an intention to follow-up participants at 12 months but when no effect

was found at three months it was decided not to undertake further follow-up since differences in weight loss trials tends to decrease over time.

Participants were instructed to weigh themselves daily to habitualise self-weighing; however on average participants weighed themselves 16.5 days using objective means and 73.1 days using self-reported data. In line with other research there was some evidence that frequent weighing was associated with greater weight loss, however due to the disagreement between objective and self-reported measures of self-weighing I am cautious about interpreting this finding^{109,114}. This discrepancy may be due to a number of reasons including self-reported data generally being unreliable or perhaps participants not using the scales properly and therefore the weights not being recorded¹⁰⁴. The self-reported self-weighing data (weight record card) was a secondary method of collecting self-weighing frequency and therefore some participants may have thought the scales were measuring the weight data and therefore not completed the diary. When asked for the record card at three months they may have imputed weight data. However I believe that the self-reported weight data may be a more accurate measure of frequency of self-weighing as the objective scales may not have been used properly. Some participants had changed the user entry and therefore some data was not downloaded at follow-up as it was on a different setting. Some participants also weighed themselves more than once per day and therefore the scales became full.

4.4.2 Results in the context of other studies

These results are similar to two previous RCTs^{112,113}. A small trial of 23 obese participants were randomised to weigh themselves daily or advised not to weigh themselves¹¹². The control group had greater weight loss than the intervention group (5.9 versus 4.6 kg) but the difference was not significant¹¹². Participants in the control group were weighed before the

group meetings therefore the effect of self-weighing may have been reduced. The second trial involved therapeutic interviews/consultations and the intervention group were additionally instructed to weigh themselves four times per day and record their weights on a chart ¹¹³. At the end of the interviews/consultations there were no significant differences between the groups, however two years later the intervention group had maintained significantly greater weight loss than controls (14.9 versus 7.8 kg). This result might suggest self-weighing could be more effective for weight loss maintenance than weight loss as found in other studies ^{109,114,139}. Participants may also need additional support, beyond simply being instructed to weigh themselves in the early stages of weight loss as they may need to acquire other tools to manage their weight. Self-weighing as an isolated intervention relies upon participants knowing what they should eat and how they should incorporate physical activity. It is a tool aimed primarily at providing feedback to enact what people know they should already do. In this trial participants lacked this knowledge or the ability to incorporate these other behavioural strategies into their daily life and is perhaps why no effect was found.

In two multi-component trials participants' adherence to self-weighing were very high compared to our trial (95% ¹⁴⁰ and 87% ¹¹⁵ versus 60%) and may reflect different recruitment methods and therefore motivation. In the trial reported here participants were recruited through primary care by sending a letter to patients, whereas the other trials used advertisements and therefore it may be plausible that participants in the trial reported here were less motivated. This is important as interventions need to be tested in settings where techniques will be utilised.

Michie and colleagues examined the effectiveness of behaviour change techniques for alcohol reduction, physical activity and healthy eating and found that self-monitoring was associated

with greater effectiveness and when adding other self-control techniques the effect size increased^{99,103}. However it is not always possible (due to costs and time) to implement interventions with multiple techniques and thus the effect of self-weighing was isolated. In this trial simply asking people to weigh themselves daily was insufficient, however multicomponent interventions that include self-weighing provide evidence that self-weighing is an effective component for weight management^{107,115}. Although daily self-weighing did not result in significant greater weight loss further research can be completed to examine other behavioural techniques that can be utilised in addition to self-weighing. Previous research has found tailored weekly feedback via email produced positive results and this now needs to be implemented/evaluated within a primary care setting¹¹⁵.

4.5 Conclusions

Whilst previous systematic reviews have shown self-weighing to be effective, in this study advice and support to encourage daily weighing did not lead to significant weight loss in a sample of patients recruited from GP practices⁹⁶. This is the first study to isolate the effectiveness of the instruction to daily self-weigh. However this instruction did not result in greater weight loss in the intervention group.

Trial Registration: ISRCTN05815264 - The effect of self-weighing as a weight loss intervention. Ethical Approval – 12/WM/0137 NRES Committee West Midlands, England 31/05/2012

CHAPTER 5

5.0 REGULAR SELF-WEIGHING TO PROMOTE WEIGHT MAINTENANCE AFTER INTENTIONAL WEIGHT LOSS: A QUASI-RANDOMISED CONTROLLED TRIAL

This chapter is based on the following published paper:

Madigan CD, Aveyard, P, Jolly K, Denley J, Lewis A, Daley A. Regular self-weighing to promote weight maintenance after intentional weight loss: a quasi-randomised controlled trial. *Journal of Public Health* (2013) doi: 10.1093/pubmed/fdt061¹³⁹.

KJ, AD, PA, JD designed the Lighten Up trial and it was coordinated by AL. JD designed and managed the Lighten Up service. I conducted the statistical analyses with support from PA. I drafted the paper with support from AD and with additional input by PA, AL and KJ. I wrote the chapter and added additional sections.

The previous chapter reported that asking participants to weigh themselves daily does not result in significantly more weight loss than a control group, however self-weighing may be more effective for weight loss maintenance. Chapter 3 also showed that all commercial programmes result in similar weight losses, however most people tend to regain weight after a weight loss intervention. This chapter will investigate a simple weight loss maintenance intervention (self-weighing) after receiving one of these programmes. A copy of ethical approval can be found in appendix 9.

5.1 Introduction

Compared with weight loss trials, only a few studies have focused on maintenance of weight loss. Maintenance trials are important because people almost invariably regain weight after

initial weight loss, therefore, finding effective strategies to minimise weight regain is critical. Systematic reviews of weight loss maintenance studies have found self-monitoring, opportunities for social comparison, peer/social support and maintaining contact with participants can reduce weight regain⁹⁴⁻⁹⁷. Research has indicated that self-weighing may be a useful method of self-monitoring for both weight loss and maintenance^{94,96}. The potential efficacy of self-weighing has been based on self-regulation theory⁶¹. Self-regulation is a process involving conscious efforts to monitor oneself and evaluate and appraise against goals which can reinforce behaviour^{61,62}. Self-weighing can show the individual how their behaviour affects their weight and allows them to adjust their behaviour to achieve their goals¹⁴¹.

Some studies^{114,140} have included self-weighing as part of an extensive multicomponent intervention, but to date only three RCTs^{112,113,142} have tested a self-weighing intervention where the emphasis of the intervention was regular self-weighing. In one case, the intervention was focused on weight loss¹¹², one on weight maintenance¹⁴² and the third on both weight loss and weight loss maintenance¹¹³. All were small (range from n=23 to 89), contained other methodological concerns such as short follow-up, making it difficult to draw conclusions. Nevertheless, the weight maintenance trials reported greater sustained weight loss in participants allocated to self-weighing, suggesting this may be effective for weight maintenance¹¹³.

5.1.1 Lighten Up

In 2008 SBPCT commissioned the Lighten Up service; this provided NHS patients with a free course of weight loss treatment for three months. The initial users of the service were enrolled in an RCT¹²⁴ to test the effectiveness of six weight loss treatments in primary care.

Participants were randomly allocated to a minimal intervention control group, or one of six weight loss treatments, or a choice of the six. The treatments were one-to-one pharmacist support, one-to-one general practice-based support, a NHS group based programme, Weight Watchers, Slimming World, and Rosemary Conley. Slimming World and Rosemary Conley are UK-based group weight loss programmes that are similar to Weight Watchers and a fuller description is provided in chapter 3 (Box 3). Only Weight Watchers and Rosemary Conley showed statistically significant greater weight loss than the control group at the end of the three-month treatment ¹²⁴. In a planned comparison, all three commercial interventions combined were more effective than the primary care interventions combined.

Based on the results of the Lighten Up RCT ¹²⁴, the Lighten Up service commissioned four of the six original treatment providers for continued use after the RCT finished recruitment. These were: Weight Watchers, Rosemary Conley, Slimming World, and NHS group based programme. Patients could choose which weight loss treatment they wanted to attend. The primary care trust (PCT) also commissioned a telephone coordinating centre to administer the service and to provide a weight loss maintenance intervention. The weight loss maintenance intervention encouraged regular self-weighing. The coordinating centre also followed up users of the Lighten Up service 12 months after starting the weight loss treatment, just as had been the case in the Lighten Up RCT. Using routinely collected data from the Lighten Up service database I have taken the opportunity to examine the effectiveness of this self-weighing maintenance intervention, by comparing the weight change in participants in the Lighten Up RCT, where participants received no maintenance intervention, with users of the Lighten Up service, who were all offered the weight loss maintenance intervention.

5.2 Methods and procedures

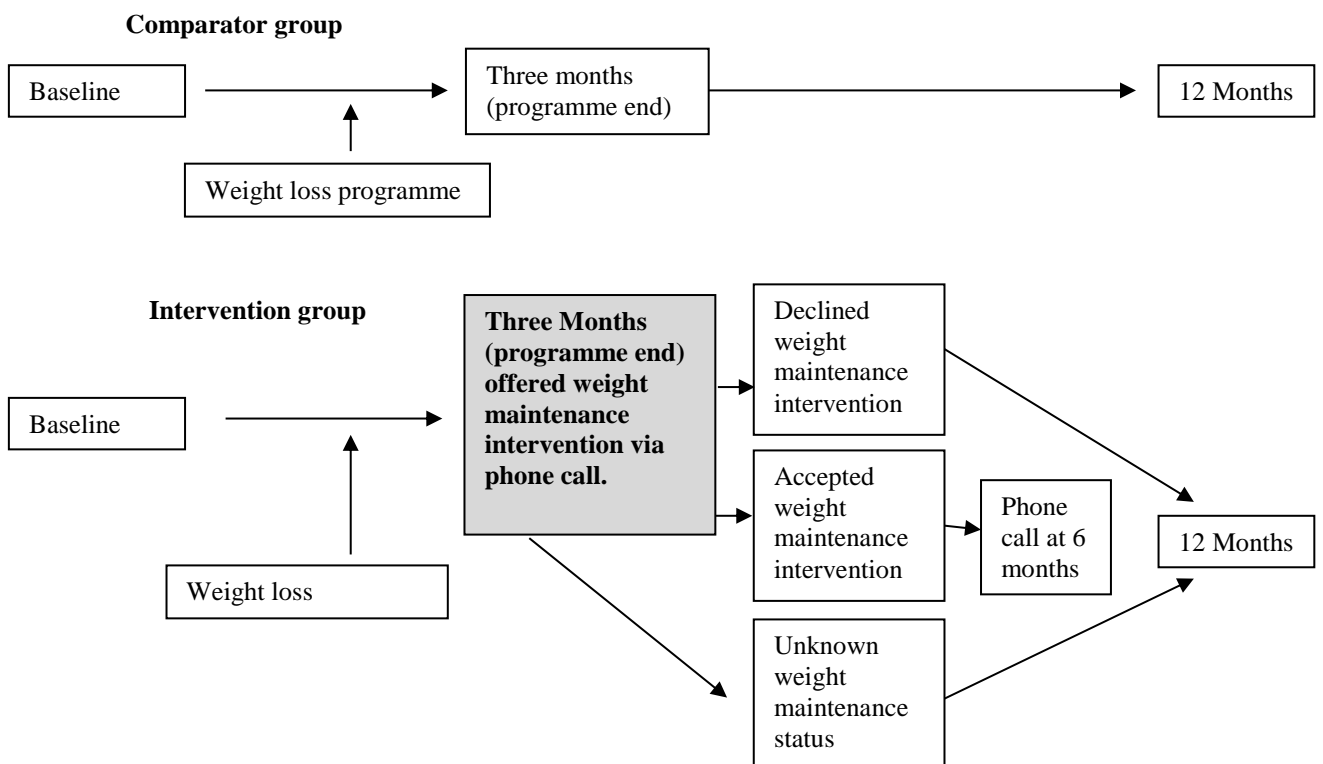
5.2.1 Setting and recruitment of participants

In both the RCT and the service GPs referred patients who wanted to follow a weight loss treatment and who met eligibility criteria to the Lighten Up call centre either by letter or in a consultation. GPs searched their computerised lists for patients of ≥ 18 years with a raised BMI recorded in the previous 15 months. Raised BMI was defined as South Asians with no comorbidities and BMI ≥ 25 kg/m², or with comorbidities and BMI ≥ 23 kg/m² and all other ethnic groups (except South Asians) with no comorbidities and BMI ≥ 30 kg/m², or with comorbidities and BMI ≥ 28 kg/m². The GP excluded patients who had a medical contraindication for any of the weight loss treatments before a letter of invitation was posted. All patients who were interested in taking part telephoned the coordinating centre where the treatment was explained. In the Lighten Up RCT, participants consented to be randomised and in the Lighten Up service they chose their weight loss treatment. RCT participants and service users were then offered a three month weight loss treatment which was no cost to them. In the RCT, there were six different weight loss treatments, but only four were subsequently offered to service users because two of the four programmes (pharmacy and GP programmes) were deemed ineffective. Therefore RCT participants that used the two ineffective programmes were excluded from this analysis. In one arm of the RCT, participants were randomised to a choice of treatments. Participants who chose their treatment lost the same amount of weight as those who were allocated randomly and therefore there is no reason to believe that choice, which all users of the service had, played any role in the results.

5.2.2 Allocation

Lighten Up RCT participants were allocated to the control group (no weight loss maintenance intervention) and Lighten Up service participants were allocated to the intervention group (weight loss maintenance intervention) based solely upon when they were recruited. The control group were recruited from January to May 2009 and subsequent patients were enrolled into the intervention group from May 2009 until March 2010. Allocation was based on these two time periods and could not therefore be influenced by participants or researchers (i.e. quasi randomised). Figure 17 depicts the pathways of the intervention and control groups.

Figure 17: Study design



5.2.3 Primary outcome and assessments

The intervention aimed to prevent weight regain after a period of weight loss, therefore the primary outcome was change in body weight between end of the weight loss treatment at three months and nine months later, 12 months after starting the weight loss treatment and herein referred to as 12 month follow-up. Both groups were weighed at baseline, prior to commencing the weight loss treatment. Both groups were weighed at the end of the weight loss treatment if they remained in contact with the provider and otherwise self-reported weight data were obtained. At 12 months, the intervention group self-reported weight only, whereas the control group were weighed.

5.2.4 Demographic information

Participants reported their age, gender, ethnicity, postcode and occupation to the call centre staff at baseline. Postcode was used to derive the IMD score, which is an area-based measure of socio-economic status, and were categorised into quartiles¹²⁶. Height was collected at baseline and BMI was calculated at baseline, three and 12 months.

5.2.5 Weight loss maintenance intervention

The call centre contacted participants in the intervention group upon completion of their three month weight loss treatment to ask if they were interested in receiving a three month weight loss maintenance intervention. The weight loss maintenance intervention was developed by SBPCT based on preliminary evidence supporting the usefulness of self-monitoring for weight management and its potential to be implemented easily within primary care^{94,96}. Participants who accepted were asked if they owned a set of weighing scales; if not, they were sent a voucher to obtain a free set from a local pharmacy. All participants who accepted the

intervention were sent a maintenance pack that consisted of a card to record weight, a hints and tips booklet about weight management and the Eat Well Plate¹⁴³ (leaflet showing the required types and proportions of food that a healthy balanced diet should contain).

Participants were instructed to weigh themselves weekly and record this on the card. The call centre staff phoned participants three months later (at six months from baseline) to encourage them to weigh themselves regularly. Call centre staff did not offer any opinions or undertake any motivational interviewing, they listened, offered positive reinforcement, encouragement and passed on factual information. The call centre was staffed by two employees trained in call centre management systems and customer relations, but not nutrition or weight management. The main aim of intervention components was to encourage and facilitate regular self-weighing.

5.2.6 Data analysis

5.2.6.1 Imputation of missing weight data

All trials suffer from loss to follow-up and this is particularly common in weight management trials, where participants who fail to lose weight are reluctant to declare or show this. Missing data was imputed to preserve the ITT principle, but our imputation was conservative. Data for the control group (Lighten Up RCT) was provided by the investigators and routine data for the intervention group (Lighten Up Service) was provided by SBPCT. In the intervention group if a participant's weight data could not be obtained from the weight loss provider, the call centre staff tried to telephone participants to obtain a self-reported weight. However they were not always able to contact them despite at least three attempts, therefore some weights were missing at three months.

As the intention was to offer the weight loss maintenance intervention to all participants, an ITT approach was used with imputed missing data. As there was a high level of missing weight data the most conservative method to impute missing weight data was used. There were two options that were considered to impute three month missing weight data, firstly the commonly used BOCF method or secondly to calculate the average weight loss per programme and impute this. This was calculated by subtracting the average weight loss achieved in those who were followed up for each weight loss treatment from baseline weight. Normally BOCF is the most conservative method in weight loss studies; however the average imputation was the most conservative approach because it resulted in the greatest weight loss between baseline and three months and allowed the possibility that more weight could be regained between three and 12 months, the primary outcome. This is shown in Table 12; both the comparator and intervention groups lost more weight using the average weight loss imputation method.

For 12 months two options were considered, either using BOCF or a method previously used in other studies that added 0.3 kg per month of missing weight data ¹¹⁴. Both resulted in similar weight changes between three and 12 months but the difference was slightly smaller between the groups using the 0.3 kg method (0.7 vs. 0.6 kg), therefore this method was chosen.

Table 12: Weight change using different methods to impute missing weight data

Mean weight change, kg (SD)		Recorded weight Loss	Average weight Loss imputed at 3 months	Baseline taken for weight at 3 months	Average weight loss imputed for 3 months and baseline for 12months	Average weight loss imputed for 3 months and Wing method for 12 months
0 to 3 months	Comparator	-4.4 (4.4)	-4.3 (4.1)	-3.6 (4.4)	NA	NA
	Intervention	-4.9 (3.8)	-4.9 (3.3)	-3.7 (4.0)		
3 to 12 months	Comparator	0.7 (6.1)	NA	NA	1.9 (5.9)	1.8 (5.5)
	Intervention	-1.1 (5.9)			1.2 (5.8)	1.2 (5.8)

5.2.6.2 Analyses

All analyses were conducted using SPSS version 18¹⁴⁴. Baseline differences between the arms were examined by comparing frequency distributions of categorical variables and means of continuous variables. The same analyses were conducted to examine baseline differences between participants who had missing and recorded weight data. The primary analysis was conducted using the ITT principle using imputed missing weight data. The analysis was repeated confined to participants where weight was reported. Linear regression was used to determine the mean difference in weight change (three to 12 months) between the group given the weight loss maintenance intervention and the group that was not, using both ITT and per protocol analyses. In the ITT analysis the mean weight change from three to 12 months was compared for the groups offered and not offered the weight maintenance programme. Not everyone offered the weight maintenance programme accepted it and in the per protocol analysis mean differences in weight change between participants that accepted the intervention and the group not offered the weight maintenance intervention were examined. Age, gender, baseline BMI, weight loss treatment, ethnicity, IMD, amount of weight loss

(baseline to three months) and occupation were included as covariates. These were accounted for as participants were not randomised to groups and these variables may influence weight loss. All continuous variables were mean centred and all categorical variables split into binary dummy variables. Continuous variables were mean centred to enable easier interpretation of the coefficients to explain the difference in relation to the mean age, BMI and initial weight loss.

It is possible that some weight loss treatments may provide participants with more effective tools to manage their weight than others. If so, the effectiveness of the subsequent weight loss maintenance intervention may depend upon the type of weight loss treatment received. This was tested for by including multiplicative interaction terms between receiving the weight loss maintenance intervention and type of weight loss treatment. Likewise, it seems likely that the weight maintenance intervention may be more effective for people who have lost most weight as they are at greatest risk of weight regain. A dummy variable was created indicating whether or not participants had lost at least 5kg in the weight loss treatment and then a multiplicative interaction term was created with whether or not participants were offered the weight loss maintenance programme.

5.3 Results

5.3.1 Characteristics at the start of weight loss maintenance intervention

The groups were generally similar on all baseline characteristics assessed prior to the start of the weight loss intervention (three months prior to enrolment in the weight loss maintenance intervention) except for gender (Table 13). After baseline, however, there was a small difference in the balance of characteristics between the weight maintenance intervention and the control group. Participants in the control group were randomised to the various weight

loss treatments so allocation was approximately equal. The intervention group were able to choose their initial weight loss treatment and a higher percentage chose Slimming World (28% versus 23.4%) and Weight Watchers (41.5% versus 26.8%) than were allocated to these in the control group.

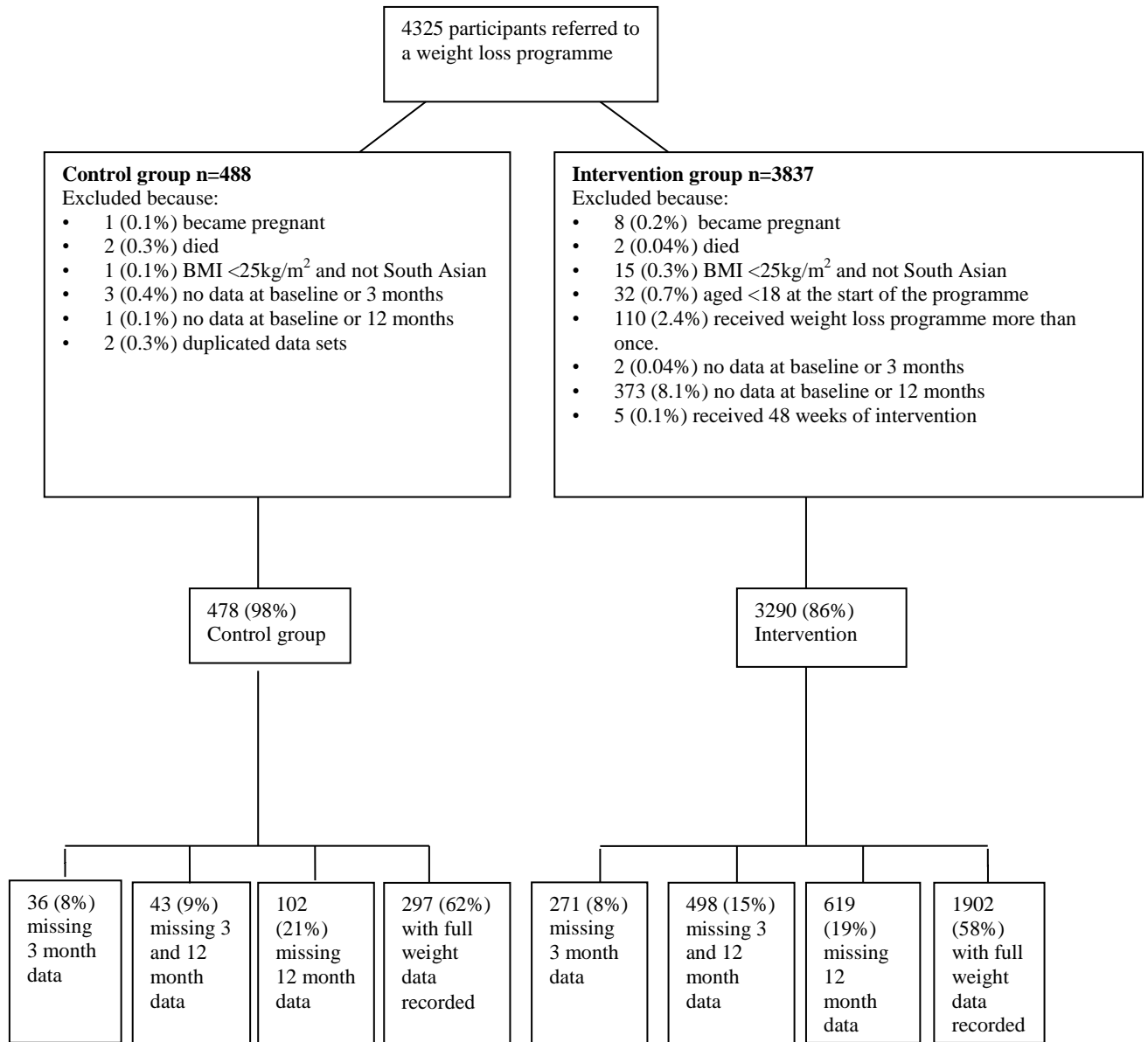
Enrolment for the weight loss maintenance intervention occurred three months after the start of the weight loss treatment. At that point, 55% of the intervention group were followed up and 60.3% of the control group were followed up. At 12 month follow-up, 62% of the intervention group were followed up and 82.7% of the control group (Figure 18).

The mean weight losses between zero and three months in the intervention and control groups was 4.9 kg (SD 3.3) and 4.4 kg (SD 4.1) respectively, meaning a slightly higher weight loss in the group offered the weight loss maintenance programme, probably because in choosing treatments, they chose a commercial provider more often than the NHS group, which was less effective. There were 3290 participants in the intervention group and of these, 900 (97%) were followed up and included in the per protocol analyses as they accepted the maintenance intervention.

Table 13: Baseline characteristics of participants

Variable	All participants n (%)	Control group (trial) n (%)	Intervention group (service) n (%)	Accepted maintenance intervention n (%)
Number	3768 (100)	478 (13)	3290 (87)	900/ 3290 (27)
Gender				
Male	589 (15.6)	153 (32.2)	436 (13.3)	129 (14.3)
Female	3179 (84.4)	325 (68.0)	2854 (86.7)	771 (85.7)
Ethnicity				
White	3185 (84.5)	424 (88.7)	2761 (83.9)	767 (85.2)
Mixed	96 (2.5)	11 (2.3)	85 (2.6)	19 (2.1)
Asian	178 (4.7)	8 (1.7)	170 (5.2)	42 (4.7)
Black	276 (7.3)	32 (6.7)	244 (7.4)	64 (7.1)
Other	31 (0.8)	3 (0.6)	28 (0.9)	8 (0.9)
Weight Loss Programme				
NHS group programme	325 (8.6)	113 (23.6)	212 (6.4)	49 (5.4)
Rosemary Conley	916 (24.3)	125 (26.2)	791 (24.0)	186 (20.7)
Slimming World	1033 (27.4)	112 (23.4)	921 (28.0)	280 (31.1)
Weight Watchers	1494 (39.6)	128 (26.8)	1366 (41.5)	385 (42.8)
Mean age in years (SD)	50.9 (14.9)	51.1 (14.7)	49.9 (14.9)	53.2 (14.7)
Baseline BMI (SD)	34.8 (5.5)	33.7 (3.6)	35.1 (5.7)	35.5(6.3)
3 month BMI (SD)	33.2 (5.4)	32.2 (3.7)	33.3 (5.6)	33.5 (6.1)
Weight loss 0-3 months kg (SD)	-4.8 (3.4)	-4.4 (4.1)	-4.9 (3.3)	-5.5 (3.9)
IMD quartile				
0 (most deprived)	1947 (51.7)	244 (51.0)	1703 (51.8)	428 (47.6)
1	1316 (34.9)	169 (35.4)	1147 (34.9)	351 (39.0)
2	449 (11.9)	57 (11.9)	392 (11.9)	110 (12.2)
3 (least deprived)	55 (1.5)	7 (1.5)	48 (1.5)	11 (1.2)
Occupation				
Employed	1916 (50.8)	271 (56.7)	1645 (50.0)	401 (44.6)
Not working/unemployed	865 (23)	66 (13.8)	799 (24.3)	205 (22.8)
Retired	854 (22.7)	103 (21.5)	751 (22.8)	282 (31.3)
Unable to code	109 (2.9)	21 (4.4)	88 (2.7)	12 (1.3)

Figure 18: Exclusions and participant flow for control and intervention groups



5.3.2 Baseline characteristics of those with missing and recorded weight data

The characteristics of those with missing weight data at three and 12 months were examined and compared (Table 14). At three months a higher proportion of Asian ethnicity participants had missing weight data (Table 14). Those with three month weight data were on average 5.5 years older and more likely to be retired (25% vs.14.7%). All other baseline characteristics were similar. At 12 months participants with missing weight data had similar baseline

characteristics except for participants providing data were on average 6.5 years older and a higher percentage were retired (27% vs. 14%).

5.3.3 Primary analysis

In the ITT analysis using imputed data both groups regained weight between the end of the weight loss treatment (three months) and 12 month follow-up. However on average the weight loss maintenance group regained 1.2 kg (SD 5.8) and the control group regained 1.8 kg (SD 5.5). There was a significant difference of 0.7 kg (95% CI 0.1 to 1.2) (about one third of weight regain) between control and intervention participants, from three to 12 month follow-up, after adjustment for covariates (see Table 15). When using data on only those participants followed up, the mean difference after adjustment between the groups was larger at 1.7 kg (95% CI 0.9 to 2.4); the intervention group lost a further 1.1 kg (SD 5.9) compared to the control group, who on average, regained 0.7 kg (SD 6.1). Adjusting for covariates did not substantially alter the results.

Table 14: Baseline data of participants providing weight data and those missing weight data

Variable	Missing three month weight data	Recorded three month weight data	Missing 12 month weight data	Recorded 12 month weight data
Number	848	2920	1262	2506
Male (%)	13.8	16.2	15.1	15.9
Ethnicity (%)				
White	78.8	86.2	81.8	85.9
Mixed	3.8	2.2	3.3	2.2
Asian	7.8	3.8	6.6	3.8
Black	8.5	7.0	7.3	7.3
Other	1.2	0.8	1.0	0.8
Weight management programme (%)				
NHS group	9.2	8.5	6.3	9.8
Rosemary Conley	30.3	22.6	27.7	22.7
Slimming World	22.1	29.0	23.9	29.2
Weight Watchers	38.4	40.0	42.2	38.4
Age (mean in years)	45.7 (14.4)	51.4 (14.8)	45.7 (14.4)	52.3 (14.7)
Baseline BMI	34.8 (5.4)	34.9 (5.6)	35.1 (5.5)	34.8 (5.5)
IMD quartile (%)				
0 most deprived	57.5	50.0	53.6	50.6
1	30.5	36.2	33.9	35.5
2	10.6	12.3	10.9	12.4
3 least deprived	1.3	1.5	1.6	1.4
Occupation (%)				
Working in employment	47.8	51.7	55.2	49.2
Not working/unemployed	31.1	20.6	27.8	20.8
Retired	14.7	25.0	14.0	27.2
Unable to code	3.5	2.7	3.1	2.8

5.3.4 Per protocol analysis

The per protocol analysis compared participants who accepted the weight loss maintenance intervention to the control group not offered it. Using imputed data the control group on average regained 1.8 kg (SD 5.5) and the intervention acceptors lost 1.4 kg (SD 6.1). After

adjusting for covariates there was a mean difference of 3.0 kg (95% CI 2.3 to 3.7) between the control group and those who accepted the maintenance intervention (intervention acceptors) (see Table 15). Using data only on those followed up, the mean difference (adjusted) was 1.9 kg (95% CI 1.1 to 2.8) between the control and intervention acceptors who regained 0.7 kg (SD 6.1) and lost 1.5 kg (SD 6.1) respectively.

5.3.5 Effect modification by type of weight loss treatment received and amount of initial weight loss

Those who lost more weight may have benefited most from the weight loss maintenance intervention; however there was no significant effect ($T=-0.95$, $df=1$, $p=0.34$). If some weight loss treatments prepared participants to be better able to manage their weight after treatment end than others, then the weight loss maintenance intervention may have been less effective for those participants. There was no evidence to support this suggestion ($F=1.99$, $df=3$, $p=0.11$).

Table 15: Mean weight change and difference in weight change between the control and intervention groups.

Mean difference between the intervention and control groups				
	Intervention group weight change between 3 to 12 months, kg (SD) Unadjusted	Control group weight change between 3 to 12 months, kg (SD) Unadjusted	Mean difference in weight change from 3 to 12 months, kg (95% CI)	
			Unadjusted	Adjusted
Imputed weight	1.2 (5.8) (n= 3290)	1.8 (5.5) (n= 478)	-0.6 (-1.2 to -0.1)*	-0.7 (-1.2 to -0.1)**
Reported weight	-1.1 (5.9) (n=1902)	0.7 (6.1) (n=297)	-1.8 (-2.5 to -1.1)**	-1.7 (-2.4 to -0.9)**
Mean difference between the control group and those who accepted the weight maintenance intervention				
Imputed weight	-1.4 (6.1) (n=900)	1.8 (5.5) (n=478)	-3.2 (-3.9 to -2.6)**	-3.0 (-3.7 to -2.3)**
Reported weight	-1.5 (6.1) (n=876)	0.7 (6.1) (n=297)	-2.2 (-3.0 to -1.4)**	-1.9 (-2.8 to -1.1)**

*Significant values <0.05

** Significant values <0.001

5.4 Discussion

5.4.1 Main findings of the study

Routine data was used from a service that was implemented within primary care and it was found that participants who were offered a weight loss maintenance intervention after completing a weight loss treatment, regained less weight than participants who were not. The intervention prevented about a third of the weight regain seen in the control group. This finding did not depend on the amount of weight lost between baseline and three months or the type of weight loss treatment received. The per protocol analysis showed a substantial difference (3.0 kg) in weight regain between those in the intervention group who accepted the intervention and those in the control group. The intervention seemed to prevent all weight regain and indeed led to a further small weight loss.

5.4.2 What is already known on this topic

These results are similar to two RCTs of weight maintenance that investigated the effect of self-weighing^{113,142}. The first report included two experiments (n=75)¹⁴². In both intervention groups participants weighed themselves daily and emailed their weight daily to the researchers who gave feedback via email. Ten weeks after enrolment, those who completed the trial in experiment one weighed a mean of 3.1 kg less than the controls, and in experiment two they weighed 2.8 kg less. In the second RCT (n=89) all participants attended an initial behaviour therapy weight loss programme and the intervention group were instructed to weigh themselves and record this four times per day¹¹³. At the end of the behaviour therapy programme (6.5 months from baseline) there was no significant difference between groups in mean weight change. After the behavioural therapy the self-weighing intervention group were instructed to continue to record their weight and at two year follow-up had regained

significantly less weight than controls (mean difference 7.1 kg). The studies described here and which have typically used per protocol analysis have reported positive findings for self-weighing as a maintenance intervention (weight loss maintenance and weight maintenance) and mean differences in these studies are much larger than reported in the ITT analyses (0.7 kg) here. However, the ITT analysis may provide a more realistic indication of the magnitude of preventable weight regain that can be expected from an intervention aiming to get participants to regularly weigh themselves during weight loss maintenance.

5.4.3 What this study adds

A large proportion of people with weight problems take action to lose weight but almost invariably put it back on. If there are a range of simple evidence-based self-help strategies that may prevent weight regain we can encourage participants to use these. Natural experiments such as this one can help identify possible strategies and this study has highlighted that an intervention including encouragement to regularly self-weigh, a hints and tips leaflet and phone prompts might be one of these strategies.

Eighty seven percent of participants were from the poorest 40% of neighbourhoods and 16% were from minority ethnic groups. This implies that a simple intervention strategy can effect behaviour change in a population that is difficult to engage. Missing data was accounted for using conservative assumptions which are likely to overestimate the weight regain. This is important because it is likely that people who have done well on a weight loss programme are more likely to report their weight than people who have regained weight. This is most likely in the intervention group who were sent weighing scales and a record card and who were telephoned twice and encouraged to continue their efforts on weight loss maintenance. Hence

why the primary analyses used ITT as people who joined the maintenance programme may have been more motivated to lose weight.

5.4.4 Limitations of this study

This natural experiment meant that participants were allocated to intervention and control groups based on the time at which their GPs started using the Lighten Up service. The service was rolled out in practices across the PCT. It is possible that there was some systematic difference between participants that were enrolled later and received the intervention and those enrolled earlier allocated to control. Our data do show some differences in gender balance and ethnicity between arms. The most important predictor of weight change at 12 months was amount of weight lost initially and participants in the intervention group lost somewhat more (0.5 kg) and therefore would have greater potential for weight regain, biasing the results in favour of the control group at 12 months follow-up. Although these variables were adjusted for, it was not possible to adjust for unmeasured differences between the groups, but there is no clear reason to assume there was such an imbalance. Future research should utilise an RCT methodology to address this question further. Whilst the study included a very large sample size the results need to be considered in the context of the rates of 40% loss to follow-up at 12 months. However, a conservative method was used to impute missing weight data but this may have overestimated the weight regained as the regain was much higher for those with imputed weight data.

The main difference between the groups is that the control group were weighed at three and 12 months whilst due to the number of participants in the intervention group self-reported weight at 12 months was used. People typically underestimate their weight when asked to self-report which may have led to bias that favoured the intervention group. Importantly

however, the Lighten Up RCT found those who self-reported their weight had a smaller weight loss (0.6 vs. 0.8 kg) than those objectively measured between three and 12 month follow-up¹²⁴. Conservative methods have been used to minimise bias but cannot control for the difference in the measurement of weight and is a limitation of this research. Lastly, frequency of self-weighing was not assessed and this would be an important feature of future studies, especially with an objective measure of self-weighing.

5.5 Conclusion

A pragmatic weight maintenance intervention that encourages regular self-weighing as well as a hints and tips booklet and phone prompts may reduce weight regain after intentional weight loss. The findings imply that minimal instruction to weigh oneself regularly together with providing the tools to do so, such as a record card to initiate the behaviour, could usefully become part of routine follow-up for people who have been through a weight loss programme.

CHAPTER 6

6.0 IS SELF-WEIGHING AN EFFECTIVE WEIGHT MANAGEMENT TOOL: A SYSTEMATIC LITERATURE REVIEW AND META-ANALYSIS

Acknowledgements: The idea for the systematic review was developed by my supervisors and me. I designed the search strategy with input from AD, KJ and AL. I conducted the search and checked all titles and abstracts for inclusion. AD, KJ, and AL independently checked one third of the search results and the same method was used for extracting data from full text articles. I drafted the paper with advice and guidance from AD, KJ, AL and PA.

Madigan CD, Aveyard P, Lewis AL, Daley AJ, Jolly K (prepared) Is self-weighing an effective weight management tool: a systematic literature review and meta-analysis.

6.1 Introduction

Chapters 4 and 5 of this thesis have examined self-weighing as an isolated strategy for weight loss and weight loss maintenance. Since the initial proposal there have been two further trials published that have focused on self-weighing. In order to place the results of the trial presented in chapter 4 into context of the current literature, here I report the results of a systematic review of self-weighing for weight management.

Finding simple, yet effective, ways in which individuals can be helped to lose weight and sustain weight loss could improve public health. One promising behaviour change technique is to prompt self-monitoring, which has been shown to be an effective technique for healthy eating, physical activity and alcohol reduction^{99,102,103}.

One technique that can be defined as self-monitoring is self-weighing. A systematic review of regular self-weighing for weight management concluded that frequent self-weighing appeared

to be a good predictor of moderate weight loss, weight loss maintenance or avoidance of initial weight gain in adults ⁹⁶. The systematic review was conducted in 2008 and included four randomised trials and eight observational studies and concluded that self-weighing was a promising intervention for weight management. As there were only a few studies and a mix of study designs, it was not possible for the authors to conduct a meta-analysis or identify the key elements of the interventions that might have led to the apparent effectiveness of self-weighing. There is a need to update the review and use the greater volume of literature to identify elements associated with greater effectiveness, focusing exclusively on studies with experimental designs.

The aim of this review is to examine whether self-weighing is effective for weight loss, preventing weight gain and for maintaining weight following successful weight loss. The review will also examine whether advising people to weigh themselves can be effective as a single intervention or only in the context of a behavioural support programme addressing other behavioural strategies. If self-weighing can be effective on its own, then potentially advice to do so might form the basis of a public health campaign. If self-weighing can work but only with additional interventions then incorporating advice on self-weighing into behavioural programmes could enhance their effectiveness. Currently, widely used behavioural programmes in the UK advise their participants against this. As documented in chapter 2, there are some concerns about the negative psychological impact of regular self-weighing ¹¹⁸, however there is a lack of evidence from randomised designs ¹¹⁹. This is important though, and the potential harms of self-weighing are considered here.

Three theoretical issues are also addressed. Firstly, for self-weighing to be enacted upon it probably needs to become habitual and this might be easier to achieve if it occurs daily rather

than weekly. Daily weighing may also be more effective than weekly because it provides more immediate feedback on how behaviour influences weight and immediate feedback can lead to greater learning than feedback that is delayed¹⁴⁵. Others argue that daily weighing is more likely to give false feedback and hence interfere with learning, though I know of no data to support this proposition. Secondly, it might be hypothesised that self-weighing is more effective when it is accompanied by goal setting, so that the person can compare their weight against those goals and those goals may in themselves motivate action. Thirdly, participants in behavioural weight loss programmes often report that it is the weekly weigh-in that is the most salient component of the programme that keeps them committed to their diet and physical activity plan, primarily because it is done in front of the group leader¹⁴⁶. Furthermore it is examined if accountability, where as part of the intervention you are answerable to someone in real time, enhances the effectiveness of self-weighing.

6.2 Methods

6.2.1 Trial eligibility criteria

RCTs and experimental designs that had a concurrent comparator/control group were included. All participants were adults (aged ≥ 18 years). Trials were included if self-weighing was the main intervention strategy or a component of a multi-component intervention. Self-weighing was defined as participants being asked to weigh themselves rather than being weighed as part of a programme. The outcome of interest was weight change at follow-up. No restrictions on location or follow-up were made. Only trials reported in the English language were included. Trials were excluded if participants were pregnant. Table 16 summarises the populations included within this review.

Table 16: PICO for review

Participants	Adults (≥ 18 years) – non pregnant
Interventions	Self-weighing as a standalone or a component of weight management intervention
Control/ comparator group	No intervention/ comparator or a weight management strategy that did not include self-weighing.
Outcome	Weight change from baseline to programme end and weight change from baseline to last follow-up point.

6.2.2 Search strategy

A systematic search of the following databases was conducted on 21st May 2013: Cochrane central register of controlled trials (CENTRAL, The Cochrane library, CINAHL (EBSCO Host) (1982 to present), MEDLINE (OVID SP) (1946 to present), EMBASE (OVID SP) (1980 to present), PsychInfo (OVID SP) (1806 to present) and Web of Science. ISCRTN and clinical trials registries were also searched for any research that may not have been published. Search terms included: body weight, weight loss, weight maintenance, self-monitoring, self-care, self-weighing and weight monitoring. MESH terms were used where applicable (Table 17). The reference lists of included trials were searched and of two previous systematic reviews of self-weighing and self-monitoring were searched^{94,96}.

Table 17: Search strategy

1	Body Weight/ (MESH term)
2	limit 1 to (English language and humans)
3	Self-monitoring.mp.
4	limit 3 to (English language and humans)
5	Self-Care/ (MESH term)
6	limit 5 to (English language and humans)
7	2 and 3

8	2 and 6
9	Weight Loss/ (MESH term)
10	limit 9 to (English language and humans)
11	6 and 10
12	4 and 10
13	Weight maintenance.mp.
14	limit 13 to (English language and humans)
15	6 and 14
16	4 and 14
17	11 or 12 or 15 or 16
18	Self-weighing.mp.
19	limit 18 to (English language and humans)
20	Weight monitoring.mp.
21	limit 20 to (English language and humans)
22	17 or 19 or 21

6.2.3 Study selection

Two independent reviewers screened all search results (titles and abstracts) for possible inclusion and those selected by either or both reviewers were subject to full-text assessment. The same process was used to assess the selected full text articles for inclusion. Any discrepancies were reviewed with consensus, overseen by a third review author who acted as arbiter, with approval by one review author and the arbiter being sufficient. The reviewers were not blinded to trial authors, institution, or publication journal.

6.2.4 Data collection process

One author independently extracted data using forms based on the Cochrane systematic review data collection forms and a second author checked the forms for any discrepancies¹⁴⁷. Disagreements were resolved by discussion between the two reviewers and if an agreement could not be reached a third reviewer acted as arbiter. Six authors were contacted for further data and two responses were received^{148,149}.

6.2.5 Data items

Information was extracted about the study design, inclusion criteria, participants, study setting, duration of intervention and follow-up, intervention and comparator group weight management strategies, number providing follow-up data, imputation method used for missing weight data and any adverse events. Information was also collected about the strategies used to help participants weigh themselves including recommended frequency of self-weighing, goal setting, accountability, methods to record self-weighing, feedback and prompts to self-weigh. Weight change data for intervention and control groups with standard deviations (SD) were recorded.

6.2.6 Risk of bias in individual trials

The risk of bias of included trials was assessed, in accordance with the Cochrane guidelines¹⁴⁷. Information on randomisation (sequence generation), allocation concealment, blinding of outcome data, missing outcome data, selective reporting and measure of outcome data was collected. This was independently extracted and checked by a second reviewer. A high risk of bias for reporting outcome data was defined as a difference in follow-up rates between the groups of $\geq 20\%$ or that there was $\geq 70\%$ attrition. The other measures of bias were based on the Cochrane guidelines¹⁴⁷.

6.2.7 Summary measures

The outcomes of interest were mean weight change from baseline to programme end and weight change from baseline to last follow-up. Follow-up was defined as a period after receiving the last intervention contact and a point of data collection. For each study weight change for each group was extracted reporting the mean, SD, and number of participants contributing data. Where SD were not presented these were calculated from standard errors using the following formula: $SD = SE \times \sqrt{n}$.

Studies varied in how they presented data, for example only data on those followed up or using various imputation methods. Synthesising such studies' raw data would create spurious differences due to this. Therefore, the imputation method was standardised by calculating change in weight using BOCF for weight loss trials¹⁵⁰. BOCF was used because this mitigates bias that may arise because participants that do less well may be reluctant to be followed up. In one trial¹⁵¹ weight change was not available but baseline and end weight were. The mean weight change and its SD was calculated using a standard formula, which imputes a correlation for the baseline and follow-up weights, which was taken from two previously published trials^{86,124}. Two trials used conservative methods of imputation that were similar to this imputation and they were included within the analysis as presented. One added 0.5 kg to the last weight observed carried forwards¹⁵² and the other added 0.3 kg per month for those missing weight data¹¹⁴.

People in weight maintenance trials are at risk of regain, so imputing BOCF would not be appropriate if one reason for loss to follow-up was failure to achieve goal of weight stability. For weight maintenance trials the control groups mean and SD of weight change were

imputed for participants in both intervention and control groups whose follow-up data was missing.

6.2.8 Synthesis of results

Meta-analyses were conducted using Review Manager 5.2. Random effects models were used as the diversity of intervention components and control conditions meant that treatment effects were expected to differ. A pooled mean difference was calculated for weight change at programme end and last follow-up and I^2 were reported to quantify heterogeneity. The range of treatment effects from self-weighing was quantified by calculating 95% prediction intervals providing there were at least four comparisons in a meta-analysis¹⁵³. Prediction intervals provide a predicted range for the true treatment effect in an individual study. This allowed the examination of the effect of self-weighing in clinical practice. If there were more than two intervention groups the comparator group was divided by the number of intervention groups and each intervention group was analysed individually.

6.2.9 Analysis strategy

Since the effectiveness of self-weighing may depend on its purpose, the trials were divided into weight loss, weight maintenance (i.e. prevent weight gain) and weight loss maintenance. Among the weight loss trials the following subgroups were analysed without testing for differences between subgroups. This was because it was expected that the effect of self-weighing would vary across the groups of trials due to different intensities. It was also examined whether advising self-weighing as a standalone intervention could be effective. Then self-weighing was examined as an addition to a behavioural programme (i.e. where the same behavioural programme without self-weighing instruction constituted the control group). Within this group, there were two subgroups: trials where self-weighing was the only

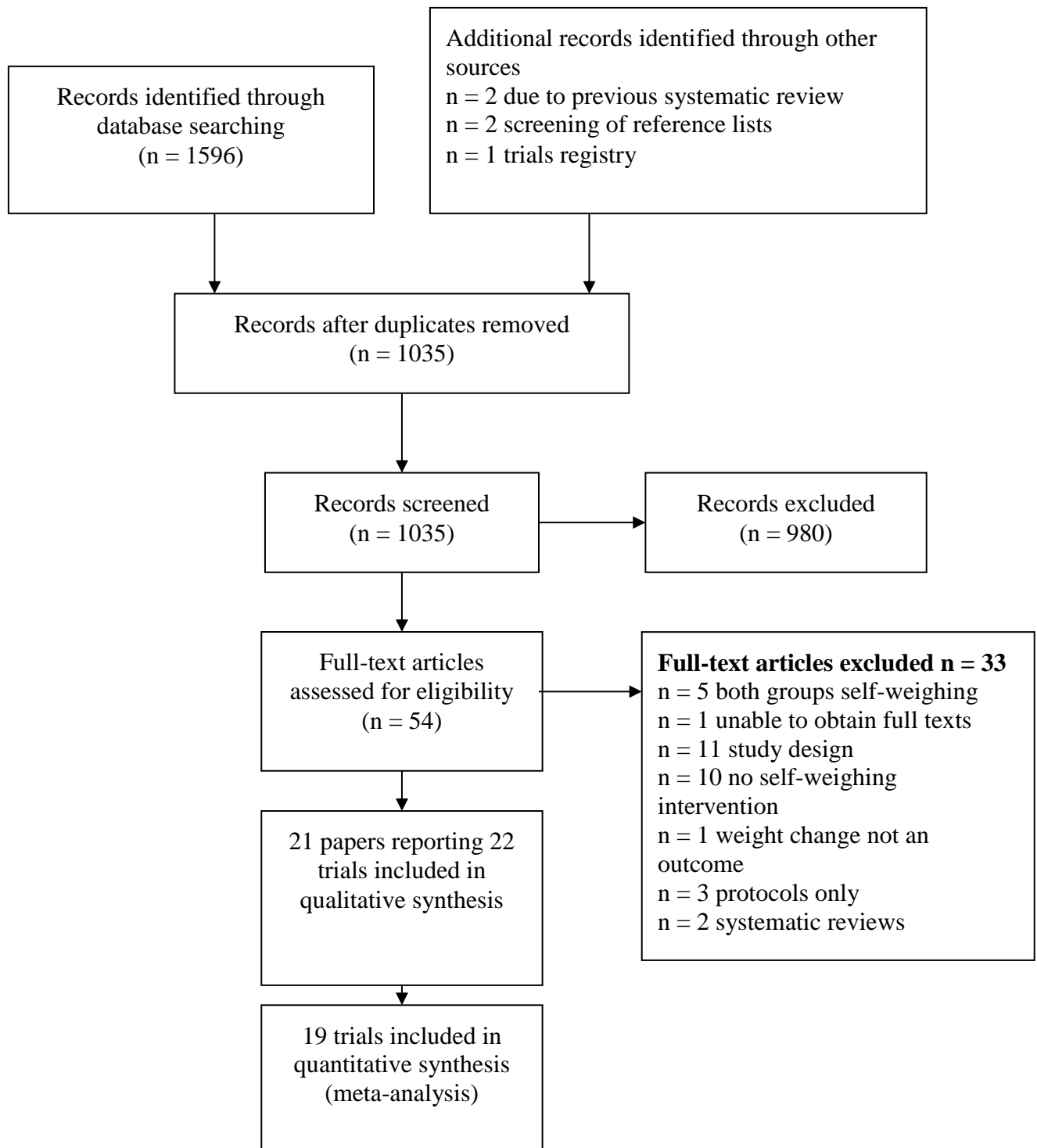
addition to the behavioural programme and trials where several self-regulatory interventions including self-weighing were added to the behavioural programme. Finally, the difference in wait list control groups and minimal/ no intervention control groups was examined. Waiting list controls may be particularly susceptible to bias because the offer of treatment in the near future could undermine the motivation of control participants to achieve immediate weight control. Subgroup analysis was used to examine for evidence that this was the case. Subgroup analysis was also used to examine whether the theoretical propositions that were identified were supported by the evidence. The differences between frequency of self-weighing (daily versus weekly) and including and not including goal setting and accountability were also tested using sub group analysis.

6.3 Results

6.3.1 Study selection

The search identified 1035 studies after duplicates were removed. Titles and abstracts were screened and 55 full text articles were assessed for eligibility. Of those, 22 trials (two trials within one publication¹⁴²) were included in the descriptive synthesis (Figure 19). The reasons for excluding studies are given in Figure 19. Data in three trials could only be included descriptively because the studies did not provide any standard deviations or sufficient alternative data to derive these^{112,154,155}.

Figure 19: Prisma diagram



6.3.2 Study characteristics

Characteristics of individual trials can be found in Table 18. All trials were RCTs with the majority conducted in the USA (n=15). The number of participants ranged from 23 to 1747 (median 96). Four trials included only women and the percentage of women in the other trials

ranged from 63.0 to 90.2% (median 83%). Seven interventions used predominantly internet interventions or a mixture of internet and face to face sessions^{114,142,149,156-159}, two were conducted in primary care^{157,160}. Intervention length varied from eight weeks to 24 months (median: 6 months). Follow-up periods ranged from the end of the intervention to two years.

Of the trials included 17 focused on weight loss, four on weight maintenance^{142,148,161} and one trial on weight loss maintenance¹¹⁴. Frequency of self-weighing was measured in nine trials^{114,115,140,148,152,156,159,160,162}. One trial examined the effectiveness of self-weighing alone compared with no effective support¹⁶⁰. Three trials examined the impact of adding self-weighing to a behavioural programme, one it was self-weighing alone¹¹³ and in two trials, self-weighing was one of several self-regulatory strategies added to the behavioural programme^{140,156}. One of these trials included self-regulatory strategies i.e. how to use and interpret the scales as well as receiving feedback about their weight. The other trial gave participants the option to record their diet and physical activity behaviours.

There were nine trials^{115,149,151,152,157-159,163,164} that examined the effectiveness of a behavioural weight loss programme that included advice to self-weigh along with regular support that were contrasted with a minimal intervention, of which four had waiting list controls^{115,149,152,158}. Of the nine trials, four instructed participants to weigh daily^{115,149,151,159} and five weekly^{152,157,158,163,164}. Only one trial did not use goal setting¹⁶⁴ and two trials did not have accountability as part of the intervention^{158,164}.

Table 18: Study characteristics

Study, Country, design	Inclusion criteria	Participants and % female	Setting	Duration of intervention and follow-up	Intervention	Control/ comparator group
Weight loss studies						
Appel et al (2011) USA RCT ¹⁵⁷	Aged ≥ 21 years. One or more CVD risk factors. A patient at the practice. Regular access to a computer and basic computer skills. Obese adults not lost $\geq 5\%$ body weight	n=415 63.6% female	Primary care, online programme and either remote support or in person support	24 month weight loss intervention and follow-up	Instructed to weigh weekly then daily. Remote group had 33 phone calls and in person group had 30 group sessions. Based on SCT with motivational interviewing, weight related goals, self-monitoring of weight, exercise and reduced calorie intake. Received feedback on progress.	Received brochures and list of recommended websites promoting weight loss. Met with a weight coach at baseline
Bacon et al (2002) USA, RCT ¹⁶⁴	Caucasian, female, 30-45, BMI ≥ 30 kg/m ² , non-smoker, not pregnant or intending to get pregnant, not lactating, restraint scale >15 , practising birth control, premenopausal	n=78 100% female	Not recorded	24 weeks weight loss followed by 6 month optional maintenance intervention. Follow-ups at 12, 24 and 52 weeks	Monitor weight weekly and complete food diaries. 24 weekly sessions, 90 minutes in length delivered by dietician. Eating behaviours, nutrition, social support and exercise. Focus on self-monitoring, stimulus control, reinforcement and cognitive change. Monthly group support sessions for weight maintenance.	Intervention about body acceptance, eating behaviour, activity, nutrition and social support delivered by counsellor. Monthly group support sessions for weight maintenance
Collins (2012) Australia, RCT ¹⁵⁸	Access to computer with email/ internet services, pass a health screen test, aged 18 to 60 years, BMI 25-40kg/m ² , not participating in another weight loss programme	n=309 58.2% female	Online programme	3 months weight loss intervention and follow-up	Based on SCT and involved self-efficacy, goal setting and self-monitoring of body weight at least weekly. Individual daily calorie targets for a weight loss of 0.5 kg to 1 kg per week. Completed food and exercise diaries, menu plans and received weekly email newsletters. Enhanced intervention got above and received enrolment reports, personalized e feedback and escalating reminders.	Wait list control group

Study, Country, design	Inclusion criteria	Participants and % female	Setting	Duration of intervention and follow-up	Intervention	Control/ comparator group
Fujimoto et al (2002) Japan RCT ¹¹³	No previous dietary intervention.	n=72 100% female	Hospital outpatient clinics	Weight loss intervention, programme end at approx. 7.2 months. Follow-up 2 years after intervention.	Same as comparator group but told to weigh four times per day during the programme and then daily. Had follow-ups at the hospital every 6 months.	Individual weekly therapy interventions and same follow-ups at the hospital every 6 months.
Gokee La Rose (2009) USA, RCT ¹⁴⁰	Aged 21-35 years, BMI 27-40 kg/m ² , no history of eating disorder or substance abuse	n= 40 % females not reported	University, group meetings	10 weeks weight loss intervention and follow-up	Received the same intervention as the comparator group but given digital scales and instructed to weigh daily. Taught how to use the scale much like a blood glucose monitor. Based on weekly weight; a colour scale based on the stop regain model was used to determine whether they needed to modify their behaviour. If in the green zone they were given a small gift.	Diet and exercise goals, behaviour modification skills for both groups over 10 weeks. Weighed at the group weekly meetings and told not to self-weigh at home.
Haapalal (2009) RCT location not recorded ¹⁵⁹	Aged 25-44 years, BMI 25-36 kg/m ² , access to mobile phone and internet connection	n=125 79% females	Internet/ mobile phone intervention	12 months weight loss intervention and follow-up	Encouraged to increase daily physical activity and daily weight reporting via text or website. Dietary records and graphs tracking ones weight. Given mobile phone programme and calculated daily energy requirement. Received feedback via text message whether they achieved their goals.	No intervention
Heckerman et al (1978) RCT, USA ¹¹²	Must be 15 pounds overweight	n=23 87% female	Weekly group meetings	4 weeks weight loss intervention, 10 weeks and 6 months follow-up	Same intervention as comparator/ control but instructed to weigh often between meetings. Stimulus control, self-monitoring, nutritional management, self-management and exercise.	Weighed at 10 weekly meetings and then monthly meetings during 6 months. Told to avoid weighing at home.

Study, Country, design	Inclusion criteria	Participants and % female	Setting	Duration of intervention and follow-up	Intervention	Control/ comparator group
Imai et al (2008) Japan, RCT ¹⁵¹	Aged 40-70 years, impaired glucose tolerance haemoglobin Alc (HbA1c) levels > 5.5- 6.1	n=100 83% female	Group sessions and individual sessions. Setting not recorded	6 month weight loss intervention with follow-up at end of intervention	Self-weighing twice a day: morning and evening. Used diaries to record weight. Educators, registered dieticians and trained nurses delivered the interventions. Portion control, exercise, set dietary goals. Educators gave support, encouragement and feedback. Set a goal of 5% body weight loss.	Received lectures about diabetes, reducing weight and increasing physical activity. Understanding food labelling. Not participant orientated and educators not trained in group dynamics.
Joachim et al (1975) USA, RCT ¹⁵⁵	Resident at location and no known physiological case of weight	n= 32 % female not reported	Institution for mildly retarded adults	8 weeks weight loss intervention and follow-up. Additional follow-up at 16 weeks.	3 IG's: 1. Weigh and record twice per day. Instructed to lose weight by any means. 2. Weigh and record twice per day. 3. Instructed to lose weight by any means. Half of each group received weekly contact and the remainder no contact.	No intervention
Leermakers et al (1998) USA, RCT ¹⁶³	Aged ≥ 18 years old, delivered a baby in the last 3 to 12 months and exceeded pre pregnancy weight by at least 6.8 kg. BMI ≥ 22 kg/m ²	n=90 100% females	Correspondence and regular phone calls	6 month weight loss intervention and follow-up	Regular phone calls and weekly weight reporting. Aerobic exercise program of walking. 16 Weekly, bi weekly then monthly written lessons covering nutrition, exercise, behaviour change strategies, set goals of 1000-1500 kcals/day, fat less than 20%. Problem solving within groups.	Given a leaflet and information brochure about healthy eating and exercise.
Linde et al (2011) USA, RCT ¹⁶²	18 to 65 years, BMI 25-35 kg/m ² , not diabetic, not trying to lose weight, not pregnant or has been within the last year. University employees	n=68 72.7% female	University and home	Single session intervention and 6 months follow-up	Given single intervention session and a self-help treatment manual, weighing scales, pedometer, food composition and physical activity book. Completed 24 weekly self-monitoring records of weight per day, frequency of weighing, pedometer use and dietary activities. Set goals and signed written contracts.	Single page flyer about nutrition

Study, Country, design	Inclusion criteria	Participants and % female	Setting	Duration of intervention and follow-up	Intervention	Control/ comparator group
Madigan (in press) UK, RCT ¹⁶⁰	BMI ≥ 30 kg/m ² , aged ≥ 18 years and not self-weighing once per week or more	n=183 63% female	Primary care	3 month intervention and follow-up	Given a set of scales and instructed to weigh daily and record it on the card provided. Sent weekly text message reminders. Same weight management consultations as control group.	Two individual weight management consultations about general strategies to aid weight loss and set a target of losing 0.5 kg per week.
Mahoney et al (1973) USA, RCT ¹⁵⁴	Minimum age 17 years, not pregnant, physicians consent, minimum of 10% overweight. Recruited by newspaper advert	n=53 90.5% female	Not recorded	4 week intervention and follow-up at 4 weeks and 4 months	Instructed to weigh bi-weekly for 7 weigh ins and keep daily weight graph. Given a behavioural diary to record “fat thoughts”, “thin thoughts”, instances of indulgence and instances of restraint. Four IG: self-reward, self-punishment, both, no reward or punishment.	Received stimulus control booklets
Pacanowski et al (2011) USA, RCT ¹⁴⁹	BMI ≥ 27 kg/m ² , aged ≥ 18 years, not diabetic and did not have history of eating disorder	n=162 81.9% female	12 month internet intervention	Follow ups at six months and 12 months after the initial session	Received an initial consultation and then an internet programme that provided daily feedback of individual’s daily weight trends via a graph. After 8 entries a green line appears 1% below current weight. The aim was to lose 10% of weight in one year. Contacted if they did not submit weights.	Wait list control group
Steinberg (2013) USA, RCT ¹¹⁵	18 to 60 years, BMI 25 to 40 kg/m ² , maximum weight 330lbs. Access to internet.	n=91 75% females	One group session followed by emails and internet.	6 months duration and follow-up.	Given set of scales and told to weigh daily. Received weekly tailored feedback via email and a web based graph of weight trends over time. Set targets of calories per day and minutes of MVPA. 22 weekly lessons on behavioural control and aim -0.5 lbs per week. Placed in categories of self-weighing frequency each week and given reinforcement of specific strategies for adopting daily weighing.	Wait list control group

Study, Country, design	Inclusion criteria	Participants and % female	Setting	Duration of intervention and follow-up	Intervention	Control/ comparator group
Van Wormer (2009) USA RCT ¹⁵²	Employees of health partners aged over 18 years, BMI ≥ 32 kg/m ² . Willing to perform daily weighing. Invited through worksite	n=100 91% female	10 counselling calls and tele-monitoring	6 months intervention and follow-up	Given a set of scales that beamed weight data to researchers who could proactively follow-up those who gained weight. The scales prompted participants to answer questions about physical activity and diet behaviours. Instructed to complete a weekly weight chart. Given programme manual: reduce calorie deficit by 500 kcals, 10,000 steps/ day, stress management, cognitive reframing, problem solving/ relapse prevention. Given a pedometer, food and activity logs.	Wait list control group
Wing et al (2010) USA, RCT (study 2) ¹⁵⁶	Able to use the website and complete a food diary. Be older than 18 years and BMI greater than 25 kg/m ²	n=128 % female not stated	Online programme using a website and GP sessions	12 weeks intervention and follow-up.	An enhanced version of the Shape up RI programme (online weight loss programme), participant's submitted data every two weeks. Self-monitor weight, diet and physical activity daily and received weekly feedback that was automated. One group session: introduction about energy balance and importance of self-monitoring.	Received standard 'shape it up' programme
Weight maintenance studies						
Levitsky et al (2006) USA, RCT experiment 2 ¹⁴²	Female freshman aged 18 years and over	n=41 100% female	Emails	10 weeks intervention and follow-up	Given bathroom scale and told to weigh each morning upon rising from bed and before voiding. Emailed daily weights to staff. After 7 days of weight data staff emailed a value of the number of calories they needed to consume to maintain/ decrease their current weight.	No intervention

Study, Country, design	Inclusion criteria	Participants and % female	Setting	Duration of intervention and follow-up	Intervention	Control/ comparator group
Levitsky et al (2006) USA, experiment 1 ¹⁴²	Female freshman aged 18-21 years	n=34 100% female	One initial meeting then daily email	4 month intervention and follow-up	Given scales and told to weigh each morning upon rising from bed and before voiding. Emailed daily weights to staff. After 7 days conducted linear regression of the slope of weight change and emailed participants daily. Instructed how to interpret the slope. Reminders to self-weigh were sent sporadically. Given basic nutrition information: eat three meals a day and avoid snacks.	Given the same basic nutrition information
Linde et al (2012) USA, Group RCT ¹⁴⁸	Worksites had 250-1000 employees, presence of food service, at least two floors with stairs, minimal seasonal fluctuation of staff. Stability of location and workforce over next several years. Participant's eligible if spent 50% of time in the office on day time shifts.	n=1747 in six sites 68.5% female	Work place	2 years intervention and follow-up at end of intervention	4 balance beam scales were placed at accessible yet private locations at each intervention site. BMI charts and weight tracking charts were put near the scales. Up to three weight tracking competitions were held to encourage social support. Food environment changes, physical activity environmental changes, health media environment changes and body weight tracking environment.	Control sites received no intervention
Strimas et al (2010) Canda, RCT ¹⁶¹	Fluent in English, 17-19 years, 1 st year university students	n=116 % female not reported	University	12 weeks intervention and follow-up	Given scales and self-monitoring cards, told to weigh upon rising from bed daily or if allocated to weekly, then on a Sunday.	Told to count heart rate, beats per minute for 60 seconds once per week. Instructed not to self-weigh during the study.

Study, Country, design	Inclusion criteria	Participants and % female	Setting	Duration of intervention and follow-up	Intervention	Control/ comparator group
Weight loss maintenance studies						
Wing et al (2006) US RCT ¹¹⁴	Lost 10% of body weight in past two years, confirmed by physician, friend or weight loss counsellor	n=314 81% female	Online and group meetings	6 months intervention and 18 month follow-up	Given scale and weight monitoring system based on colours and taught to adjust energy balance behaviour by weighing daily. Submit weekly weights through automated telephone or web based form. Positive reinforcement with small gifts if remained in green zone. Used problem solving skills if gained weight. If gained too much weight instructed to restart weight loss efforts and given a toolkit consisting of own success story, self-monitoring diaries, meal replacements and pedometer. Individual counselling either face to face or through internet depending on group, weekly then monthly.	Quarterly newsletter

BOCF = baseline weight observed carried forwards CG= control group, IG= intervention group, LOCF = last weight observed carried forwards, MVPA = moderate to vigorous physical activity, SCT= social cognitive theory

6.3.3 Risk of bias

Risk of bias for individual trials is documented in Table 19. Several trials did not give sufficient information to assess risk of bias in detail. Seven trials ^{113,148,152,157,158,160,162} were at low risk of bias for sequence generation; for the other trials it was unclear since they did not provide enough information. Four trials had low risk of bias ¹⁵⁷⁻¹⁶⁰ for allocation concealment and four trials were considered as high risk ^{115,148,152,162}, the remainder were unclear.

One trial ¹⁶² did not blind staff to treatment condition at outcome assessment and five trials were classified as low risk of bias for this outcome ^{148,156-158,160}. All trials except one reported percentage of participants with outcome data and of these 15 were classified as low and seven as high risk of bias ^{112,113,142,154,155,162,164}, mainly due to differing follow-up rates between groups. There were only two trials in which selective reporting could be assessed, i.e. a protocol was available. All trials except for one used objective data to report weight change. Fujimoto and colleagues ¹¹³ did not report that weight was measured objectively, but follow-up took place at a hospital so it is probable that weight was measured and not self-reported.

Table 19: Risk of bias

Study	Sequence of generation	Allocation concealment	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias Measurement of weight outcome
Weight loss studies						
Appel et al (2011) ¹⁵⁷	Low risk of bias: Randomisation was stratified and generated in blocks of three and six using a web based programme.	Low risk of bias: Used a web based programme.	Low risk of bias: The research staff who notified participants of assignment were not involved in collection of follow-up data.	Low risk of bias: 94.5% follow-up rates and groups had similar rates. Imputed missing weight data using random sequence.	Unclear risk of bias	Low risk of bias: weight measured.
Bacon et al (2002) ¹⁶⁴	Unclear risk of bias: “Participants were divided into BMI quartiles, age, high/ low sets for dietary restraint, degrees of flexible and rigid control of eating, and self-reported activity level and then randomised.”	Unclear risk of bias: allocation concealment not stated.	Unclear risk of bias: not stated.	High risk of bias: At 24 weeks 59% of IG and 92% of the CG provided data. No method of imputation.	Unclear risk of bias.	Low risk of bias: weight measured.
Collins et al (2012) ¹⁵⁸	Low risk of bias: Stratified randomisation block design with variable block lengths of 3 or 6 generated by a statistician.	Low risk of bias: A researcher not involved in data collection distributed sequentially numbered sealed envelopes with allocation details and a log in code.	Low risk of bias: assessors were blinded at baseline and 12 weeks. Participants were asked not to inform assessors of their group allocation.	Low risk of bias: Loss to follow-up was different across arms - the control group were more likely to attend than the basic group 84.2% follow-up. Used ITT analysis using BOCF.	Low risk of bias: published protocol and reported outcomes.	Low risk of bias weight was measured.

Study	Sequence of generation	Allocation concealment	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias Measurement of weight outcome
Fujimoto et al (1992) ¹¹³	Low risk of bias: randomisation table.	Unclear risk of bias: allocation concealment not stated.	Unclear risk of bias: not stated.	High risk of bias: Difference in follow-up rates 87% in the IG provided follow-up data at two years and 65% in the CG. At the end of therapeutic interviews the follow-up rates are not clear.	High risk of bias: analysed groups by those who had follow-up data at 24 months. Did not randomise males therefore male data is not included.	Unclear risk of bias: weight measures not stated but probable that weight was measured at the hospital visits.
Gokee La Rose (2009) ¹⁴⁰	Unclear risk of bias: “Participants were randomised to one of two groups.”	Unclear risk of bias – allocation concealment not stated.	Unclear risk of bias: no blinding of outcome was stated.	Low risk of bias: 93% follow-up, similar rates for both groups. No method of imputation.	Unclear risk of bias.	Low risk of bias: weight measured.
Haapala et al (2009) ¹⁵⁹	Unclear risk of bias: “Randomisation was performed within gender to one of two groups.”	Low risk of bias: the study nurse was blinded to the randomisation procedure.	Unclear risk of bias: no blinding of outcome was stated.	Low risk of bias: Similar dropout rates for both groups, however the IG dropouts had lost significantly less weight by 3 months than those who continued. Used BOCF or LOCF whichever was higher.	Unclear risk of bias.	Low risk of bias: weight measured.
Heckerman et al (1978) ¹¹²	Unclear risk of bias: “Subjects were randomly assigned to 1 of 2 conditions.”	Unclear risk of bias: allocation concealment not stated.	Unclear risk of bias: no blinding of outcome was stated.	High risk of bias: follow-up rates were low at 6 months, 42% IG and 18% CG. No imputation of missing weights.	High risk of bias: standard deviations not reported.	Low risk of bias: weight measured.
Imai et al (2008) ¹⁵¹	Unclear risk of bias: “Stratification randomisation that considered gender, age and weight.”	Unclear risk of bias: allocation concealment not stated.	Unclear risk of bias: no method of blinding recorded.	Low risk of bias: 92% completed follow-up and dropouts were similar within each group. No method of imputation.	Unclear risk of bias.	Low risk of bias: weight measured.
Joachim et al ¹⁵⁵	Unclear risk of bias: “subjects were randomly allocated to one of four groups.”	Unclear risk of bias: allocation concealment was not stated.	Unclear risk of bias: no method of blinding recorded.	Unclear risk of bias: Follow-up rates were not stated.	High risk of bias: standard deviations not reported.	Low risk of bias: weight measured.

Study	Sequence of generation	Allocation concealment	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias Measurement of weight outcome
Leermakers et al (1998) ¹⁶³	Unclear risk of bias: "Participants were randomly assigned to one of two conditions."	Unclear risk of bias: allocation concealment not stated.	Unclear risk of bias: no method of blinding recorded.	Low risk of bias 69% provided follow-up data and attrition did not vary by group. Used BOCF.	Unclear risk of bias.	Low risk of bias: weight measured.
Linde et al (2011) ¹⁶²	Low risk of bias: random number table.	High risk of bias: no allocation concealment.	High risk of bias: study staff were not blinded to participant treatment assignment.	High risk of bias: Different follow-ups at 6 months; 64.7% of IG and 76% of CG.	Unclear risk of bias.	Low risk of bias: weight measured.
Madigan et al (in press) ¹⁶⁰	Low risk of bias: table random block sizes of between 2 and 8.	Low risk: opaque sealed envelopes. Participants were blinded to group allocation.	Low risk of bias: weight at three months was collected by independent researchers.	Low risk of bias: 92.4% of IG and 85.7% of CG provided follow-up data. Used BOCF	Low risk of bias: analyses conducted according to protocol.	Low risk of bias: weight measured.
Mahoney et al ¹⁵⁴	Unclear risk of bias: "The subjects were ranked according to degree of obesity and randomly assigned to groups."	Unclear risk of bias: allocation concealment not stated.	Unclear risk of bias: no method of blinding recorded.	High risk of bias: 45% provided follow-up data. No imputation	High risk of bias: standard deviations not reported	Low risk of bias: weight measured.
Pacanowski & Levitsky ¹⁴⁹	Unclear risk of bias: "Individuals randomised to one of two groups."	Unclear risk of bias: allocation concealment not stated.	Unclear risk of bias: no method of blinding recorded.	Low risk of bias: 83.3% provided follow-up data. Used LOCF.	Unclear risk of bias.	Low risk of bias: weight measured.
Steinberg et al (2013) ¹¹⁵	Unclear risk of bias: "Participants were randomised to one of two treatment groups."	High risk of bias: no allocation concealment.	Unclear risk of bias: no method of blinding recorded.	Low risk of bias: follow-up rates of 96% in IG and 95% in CG. Random effects imputation used.	Unclear risk of bias.	Low risk of bias: weight measured.
VanWormer et al (2009) ¹⁵²	Low risk of bias; Used a computer generated block randomisation list.	High risk of bias: No allocation concealment.	Unclear risk of bias: no method of blinding recorded.	Low risk of bias: 87% of IG and 84% of CG provided follow-up data. Used LOCF and added 1.2lbs per follow-up time period.	Unclear risk of bias.	Low risk of bias: weight measured.

Study	Sequence of generation	Allocation concealment	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias Measurement of weight outcome
Wing et al (2010) ¹⁵⁶	Unclear risk of bias: Randomly assigned with their team mates to 1 of 2 groups. A 2:1 randomisation ratio was used.	Unclear risk of bias: allocation concealment not stated.	Low risk of bias: assessors were blinded to treatment allocation.	Low risk of bias: 87.5% provided follow-up data and no significant difference between groups. Used BOCF.	Unclear risk of bias.	Low risk of bias: weight measured.
Weight maintenance studies						
Levitsky et al (2006) experiment 2 ¹⁴²	Unclear risk of bias "Participants were randomised to one of two groups."	Unclear risk of bias: allocation concealment not stated.	Unclear risk of bias: no method of blinding recorded.	High risk of bias 94% of IG and 67% of CG provided follow-up data. No method of imputation.	Unclear risk of bias.	Low risk of bias: weight measured.
Levitsky et al (2006) experiment 1 ¹⁴²	Unclear risk of bias "The participants were randomly divided into two groups."	Unclear risk of bias: allocation concealment not stated.	Unclear risk of bias: no method of blinding recorded.	High risk of bias: 69% of IG and 94% of CG provided follow-up data. No method of imputation.	Unclear risk of bias.	Low risk of bias: weight measured.
Linde et al (2012) ¹⁴⁸	Low risk of bias: Blocked randomisation at the worksite level (block size 2) computer generated algorithms.	High risk of bias: No allocation concealment.	Low risk of bias: no blinding of outcome measure but the measurement team did not participate in intervention delivery.	Low risk of bias: 80.4% provided follow-up data. No method of imputation used for missing weight data.	Unclear risk of bias.	Low risk of bias: weight was measured at follow-up.
Strimas et al (2010) ¹⁶¹	Unclear risk of bias: "Participants were randomised into one of three groups."	Unclear risk of bias: allocation concealment not stated.	Unclear risk of bias: no method of blinding recorded.	Low risk of bias: 86% follow-up rate and no significant difference in attrition rates between groups. No method of imputation.	Unclear risk of bias.	Low risk of bias: weight measured.
Weight loss maintenance studies						
Wing et al (2006) ¹¹⁴	Unclear risk of bias: "Participants were stratified according to the amount of prior weight loss and then randomly assigned to one of three groups."	Unclear risk of bias: allocation concealment not stated.	Unclear risk of bias: no method of blinding recorded.	Low risk of bias: 97% of internet IG, 88% of face to face IG and 93% of CG provided follow-up data. 0.3 kg of weight added per month to those that dropped out.	Unclear risk of bias.	Low risk of bias: weight measured.

6.3.4 Synthesis of results

Before I present the main results I am going to explain the how I synthesised the data. In one study after the initial intervention, participants in both groups were given an optional weight loss maintenance intervention, therefore end of treatment weight only was included in this analysis ¹⁶⁴. Two weight loss trials had a later follow-up and were thus analysed separately. One involved one treatment session and no contact ¹⁶² and the other had end of treatment weights and follow-up weights two years from baseline ¹¹³. As there were only a few weight maintenance trials and a single weight loss maintenance trial sub group analyses of these studies was not undertaken. The results of the weight loss sub group analyses are presented prior to the weight maintenance and weight loss maintenance results. A summary of the meta-analyses can be found in Table 20.

6.3.5 Weight loss

One trial examined the impact of self-weighing without a behavioural programme to achieve weight loss. The mean effect of this intervention was 0.5 kg (95% CI -1.3 to 0.3) ¹⁶⁰. Three trials ^{113,140,156} compared a behavioural weight management programme plus self-weighing/self-regulation components with a behavioural weight management programme alone (Table 20). The self-weighing/intervention arms resulted in a significantly greater mean weight loss of -1.6 kg (-2.6 to -0.7). All of these trials instructed participants to weigh themselves daily.

Nine trials ^{115,149,151,152,157-159,163,164} were categorised as multicomponent interventions that included self-weighing compared with a no/minimal control group. The mean difference was -3.4 kg (95% CI -4.2 to -2.5). The 95% prediction intervals indicate that 95% of interventions

effectiveness would lie between -6.0 to -0.8 kg, indicating most interventions would result in weight loss. The test for sub group differences found no significant differences between those interventions that had a waiting list control group and those that had no/minimal control group ($p=0.45$).

Theoretical concepts

Of the multicomponent interventions four trials asked participants to weigh themselves at least daily^{115,149,151,159} and the mean difference was significant at -3.0 kg (95% CI -5.0 to -0.9) but there was high heterogeneity (I^2 : 81%). The 95% prediction intervals were also very wide from -30.0 to 24.0 kg. Five trials asked participants to weigh weekly^{152,157,158,163,164} and the mean difference was -3.5 kg (95% CI -4.3 to -2.6). In contrast to daily weighing the 95% prediction intervals suggested that all such interventions would result in weight loss (-5.9 to -1.1 kg). However, using meta regression there were no significant differences found between the sub groups of weekly weighing and daily weighing sub groups (see Table 20). Only three trials measured adherence to self-weighing instruction and of these one asked participants to weigh weekly (50% adherence)¹⁵² and two instructed daily weighing with adherence rates of 44%¹⁵⁹ and 95%¹¹⁵.

Only one trial did not use goal setting as a strategy¹⁶⁴ and there were no significant differences ($p=0.85$) between this trial and interventions that did use goal setting. In eight trials, the intervention group asked to self-weigh knew that they were accountable to a therapist for their weight^{115,149,151,152,157-159,163} while this was not the case in two trials^{158,164} (Table 21). The mean weight difference between intervention and control groups for those with accountability was -3.8 kg (95% CI -4.8 to -2.8) and it was -2.6 kg (95% CI -3.4 to -1.8) for trials without accountability. This difference was not significant ($p=0.07$). The

intervention in two trials had particularly strong accountability because participants knew that their weight was being remotely monitored by a therapist. The difference between intervention and control was larger in these trials than in the other trials (-5.6 kg 95% CI -7.1 to -4.1¹¹⁵ and -8.8 kg 95% CI -12.8 to -4.7¹⁵²). The other trials had less accountability as they involved either weekly or less meetings and the focus was not on whether participants had self-weighed daily.

Two trials^{113,162} followed up participants beyond the end of the intervention. The first trial followed up participants approximately 18 months from the last intervention contact and resulted in a mean difference of -8.0 kg (95% CI -12.5 to -3.5)¹¹³. The second trial followed up participants six months after the last intervention contact and resulted in a mean difference of -0.3 kg (95% CI -11.4 to 3.7)¹⁶². The three trials that could not be included in the meta analysis found no differences between groups at programme end^{112,154,155}.

Table 20: Weight change outcomes

		Trials n (number of participants)	Mean difference, kg (95%CI)	I²	P	95% prediction intervals	Sub group analysis P
	Weight Loss						
Weight change	Mean weight change at programme end	13 (1888)	-2.8 (-3.7 to -1.9)	77%	<0.01	-6.1 to 0.5	—
	Mean weight change at follow-up	2 (140)	-3.8 (-11.4 to 3.7)	90%	0.32	—	—
Self-weighing/ self-regulation isolated.	Isolated strategy	1 (183)	-0.5 (-1.3 to 0.3)	—	—	—	—
	Behavioural weight management programme plus self-weighing/self-regulation components compared to the same behavioural programme	3 (240)	-1.6 (-2.6 to -0.7)	0%	<0.01	—	—
Multi component interventions	All	9 (1465)	-3.4 (-4.2 to -2.5)	62%	<0.01	-6.0 to -0.8	—
	Wait list control group	4 (662)	-3.8 (-5.3 to -2.3)	83%	<0.01	-11.1 to 3.5	0.45
	Minimal/ no intervention	5 (803)	-3.1 (-4.0 to -2.2)	0%	<0.01	-4.6 to -1.6	
	Daily weighing	4 (473)	-3.0 (-5.0 to -0.9)	81%	0.005	-30.0 to 24.0	0.66
	Weekly weighing	5 (992)	-3.5 (-4.3 to -2.6)	44%	<0.01	-5.9 to -1.1	
	Uses goal setting	8 (1387)	-3.4 (-4.3 to -2.5)	66%	<0.01	-10.2 to 3.4	0.85
No goal setting	1 (150)	-2.9 (-4.8 to -1.0)	0%	0.002	—		
Accountability	Has accountability	8 (1152) ⁺	-3.8 (-4.8 to -2.8)	53%	<0.01	-6.6 to -1.0	0.07
	No accountability	2 (229) ⁺	-2.6 (-3.4 to -1.8)	0%	<0.01	—	
	Weight maintenance						
Weight change	Mean weight change	4 (1936)	-0.9 (-2.2 to 0.5)	96%	0.2	—	—

Figure 20: Forest plot of weight loss studies at programme end

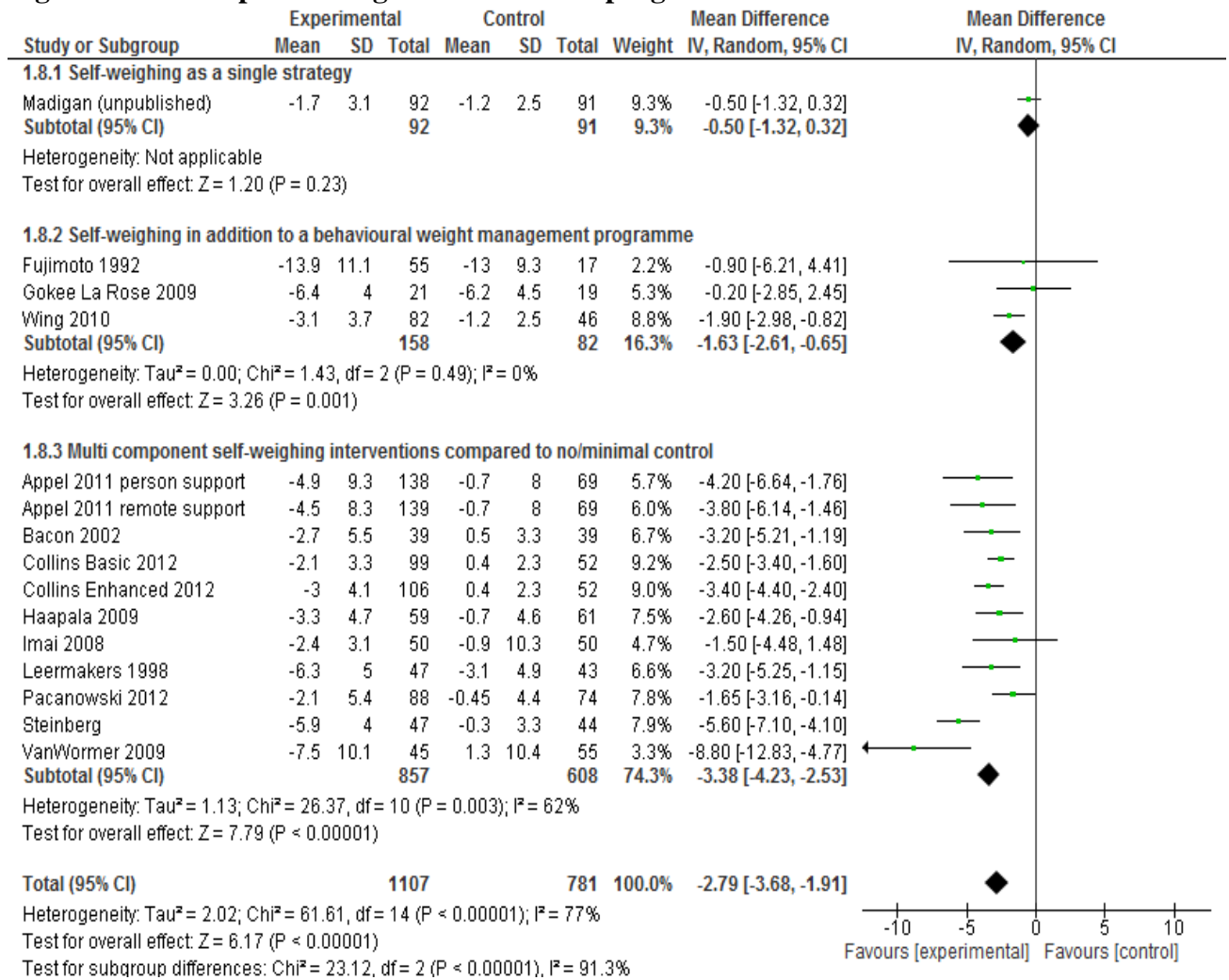


Figure 21: Forest plot of weight loss studies with follow-up

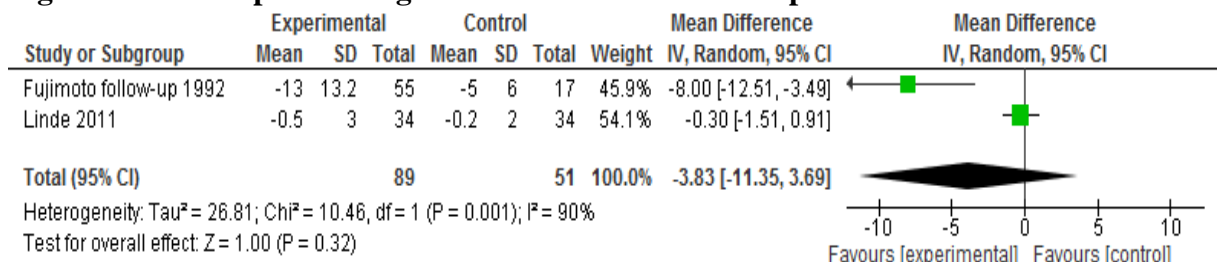


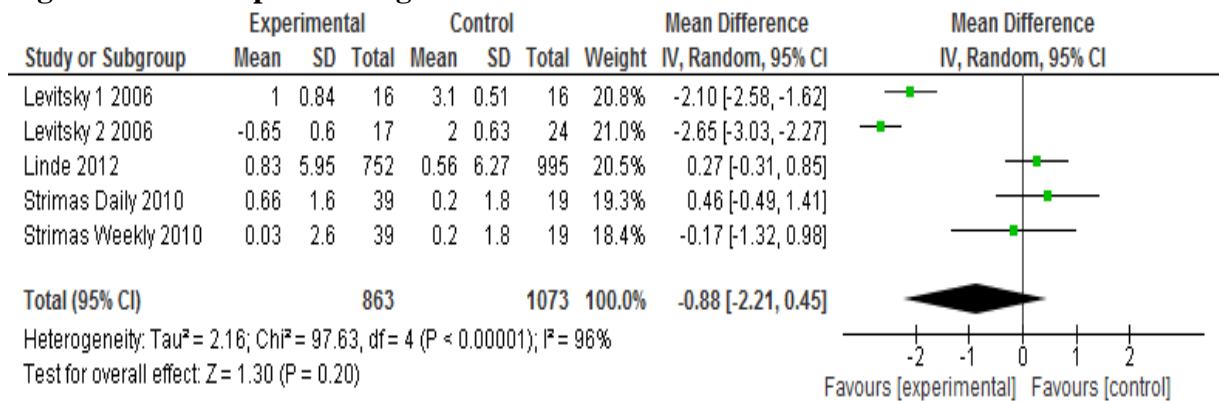
Table 21: Behavioural strategies used in interventions

Study	Self-weighing frequency		Goal setting	Accountability	Feedback	Method of recording self-weighing		Prompts and cues to self-weigh
	Daily	Less than daily				Paper	online	
Weight loss								
Appel et al 2011		X	X	X	X	X	X	
Bacon et al 2002		X						
Collins et al 2012		X	X	X (enhanced only)	X		X	X
Fujimoto et al 2002	X			X	X	X		
Gokee LaRose et al 2009	X		X	X	X	X		
Haapalal et al 2009	X		X	X	X		X	
Heckerman et al 1978		X		X	X			
Imai et al 2008	X		X	X	X	X		
Joachim et al 1975	X			X (weekly only)	X	X		X
Leermakers et al 1998		X	X	X				
Linde et al 2011	X		X	X		X		
Madigan et al (in press)	X		X			X		X
Mahoney et al 1973	X					X		
Pacanowski et al 2011	X		X	X	X		X	
Steinberg et al 2013	X		X	X	X		X	X
VanWormer et al 2009		X	X	X	X	X		X
Wing et al 2010	X		X		X		X	
Levitsky et al 2006 experiment 2	X		X	X	X		X	X
Levitsky et al 2006, experiment 1	X		X	X	X		X	X
Linde et al 2012		X				X		
Strimas et al 2010	X	X				X		
Weight loss maintenance								
Wing et al 2006	X		X	X	X		X	

6.3.6 Weight maintenance

Three publications^{142,148,161} (four trials) were included in the analyses. The mean difference at programme end was -0.9 kg (95% CI -2.2 to 0.5) (Figure 22), heterogeneity was high (I^2 : 96%) and the difference was not significant. One trial directly compared weekly and daily weighing intervention groups and there were no significant differences between the intervention groups¹⁶¹. The other study that instructed participants to weigh daily in both trials found significant weight differences in favour of the intervention groups¹⁴². In this same study participants in the intervention groups were instructed to submit daily weights via email. In contrast the previous trial that instructed participants to weigh daily and weekly but did not have accountability found no significant differences between the control and intervention groups¹⁶¹. Goal setting was used in the study that found significant differences but was not used in the other studies.

Figure 22: Forest plot of weight maintenance trials



6.3.7 Weight loss maintenance

Only one trial included an intervention that focused on weight loss maintenance. There were two intervention groups compared to a control group within this trial and there was a mean

difference of -1.4 kg (95% CI -3.5 to 0.8) in favour of the intervention groups but this was not significant.

6.3.8 Adverse events

Most trials^{112,142,148,149,151,154-156,158,159,161-164} did not report any information about adverse effects. Three trials stated there were no serious adverse events related to self-weighing^{114,152,160} and three trials examined the effect of daily self-weighing and found no evidence of negative psychological effects^{115,140,160}.

6.4 Discussion

Only one trial has tested the effectiveness of self-weighing as a single intervention compared with no intervention and there was no evidence that it was effective. There was evidence that adding advice to self-weigh daily to a behavioural programme adds to its effectiveness, but only three trials have assessed this and the estimate of effect was imprecise and clouded by the use of self-regulatory elements such as monitoring diet and physical activity. There was strong evidence that behavioural weight loss programmes that incorporate self-weighing are more effective than minimal/no interventions. Almost all trials that tested self-weighing asked participants to set weight loss goals as well as self-weigh, but there was no evidence that not setting goals reduced its effectiveness. There was insufficient evidence to assess whether adding accountability to a self-weighing programme improves its effectiveness. There was no evidence that self-weighing was effective for weight maintenance or weight loss maintenance.

The previous systematic review of self-weighing⁹⁶ suggested that self-weighing was beneficial for weight loss and weight maintenance and based on descriptive analysis would result in a 5.4 to 8.1 kg weight loss. The findings here are similar but predictions of weight change are slightly less as they represent mean differences between intervention and control

groups rather than actual weight losses. In the present review only experimental studies with a control group (imputing BOCF for missing weight data) were included which may explain the lower weight change. In addition, the previous systematic review did not consider the potential difference in weight loss, weight maintenance and weight loss maintenance.

Michie and colleagues' two reviews of effective behavioural techniques for healthy eating, physical activity and reduction of alcohol consumption inferred that self-monitoring was effective but when combined with other techniques the effect size nearly doubled^{99,103}. The other techniques were prompt intention formation, prompt specific goal setting, prompt review of behavioural goals and provide feedback of performance⁹⁹. However, unlike findings from Michie and colleagues, there was no evidence that self-weighing as a sole strategy was effective although only one study investigated this. It was found that adding self-weighing/self-regulation components to the same behavioural weight management programme resulted in greater weight loss than comparators. This highlights the potential to increase the effectiveness of behavioural weight management programmes by adding daily self-weighing/self-regulation components. This conclusion is only tentative because one intervention added self-weighing only, one intervention included techniques to help improve self-regulation focusing on self-weighing, and the other asked participants to also monitor their, diet and physical activity. It is also important to note that these interventions all instructed participants to weigh themselves on a daily basis.

Multicomponent programmes that included self-weighing compared with a minimal/no comparator group resulted in significant weight loss (-3.4 kg (95% CI -4.2 to -2.5)). It was hypothesised that those interventions that had a waiting list control would have greater mean differences because they were waiting to start their treatment but there was no evidence of

this. These findings are similar to a systematic review of behavioural weight management programmes that found a significant difference of -2.6 kg (95% CI -2.8 to -2.4)⁸². This was 12-18 months after the start of the programme and may explain the slightly smaller mean difference than found here. Although these trials do not directly inform us about the effectiveness of self-weighing, they do reassure programme providers, such as those in the UK that adding self-weighing does not undermine weight loss programmes effectiveness.

It was hypothesised that frequency of self-weighing may influence effectiveness and in particular daily weighing may be easier to become habitual, however no differences were found, although no trials directly compared these frequencies. Daily self-weighing seems to be acceptable and implementable by participants as the three trials that reported adherence rates ranged from 44 to 95% for daily-weighing. Previous research has examined self-weighing frequency for both weight loss and weight maintenance using a prospective design without a comparison group¹⁶⁵. Higher weighing frequency was associated with greater weight loss and less weight regain at 24 months follow-up. However greater motivation to maintain weight or success in achieving weight maintenance may reflect in greater frequency of self-weighing, which makes observational data difficult to interpret. The only trial that directly compared weekly and daily weighing was for weight maintenance and found no significant differences¹⁶¹.

It was thought that goal setting would enhance the effectiveness of self-weighing. However, only two trials did not report using goal setting and there were no differences between these trials and those that did set goals. Self-weighing may feel pointless without a goal. Similar to the findings here, a systematic review found no evidence that goal setting enhanced the effectiveness of self-monitoring in improving physical activity¹⁶⁶. It was also hypothesised

that accountability could enhance the effectiveness of self-weighing as participants may feel the need to conform as others were observing what they were doing. The findings of the systematic review presented here were inconclusive, although trials with accountability had non-significantly greater weight loss (-3.5 kg versus -2.6 kg). Gardner and colleagues conducted a systematic review examining similar behaviour change techniques to accountability called audit and feedback¹⁶⁷. They investigated whether audit and feedback changed healthcare professionals' behaviour and found a significant effect (OR=1.43 95% CI 1.28-1.61). Audit and feedback are similar to accountability as participants are aware of being observed, however there is the additional technique of providing feedback of that observation. The influence of feedback was not considered within this analysis because only a few studies included this.

For weight maintenance; the self-weighing intervention group was favoured but was not significant. There were only four trials, with wide prediction intervals, and there was significant heterogeneity which could be due to the differences in length of interventions and specific populations studied. Three trials^{142,161} recruited university students and the fourth trial¹⁴⁸ recruited from workplaces. Previous research has shown that students tend to gain weight when studying at university¹⁶⁸. Thus there may have been potential for prevention of greater weight gain in the trials in students compared to employees at work. Based on the evidence it seems plausible that self-weighing interventions may help people to maintain their weight but due to the variability of trials it is difficult to interpret. Self-weighing may be more useful at specific life stages (e.g. when attending university or perhaps during holiday periods when weight gain occurs¹⁶⁹).

Observational data suggests that self-weighing is a strategy that people use to maintain weight loss^{105,170}. However, there has only been one RCT that has investigated this¹¹⁴ and when the two intervention groups were combined no significant differences were found. Whereas a previous study (quasi-randomised controlled trial) investigating an intervention focused on self-weighing found it prevented 0.7 kg (95% CI -1.2 to -0.1) weight regain in the intervention group¹³⁹. Conclusions about the effectiveness of self-weighing for weight loss maintenance cannot be made.

There were no adverse effects of the trials reported, however few trials assessed whether self-weighing led to psychological problems. Those that did found no evidence of negative consequences.

6.4.1 Strengths and limitations

This is the first systematic review to include only experimental studies to examine the effect of self-weighing. The risk of bias was also reduced by imputing missing weight data using the same method for all studies. There was significant heterogeneity between trials, although this was expected and random effect models and planned sub-group analysis were conducted.

However even after sub-group analyses were performed, there was still significant heterogeneity. This suggests that other factors that were not taken into account could explain some of the variance.

There were only a small number of trials and thus interpretation was difficult. The studies had different comparator groups, differing lengths and involved different intensities and therefore no overall effect could be established. Comparative analysis was undertaken examining theoretical concepts but this was observational and we cannot attribute causation.

6.4.2 Future research

There was insufficient evidence that self-weighing alone is effective but it is an appealing self-help strategy. Future research should examine other behavioural techniques that can be effectively combined with self-weighing. Adding accountability may improve the effectiveness of self-weighing. Both daily and weekly weighing may be effective strategies for weight loss but it is not clear whether one is more effective than the other. Future research should compare the two frequencies using an experimental design.

Not all interventions will result in effective weight management for all people. Hence there is a need to firstly offer a range of programmes and strategies and secondly identify who self-weighing is most appropriate for. Pacanowski reported that people with internal weight locus of control tend to do better with a self-weighing intervention, and men lose more weight than females¹⁰⁷. This needs further research to identify effective screening tools for patients as more support could then be given to those who need it most.

Further research could also examine the effect of adding daily self-weighing to behavioural weight management programmes as there is potentially an improvement in weight loss. This would need careful consideration as to how this would interact with current techniques used in behavioural weight management programmes.

6.5 Conclusions and implications

Self-weighing as part of a multicomponent programme is effective and there is some evidence that adding daily self-weighing/self-regulation components to behavioural weight management programmes may result in greater weight loss. However as an isolated intervention there is yet no evidence of effectiveness. There is insufficient evidence to make conclusions about self-weighing for weight maintenance and weight loss maintenance.

CHAPTER 7

7.0 DISCUSSION, IMPLICATIONS AND CONCLUSIONS

7.1 Summary of findings

This research has investigated behavioural weight management practices that could be used in primary care. Chapter 3 investigated whether four behavioural weight management programmes resulted in similar weight losses at both programme end (12 weeks) and at 12 months follow-up using a noninferiority analysis. The three commercial weight management programmes (Rosemary Conley, Slimming World and Weight Watchers) had similar weight losses at both programme end and 12 months follow-up. However, the NHS group based programme was inferior at three months follow-up and the data was inconclusive at 12 months follow-up. The findings suggest that commercial programmes may result in better weight losses than the NHS group programme compared here.

Chapter 4 presented a randomised controlled trial of self-weighing as an isolated weight loss intervention and found no significant difference between the intervention and control groups. A sub-group analysis found no association between the frequency of self-weighing and weight loss, although there was conflict between measurements of self-weighing. The findings suggest that self-weighing may need to be combined with other behaviour change techniques to be effective. However, I cannot be sure whether the result is due to self-weighing being ineffective or whether it can be explained by participants not weighing themselves daily. It can be concluded that the instruction to self-weigh daily does not result in greater weight loss regardless of whether participants self-weighed or not.

Chapter 5 investigated a pragmatic weight loss maintenance intervention after receiving one of the weight loss programmes presented in chapter 3. The main intervention component was self-weighing and a quasi-randomised controlled trial design was used. The intervention prevented 0.7 kg regain over the subsequent nine months using intention to treat analysis. However, when using completer data it was found participants on average continued to lose weight, although this may partially reflect motivation. Self-weighing as part of a simple weight loss maintenance intervention appears to be a promising strategy to prevent weight regain after weight loss.

The fourth study was a systematic review and meta-analysis of self-weighing for weight management and included the trial reported in chapter 4 of this thesis. One study examined self-weighing as a single strategy and it was ineffective. Adding self-weighing/self-regulation techniques to behavioural programmes resulted in a significant difference of -1.6 kg (95% CI -2.6 to -0.7). Multi-component interventions including self-weighing compared to no/minimal control resulted in significant mean differences of -3.4 kg (95% CI -4.2 to -2.5). There was no evidence to suggest that daily self-weighing was more effective than weekly-weighing although few studies measured adherence, particularly with objective measures. Goal setting and accountability were hypothesised to increase the effectiveness of self-weighing, however no significant differences in sub groups were found. Nevertheless, those interventions that had accountability tended to have greater weight loss. There was no significant effect of self-weighing for weight maintenance although no definitive conclusions could be made as there were only four studies and high heterogeneity. Only one trial investigated weight loss maintenance and found significant differences in favour of the face to face intervention group but not the internet intervention group and combined there was no significant difference¹¹⁴.

7.2 Strengths and weaknesses

The strengths and weaknesses of each study have been reported in each corresponding chapter therefore this section will describe the overall methodological strengths and weaknesses. A range of methods were used to investigate behavioural weight management practices in primary care, which is a particular strength. I have used a prospective cohort study with noninferiority analysis (chapter 3), an RCT (chapter 4), a quasi-randomised controlled trial (chapter 5) and a systematic review (chapter 6). Each study design has been appropriate for the research questions and the three years available.

Routinely collected data by the Lighten Up weight management service was utilised as part of this research (chapters 3 and 5) and there are both strengths and weaknesses to this approach. This has allowed analyses of large numbers of participants and I was therefore able to conduct a noninferiority analysis, which would have otherwise been impossible in the time available to complete this PhD. Additionally it is unlikely a trial of that size would ever be funded; therefore the research is valuable and has not been previously undertaken. That said, the methods of collecting data were not as stringent as a trial, therefore a proportion of data was missing which could have introduced follow-up bias. A conservative method was used to impute missing weight data at follow-up in both studies (chapters 3 and 5) and this may have underestimated weight change, however it would have reduced the potential for type 1 errors.

In the study presented in chapter 5 it was difficult to identify who had received the weight loss maintenance intervention, as this was not clearly reported in the Lighten Up database.

Therefore it was assumed in the primary analysis that all participants were offered the weight maintenance intervention. This is likely to underestimate the true effect of the programme, but did show significant effects, albeit small, and it is probable that the effect will be greater, as

potentially some people did not receive the intervention. As part of the weight loss maintenance intervention, participants did not have to lose a set amount of weight to be eligible and this may mean that the programme helped participants to continue to lose weight rather than maintain it; this is equivocal as both are important for health. Despite these limitations, this was a service being implemented in a real life setting and using natural experiments such as this is one is important for evaluation and commissioning. Real services involve people that have not been selected for research and it is plausible that volunteers for research may be more adherent to interventions.

Additionally, there was no measure of self-weighing for the weight loss maintenance intervention described in chapter 5 as it was part of service data and this information was not collected. I cannot therefore be sure that self-weighing was the effective part of the intervention as there were no measures of adherence. That said, self-weighing was the main emphasis of the weight loss maintenance intervention and it is unlikely that the two phone calls to promote self-weighing or hints and tips leaflet could solely explain the difference. The hints and tips leaflet was very basic and had a series of behavioural strategies that participants could choose to focus on and therefore is unlikely to explain the effect.

To my knowledge the RCT in chapter 4 is the largest to date that has isolated the effect of self-weighing for weight loss. The trial recruited a large number of participants classified as living in socio-economic disadvantage which is both a strength and weakness. Deprivation is associated with obesity and therefore the intervention has been targeted at those most in need. However, this may have decreased the generalisability of the findings. Participants who live in areas of socio-economic disadvantage may have less knowledge, skills and self-efficacy about how to change behaviour and therefore require more support. As there were few

exclusions to participating in the trial, there were quite a few participants who had other health conditions and therefore perhaps less ability to change their behaviour. No previous study of self-weighing that I am aware of, or included in the systematic review, excluded participants who were currently weighing themselves regularly, but this may be due to more intensive interventions or practicality reasons. In the trial reported in Chapter 4 participants who were already weighing themselves regularly (at least once per week) were not included in the analysis. If individuals are already weighing themselves it is perhaps easier to get them to weigh daily. Most other studies have used volunteers that are generally white, female and highly educated^{107,115}. In contrast this study had a diverse population.

The RCT that isolated self-weighing found no significant difference in weight change at three months, therefore it was decided not to follow-up participants at 12 months due to associated costs and weight loss curves tending to converge. However, self-weighing may have been more important for weight maintenance than weight loss but conclusions cannot be made without longer term follow-up. If participants were not weighing themselves regularly at three months it is unlikely they would do so at 12 months and that an effect would be found at this point. As part of the trial I utilised an objective measure of self-weighing. There were some technical difficulties with this objective method and therefore I cannot be sure the scales reflect a true account of how frequently people weighed themselves. The difference in adherence measures have been discussed in chapter 4 but with hindsight I should have tested the objective weighing scales in a pilot study as there may have been methods to overcome the issues that were faced. For example, giving participants written instructions (as well as verbal instructions) and also instructing the research assistants who downloaded the data to download all users' data as perhaps the user settings were sometimes switched accidentally. This is something to consider in future research.

The systematic review of self-weighing presented in chapter 6 for weight management is the first to include only experimental studies and the first to meta-analyse studies in the area of self-weighing research. Missing weight data was imputed in studies that reported complete data only to reduce bias and provide more accurate effect sizes and is a particular strength.

There are some concerns that asking people to weigh themselves daily will result in negative emotional well-being¹¹⁸, this was measured in the RCT (chapter 4) and there was limited evidence to support these suggestions. Similarly no adverse effects were found in the systematic review (chapter 6). However it would be important in future research to use a standardised measure to investigate any adverse effects of self-weighing.

7.3 Research in relation to other findings

The findings of the individual studies reported in the previous chapters have been compared to previous research. This section will highlight and compare overall findings in relation to key areas of research.

This research found commercial weight management programmes result in similar weight losses. A previous systematic review of behavioural weight management programmes found in a sub group analysis that commercial group based weight management programmes resulted in a mean difference of -2.2 kg (95% CI -2.9 to -1.5) compared to primary care programmes, mean difference -0.5 kg (95% CI -1.3 to 0.4)⁸². This research supports the findings of this thesis that the NHS group based programme was inferior at three months and inconclusive at 12 months. However the systematic review only included trials that had follow-ups at 12 months. The RCT (chapter 4) of self-weighing that was conducted in a primary care setting also resulted in a mean difference of -0.5 kg (95% CI -1.3 to 0.3) but at

three months, the same findings as the sub group of primary care programmes within the systematic review⁸². However, the primary care programmes in the systematic review were compared to a minimal comparator group and were more intensive than the self-weighing intervention investigated in this thesis. Thus it could be assumed that if follow-up had taken place at 12 months the difference would have been smaller than found in the systematic review.

Previous reviews of behaviour change techniques have found self-monitoring to be effective for alcohol reduction, increasing healthy eating, physical activity and reducing weight^{99,102,103}. However meta-regressions by Michie and colleagues have also found that self-monitoring plus other behaviour change techniques result in greater effect sizes⁹⁹. The findings from the RCT reported in chapter 4 and the systematic review (chapter 6) are consistent with these findings. Self-weighing as an isolated strategy did not result in more weight loss compared to a control group. Whereas self-weighing as part of a multi component programme results in significant weight loss compared to no/minimal intervention control group.

One promising strategy to combine with self-weighing could be accountability. This is similar to the weekly weigh-ins used as part of a behavioural weight management programme which are often reported by participants as an effective component¹³³. Participants in the RCT presented in chapter 4 reported wanting more contact with the weight management practitioner and the systematic review found greater mean weight differences in the trials that used accountability although, this was not significant. In particular, Steinberg and colleagues found significant weight loss in the intervention group who were instructed to weigh themselves daily and had scales that sent weights back in real time to the researchers who

could then pro-actively follow-up participants ¹¹⁵. It is not clear whether it was the accountability or the proactive follow-up that was the most important technique or whether it was a combination of the two.

Chapter 4 found that self-weighing was effective for weight loss maintenance. However there has been only one previous trial that has investigated this, and self-weighing was included within a multi-component intervention ¹¹⁴. In this three arm trial there were significant differences between the face to face intervention group and control group but not the internet intervention group and control group. This suggests that self-weighing may not have been the active ingredient, conversely observational data suggests that self-weighing is associated with weight loss maintenance ^{96,110}.

7.4 Future research

In Chapter 3 I examined four different weight loss programmes and found similar results for the commercial weight loss programmes. Future research should examine why patients choose a programme as this may help with identifying other reasons about which programmes to commission. For example do patients choose a service because of location, timings, support outside of group sessions or a supervised exercise component to name a few.

Most people tend to regain weight, therefore finding ways to help weight loss maintenance is important for public health. The self-weighing intervention for weight loss maintenance showed promising results. Further research should use an RCT methodology to investigate a self-weighing weight loss maintenance intervention with a longer follow-up of 12 months post randomisation. This will allow greater control over the data collected, remove potential biases and allow collection of data to examine mechanisms of self-weighing. There is a lack

of research in this area and I would like to investigate this further by identifying other techniques that will help people to maintain their weight.

The instruction to daily self-weigh was shown to be ineffective. Further research should examine behavioural strategies that can be combined to improve effectiveness whilst also being low cost and implementable within health care settings. Two issues participants highlighted in the RCT, in chapter 4 were accountability and more support. In the systematic review it was also highlighted that accountability may be an effective technique to combine with self-weighing, I would like to investigate this further and how this could be implemented in a primary care setting.

7.5 Implications and conclusions

7.5.1 For commissioners

Commercial weight management programmes are effective at weight loss. The programmes examined here result in similar weight losses and if participants have a choice of programmes it may increase uptake, although this requires further research. Nevertheless I also recognise that when commissioning services other factors are considered and the cost of the service per participant may be more important. A further consideration is access to services, as some commercial programmes may not be culturally tailored or acceptable to some populations. Additionally, commercial programmes may not be accessible in disadvantaged areas as there may be less demand from paying clients. Therefore commissioners may have to commission other services that are less effective but accessible in those areas. Commercial programmes appear to have similar outcomes and this provides commissioners with evidence to support offering patient's choice and perhaps promote competition in price.

Self-weighing as a strategy for weight loss maintenance shows promise and could be offered as advice within weight management care pathways. The pragmatic weight loss maintenance intervention could be adopted by other commissioners of weight management services although more research is needed using an RCT design. As part of the care pathway for weight management the instruction to self-weigh regularly can be given, particularly as part of tier one services of the weight management care pathway but should be offered with other strategies such as food and physical activity diaries.

7.5.2 For patients

Patients need to find the right weight management programmes for them but this research provides evidence that three commercial weight management programmes result in similar weight losses. Patients should be advised that weighing themselves regularly at least once per week may help them manage their weight.

7.5.3 For healthcare professionals

Healthcare professionals can be confident that referring patients to a commercial weight management programme may help most patients lose weight. Once they have completed the programme healthcare professionals should encourage participants to weigh themselves regularly for weight loss maintenance. Healthcare professionals may also wish to weigh patients regularly to encourage accountability, although this needs further research.

7.6 Conclusions

Commercial weight management programmes investigated here result in similar weight losses and therefore all could be commissioned and referred to within primary care. A simple weight loss maintenance intervention focused on self-weighing prevents weight regain after attending

a behavioural weight management programme. Self-weighing appears to be a behaviour change technique that is effective when used in combination with other techniques. However there is insufficient evidence to conclude that it is effective as a single strategy.

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APPENDIX 1

Publications arising from this research

Madigan CD, Jebb SA, Jolly K, Aveyard P. Public health benefits of weight loss may be enhanced with multiple providers: a comment on Dixon et al. *Journal of Public Health* 2013; doi: 10.1093/pubmed/fdt023

Madigan CD, Daley AJ, Lewis AL, Jolly K, Aveyard P. Which weight loss programmes are as effective as Weight Watchers: noninferiority analysis. *British Journal of General Practice*, 64(620) e128-136

Madigan CD, Aveyard, P, Jolly K, Denley J, Lewis A, Daley A. Regular self-weighing to promote weight maintenance after intentional weight loss: a quasi-randomised controlled trial. *Journal of Public Health* (2013) doi: 10.1093/pubmed/fdt061

Conferences

Madigan CD, Jolly K, Lewis A, Denley J, Aveyard P, Daley A. A controlled trial to examine the effectiveness of regular self-weighing to prevent weight regain. Association Study Obesity (ASO) conference titled "Lightening the Load in Primary Care." 28th March 2012. Poster presentation

Madigan CD, Jolly K, Lewis A, Denley J, Aveyard P, Daley A. A controlled trial to examine the effectiveness of regular self-weighing to prevent weight regain. Graduate School poster conference. Poster presentation

Madigan CD, Jolly K, Lewis A, Denley J, Aveyard P, Daley A. A controlled trial to examine the effectiveness of regular self-weighing to prevent weight regain. The psychological aspects of physical activity and health across the lifespan. 10th May 2012. Poster presentation

Madigan CD, Jolly K, Lewis A, Denley J, Aveyard P, Daley A. A controlled trial to examine the effectiveness of regular self-weighing to prevent weight regain. Treatment of Obesity conference 29th June 2012. Poster presentation

Madigan CD, Daley A, Lewis A, Denley J, Aveyard P, Jolly K. Who loses the most weight after being referred to a 12 week weight loss programme by their GP? UKSBM December 2012, Poster Presentation.

Madigan C, Daley A, Lewis A, Denley J, Aveyard P, Jolly K. Which weight loss programme is more effective? UKSBM December 2012, Oral Presentation.

Madigan C, Aveyard P, Lewis A, Jolly K, Daley A. Scale Down: The efficacy of self-weighing for weight loss: randomized controlled trial. UKSBM December 2013, Oral presentation.

Madigan C, Aveyard P, Lewis A, Jolly K, Daley A. The Efficacy Of Self-weighing As a standalone weight loss intervention: randomised controlled trial (SCALE DOWN) International Congress of Obesity, March 2014, Kuala Lumpa. Poster presentation.

Other

A seminar at the University of Sydney, the BODEN institute seminar series. Behavioural weight management interventions in primary care.

A seminar at the University of Queensland, School of Human Movement Studies seminar series. Behavioural weight management interventions in primary care.

A seminar at the University of Birmingham, School of Health and Population. Behavioural weight management interventions in primary care

Funding

Menzie bicentennial scholarship to conduct research at the University of Queensland (£1000).
Medicine and Dentistry travel scholarship to conduct research at the University of Queensland (£759).

APPENDIX 2



Version 2: 23rd May 2012

Patient information sheet:

Scale Down Study

PART 1

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. Do ask us any questions you have about the study. Take time to decide whether you wish to take part.

What is the purpose of the study?

We would like to investigate two approaches to weight management. This study will compare how useful the different programmes are at helping people to lose weight and to sustain their weight loss over time. One approach will focus on food intake and the other on self monitoring.

Why have I been chosen?

You had a raised body mass index (BMI) recorded in your primary care notes within the last 15 months and so your doctor has invited you to take part in the study.

What will happen to me if I take part?

You will continue to receive usual care from your health team regardless of whether you decide to take part or not. You have an equal chance of being assigned to one of two groups which will focus on different weight management strategies, depending on the group you are

allocated to. Some people will be asked to focus on their food intake and others will be asked to monitor their lifestyle.

Regardless of which group you are in, we will ask you to attend an appointment at your general practice to have a 40 minute consultation with a weight management practitioner.

During the consultation we will measure your height and weight and ask you to complete a brief questionnaire about yourself and any weight management strategies you have tried before. We will also ask you to log the meals you eat over four days and to come back a week later to discuss this with the weight practitioner.

We will then contact you three months later to ask you to come to the practice to measure your weight and answer a brief questionnaire to see how you have been getting on.

We may contact you nine months later to measure your weight and review your progress again. Finally, we may ask you a few questions over the telephone to hear your views about taking part in the study. We will contact you about this at a later date and the interviews will be audio recorded.

Your involvement in the study will last 12 months. Your GP will also be informed that you are taking part in the Scale Down Study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive from your healthcare team.

What are the possible disadvantages and risks of taking part?

We do not anticipate any risks or side-effects from the consultation.

What are the possible benefits of taking part?

The results of this study will help us decide whether the weight management approaches used in this study are useful in helping people to lose weight. Taking part in the study does not guarantee weight loss but we hope it may help.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. We will not release any information about you to any external organisation.

Once the study has been completed our record of your name and address will be destroyed.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What will happen if I don't want to carry on with the study?

If you do not want to take part in the research at any time you can withdraw without affecting your care.

What will happen to the results of the research study?

The results of the study will be published in 2014. No individual will be able to be identified in the published information. You will be mailed a newsletter detailing the findings of the study.

Who is organising and funding the research?

The research is being organised by the University of Birmingham. It is funded by the Department of Health.

Who has reviewed the study?

West Midlands Research Ethics Committee have reviewed and approved the study. The study reference number is 12/WM/0137.



APPENDIX 3

Weighing Record Card



Week 1		Kg/stone/lbs		Week 2		Kg/stone/lbs	
Monday				Monday			
Tuesday				Tuesday			
Wednesday				Wednesday			
Thursday				Thursday			
Friday				Friday			
Saturday				Saturday			
Sunday				Sunday			
Average Weight for the week <i>(add every day and divide by 7)</i>							
Week 3		Kg/stone/lbs		Week 4		Kg/stone/lbs	
Monday				Monday			
Tuesday				Tuesday			
Wednesday				Wednesday			
Thursday				Thursday			
Friday				Friday			
Saturday				Saturday			
Sunday				Sunday			
Average Weight for the week							

Week 5		Kg/stone/lbs		Week 6		Kg/stone/lbs	
Monday				Monday			
Tuesday				Tuesday			
Wednesday				Wednesday			
Thursday				Thursday			
Friday				Friday			
Saturday				Saturday			
Sunday				Sunday			
Average Weight for the week							
Week 7		Kg/stone/lbs		Week 8		Kg/stone/lbs	
Monday				Monday			
Tuesday				Tuesday			
Wednesday				Wednesday			
Thursday				Thursday			
Friday				Friday			
Saturday				Saturday			
Sunday				Sunday			
Average Weight for the week							

APPENDIX 4

UNIVERSITY OF
BIRMINGHAM

Scale Down
Food Diary



Version 1:

	Day 1: _____	Day 2: _____	Day 3: _____	Day 4: _____
Breakfast				
Lunch				
Dinner				
Snacks				
Drinks				

APPENDIX 5

Scale Down Study

Comments about the study

Thank you	No affect	Reasons for not losing weight	improvements
Thank you - grateful for the support!	My weight went down and up. Not much changes. I weighed myself every morning up until 20/12/12	Due to my general health not able to keep to strict regime.	The food diary could have been continued for a longer period. More regular consultations would have been useful to me and perhaps after a few weeks of keeping a diary it would have been helpful to know what to cut down on.
I am very glad to meet you and I will carry on if I feel better, thank you.	It did not help me as I know how to lose weight just no _____ to do it	Good communication. All the information is there hard to put into practice because of job.	If _____ was to have more support with Claire it would be more beneficial
Glad to say I lost 12 pound in three months and feel much better from losing the weight.	Bit disappointed I didn't meet target, cutting out rubbish	Arthritis in both legs, diabetic, overweight etc too much pain in back, legs cannot support weight.	3 months awfully long time. More frequent meetings would be more helpful - remind you what it is you were doing (more pressure)
I had already lost 13 stone and found that Claire was excellent in every aspect of the study. A nice lady with lots of information that related to me personally.	I wasn't really told anything I didn't already know but it was useful to have someone to talk to about my weight problem.	I feel I eat healthily three times per day but my downfall is craving sweet things especially in the evening when I am restricted as far as a social life (carer)	Takes 3 months for bone and soft tissue to cope with strenuous exercise- patients should be advised. Excellent idea - needs to be more widely available also 3 month mentoring until weight loss objective truly realised. Overall thanks
The programme has encouraged me to continually watch what I eat and weigh myself regularly, also helped me to exercise and has even been able to register with the gym and to continue with other exercises beneficial to my health.	Only attended one session as had to cancel my appointment but no one got back to me.	The past month has been the Christmas holidays so it's very hard to keep to the plan i.e. Diet went out of the window. I try my best to get on track these coming months.	Useful food diary at beginning. Good better to have consultations more often for support. Every three months to help refresh memory. Would like leaflets on activities could be doing.
Usually people talk down to you when you are overweight; Claire and Sarah made me feel at ease and were very helpful.		It's difficult for me because of cancer and diabetes. Weather affects my mobility, more active in warm weather.	Going to carry on keeping a food diary, found that helpful.
This course has helped me realise how I need to look at portion size and drink a lot more in order		I have serious health problems, mental and physical reasons. Doctor's advice and waiting to see consultants.	I liked to get the text it seems as if someone cared that I was doing well.

to lose weight.			
This programme should continue. I am sure if it includes the benefits of the types of food and their properties, and of course portions of each combined together for a balanced meal, for your daily intake.		I would like to further reduce my weight but due to the climate/domestic conditions I could not do much. However feel looking doing much to scale down.	He felt he knew a lot of the info but needed to hear it. He thought the texts were useful.
It helped me a lot and feel better without all the weight, thank you.		As I have been quite ill over the period of last being seen I have not managed to keep up with activities or my diet as I should have. I hope to improve on this in the future.	Good to receive text reminder and encouragement.
Both girls were very good although it's very hard for me to diet. I do try!		I would have benefited more; unfortunately I started a new mostly sedentary job and had two holidays and Christmas in the period of the study.	All very useful needs to go on longer otherwise I can see myself going backwards again.
Very commendable		Useful to do but just wish I had taken part another time other than over Christmas.	Amount of sugar in drinks was useful to know as I realised I was having my daily intake in four drinks of one evening.
The consultant was very easy and made me feel at ease and made sure I understood everything properly.		Have tried to stick with it, having a few family problems, once these settle will be hitting the plan again as did see the benefits.	Doing the food diary was the most useful one it made me realise what to reduce and portion size.
I was happy when Claire pointed out to me about the sugar levels I was taking in, not realising that it was harming me like it was, now I go down to one sugar.		I did appreciate the help and advice Claire gave me it's just a pity I never followed it through and I'm sorry I'm so forgetful.	The weight management practitioner was very clear when it came to reading through and explaining the questionnaire and the 2 methods in the study. However I was surprised to learn that it would be 14 weeks to my next weigh in, after the initial one. More consultations were needed.
I now take more care about the foods that I eat and have now got use to eating smaller portions.		Unfortunately due to me having bouts of depression I didn't complete the trial very well as in weighing myself everyday and keeping a food diary. At times I didn't eat or comfort ate due to my low moods.	12 week study - maybe about four consultations would have kept up encouragement a bit more.
This has been very useful particularly as it did not make any unrealistic demands and re-assured me I can go at my own pace. I have not followed anything rigorously but am quietly		Unable to walk or take exercise due to health problems, unable to stand, sit for any length of time due to pains and oedema.	My fitness pal helped a lot to see how many calories in everything.

aware of the principles involved.			
Excellent in always. Shame there is not more people like you help out people like me.			wanted more support and free access to gym and swimming
Sarah was very friendly and I don't feel totally defeated. In laziest days go for fruit instead.			Could have done with regular weighing to keep me motivated.
Claire was really calm in conducting the plan of action, and understood my needs as a client. I've got a long way to go although I feel Claire has been a credit to that journey.			
Very encouraging			
Claire was very pleasant and helpful			
Very helpful and understanding			
Been very helpful makes me pay attention to meals more now than I did before.			
I felt Claire was very good at explaining herself to me.			
I enjoyed the experience.			
Made me realise how important a regular healthy diet is.			
Generally been helpful and increased motivation			
Thank you			
It was a help			
Claire shared useful weight loss knowledge with me she was very helpful and put me at ease. She was also very understanding and communicated very well with me.			
I'm still fat but getting thinner (two lovely girl practitioners)			

APPENDIX 6

Self-weighing, how did it make participants feel?

Fine	Good	Problem
Here or there	Good	Nuscience
No problem n=6	Quite good as never use to weigh yourself and got into habit.	Embarrassed
I did not mind n=6	It makes me feel more aware of my weight and I know that I need to lose weight and it is To me but hard.	At first it was easy to weigh myself daily but later on I would forget or due to work I wasn't able to weigh myself.
I was ok about it, doesn't bother me.	It was good and appreciated the reminder since I was becoming a bit relaxed about weight watching and I have benefited from the consultation and I am even encouraging friends to weight watch.	Ok but felt every day was too much for me as my health is all over the place and I felt if I gained weight by the daily weighing I was upset with myself.
Fine n=2	Good when I lost weight, disappointing when I plateaued but made me continue to try.	Sometimes seeing the weight go up and down even when I have tried really hard to eat well gets you down a bit.
Ok n=6	I am happy about self-weighing myself	Did not feel I was particularly obese but no need to do more exercise
Not bad	Very good	Apprehensive
Didn't really bother me as I do this anyway	Made aware of weight gain and become a trigger for weight loss. Feel that daily weighing works for her	At first I really got into it and was looking forward to seeing it but over the period of 12 weeks the weight did fluctuate with made me feel demoralised, especially when I put some weight on around Christmas.
Didn't mind, shifts made it difficult to weigh as sometimes sleep over at work and there are no scales.	Found it to be an incentive	Depressed at the time this was more to do with general health rather than weighing myself.
My weight has been around the same the past 2 years - not bothered.	Very pleased, really helped, he realised that whatever he eats he will see on the scales in the morning.	
Bit difficult at first but became easier	I'm ok with that, I find it very helpful.	
Became routine and didn't mind. A bit fed up when kept going up.	Quite pleased	
Ok done it every morning in the beginning.	At first strange and then enlightening	
Something to do	Good	
Ok made me more aware and to control my weight.	At first horrified, but then I got used to it and was quite involved in it.	
Didn't mind had to be faced	Nice and losing the weight was good and feel confident	

I didn't mind weighing myself but it makes me think about what I am eating.	At first I was a bit self conscious but could see benefits of it - it was just mood dependent for me.	
No different		
No problem as anxious to lose weight. Sarah helped to do it/		
Make mind and do it believe to do it		
Fine, quite easy to do as I've put the scales in the hallway.		
Don't mind if it helps other people		
Uneasy at first, but soon passed and became normal practice.		
Ok it has helped to make me realise how easy it is to put on weight by not weighing myself.		
First it can be a bit wary, but after the first week it came naturally		
It felt alright, I like weighing myself but don't like what I see on the scales		

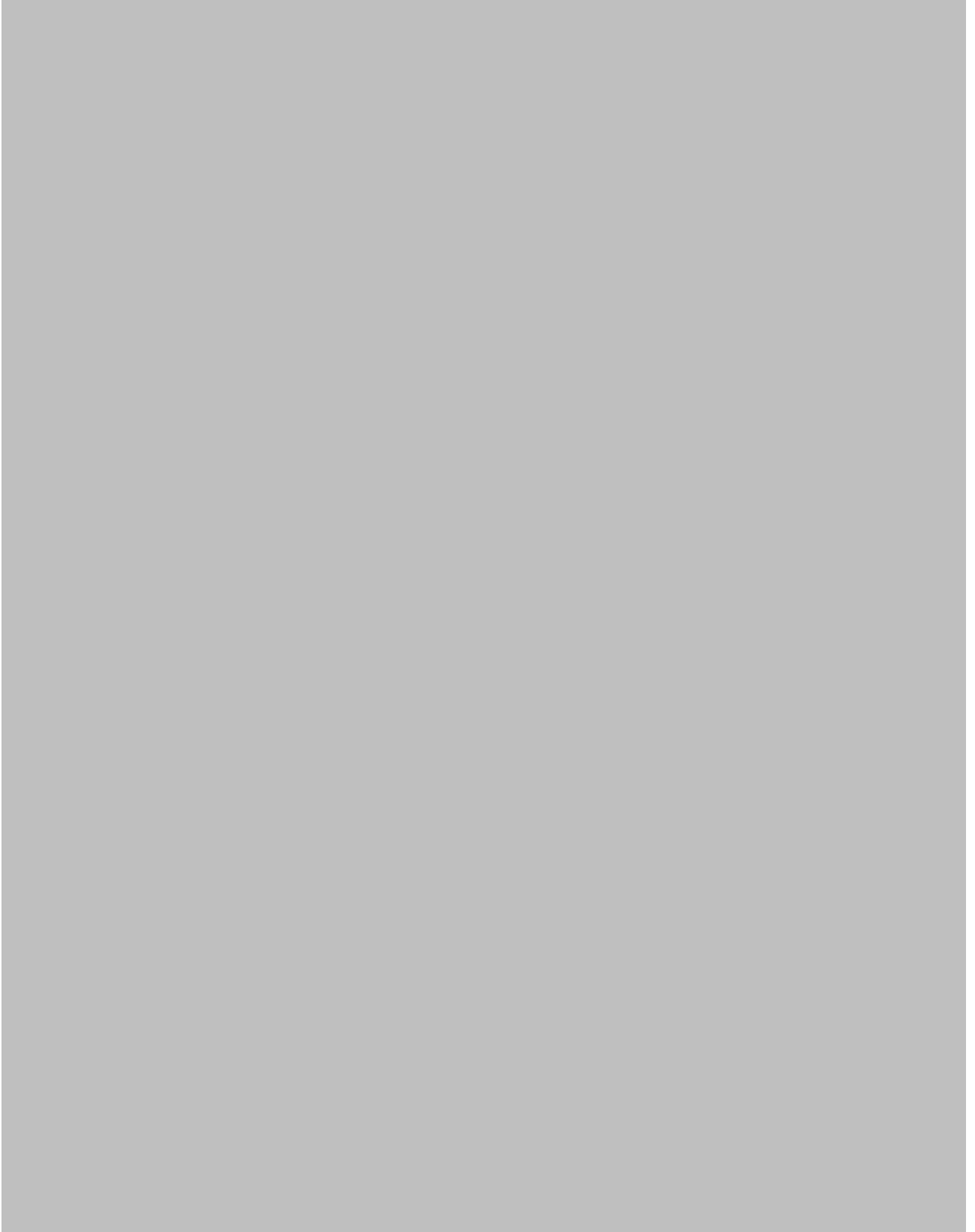
APPENDIX 7

Additional comments about self-weighing

Positive	Negative	Other
	Working away made it difficult to weigh self.	I don't mind weighing myself but not every day
Normal from now on	Very self conscious	
I think this was a good idea and I received a lot of useful information, but I would still like to lose 10-12kg	Wouldn't want to do it every day could become obsessive	Great when I weighed less not so great if weight went up.
Found it useful recording weight regularly, would like another. A bit more support is needed 3 months is a long time.	Feeling down about my physical and mental health	When I weighed myself and lost weight it made me feel better but when I gained a few pounds that I had lost it was a little disheartening as I am not entirely happy with my weight losing weight made me happier than gaining made me unhappy.
I enjoyed talking about how to lose the weight because most people don't like to talk about weight but I feel Claire made me feel better as if she understood how I felt.	Not dislike my body but more think about what I should not have eaten that day or what I should have done and not done. Very helpful.	Weighing affect mood- depends on the way it went, weight down happy, weight up a bit down.
I have made it part of my routine to continue weighing myself every other day the situation permitting.	Do not like to see how much I weigh	Maybe weigh myself more but not every day, just to keep an eye on my weight.
Will continue to weigh more often		Felt good if I lost weight, bad if I put weight on.
Good to see drop encouraging.		Wish I had weighed myself more and stuck to advice I was given but this is my problem not weight management leaders.
Became a routine		
It's nice to see my body changing and my clothes getting loser around my belly.		
Inspired me to do something about me.		
Easy to do.		
I didn't mind doing it and pleased I have lost some weight.		
I am going to continue to do it		
It doesn't bother me to weigh myself I just wish I could lose the weight.		
Good keeps you on track.		
The fluctuations in my weight were enough to dishearten me even when I made a conscious effort to manage my food intake and monitor the times I ate.		
It was very good		
Gave me a target- see what was working.		

Self-weighing makes me think about what did I eat for my weight to go up. Keeps me on the straight and narrow.		
Getting use to weighing myself every day if you feel good you look good.		
If weight went up made me upset and eat more.		
Fine		
I would like to lose more weight.		
Weighing was fine until I put weight on.		
Depressed due to severe weight gain, not being able to walk etc. I think dieting and exercise go hand in hand, unsuccessful this time. But I will definitely try to lose weight between now and summer for general wellbeing and confidence.		

APPENDIX 8



APPENDIX 9

