## Putting The Person Back Into Weight Loss And Weight Loss Maintenance: The Role Of Affect, Cognition, Behaviour And Motivation

Kyriaki Myrissa Submitted in accordance with the requirements for the degree of Doctor of Philosophy

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#### ABSTRACT

Obesity is one of the most serious health problems facing modern society and strategies to address this pandemic have so far been ineffective. Although weight loss (WL) is achievable, prevention of weight regain is a major challenge. The overall aim of this thesis was to identify predictors of WL and weight loss maintenance (WLM) to promote better tailored and sustainable interventions. A systematic review evaluated the evidence from 80 studies examining predictors of WL and/or WLM in behavioural and/or dietary WL interventions (with or without exercise) in overweight and obese individuals. Aside from physiological factors such as initial weight loss, a number of personal characteristics broadly conceptualised as reflecting affective, cognitive, behavioural and motivational factors were acknowledged as potential predictors of WL and/or WLM. Affective (e.g. anxiety), behavioural (e.g. eating behaviour, self-monitoring, social support, physical activity, treatment adherence, previous WL attempts) and motivational factors (e.g. self-efficacy) were the strongest predictors identified. Study 1 assessed predictors of WL and WLM in free-living participants (N=71) who received healthy eating advice with (HE+F) or without (HE) advice to increase dietary fibre. Predictors of WL were age, body weight and body image at baseline (affective), fasting plasma leptin and disinhibition (behavioural) with some differences according to diet group. These also predicted WLM at 1 month followup. At 12 month follow-up, having a higher body weight at week 12 and greater depression (affective) at follow-up were associated with greater weight regain. Additionally, having stronger beliefs that medical reasons cause obesity (cognitive) and less stressful life events (affective) were associated with better WLM. Study 2 utilised an online survey and cluster analysis to examine affective, cognitive, behavioural and motivational factors in a real world setting with individuals (N=314), who had previously attempted to lose weight using different WL methods. Two distinct clusters were identified: less successful (Cluster 1) and more successful (Cluster 2). Cluster 2 was associated with lower emotional and external eating, lower disinhibition and higher restraint (behavioural), less depression, anxiety and stress (affective), and significantly higher diet satisfaction, eating self-efficacy (motivational) than Cluster 1. Study 3 examined predictors of WL in an NHS delivered 12 week community based weight management programme (N=22). Higher diet satisfaction, an improvement in body image and higher baseline body weight were significant predictors of WL. Based on the evidence presented in this thesis, there are clear personal characteristics which promote and sustain obesity. WL and WLM is clearly not just a problem of appetite control. Affective (stressful life events, body image, diet satisfaction and depression), behavioural (eating behaviour) and motivational factors (self-efficacy and motivation) were the most consistent psychological predictors of WL and/or WLM across all studies. Interventions should therefore target these personal characteristics in order to promote WL and prevent weight regain. The paucity of studies incorporating long-term follow-up shows that further research is needed to examine the role of affect, cognition, behaviour and motivation in the long term. A multidisciplinary approach to tackle obesity, which addresses psychological, social, environmental, and biological factors is essential to ensure comprehensive care, best practice and outcomes.

## List of publications and presentations from this thesis

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### **Table of Contents**

Chapte	er 1 – General Introduction & Thesis Aims	31
1.1	Background	31
1.2	Causes of obesity	32
1.3	Definition of successful weight loss and/or weight loss mainter	nance33
1.4	Different types of interventions for weight management	35
1.5	Dietary interventions	35
1.6	Physical activity interventions	37
1.7	Pharmacotherapy	38
1.8	Bariatric surgery	39
1.9	Behavioural interventions	40
1.10	Commercial programmes	42
1.11 Healt	Weight management programmes provided within the UK Nati th Service (NHS)	
1.12	Internet-based interventions	46
1.13	Comparison amongst different weight loss interventions	48
	Factors associated with weight loss and/or weight loss mainter	
1.15	Barriers to the prediction of weight loss success	51
1.16	Current Statistical Analysis Approaches	52
1.17	Thesis aims	53
-	er 2 - Psychosocial/behavioural Predictors of Weight Loss and/o laintenance: A Systematic Research Review	-
2.1	Introduction	56
2.2	Literature search	57
2.2	2.1 Search strategy and search terms	57
2.3	Inclusion and exclusion criteria	58
2.4	Tabulation of Studies	60
2.5	Results	61
2.6	Eating Behaviour	106
2.7	Emotional states (depression, mood, anxiety, anger)	108
2.8	Self-efficacy	111
2.9	Binge eating	112
2.10	Physical activity	114

2.11	Body image115
2.12	Self-monitoring and self-weighing116
2.13	Motivation117
2.14	Social support119
2.15	Stress and coping skills120
2.16	Self-esteem
2.17	Health Related Quality of Life122
2.18	Weight loss goals/expectations124
2.19	Treatment adherence/attendance125
2.20	Personality traits126
2.21	Initial weight loss/previous weight loss attempts127
2.22	Weight bias/attitudes128
2.23	Quality of Sleep129
2.24	Dichotomous thinking style129
2.25	Locus of control130
2.26	Beliefs about causes of obesity131
2.27	Discussion
	Summary of psychosocial and behavioural characteristics linked to
•	nt loss and weight loss maintenance135
	Conclusions
weight	r 3 - Physiological and psychological predictors of weight loss and loss maintenance following a dietary intervention – the Leeds Women's ing (LWW) Study138
3.1	Overview138
3.2	Introduction138
3.2	.1 Dietary Fibre and Satiety140
3.2	.2 Rationale for the present study141
3.2	.3 Aims of the present study141
3.3	Methods142
3.3	.1 Study Design142
3.3	.2 Participants
3.4	Compliance with dietary advice and recommendations150
3.5	Study Measures150
3.5	.1 Anthropometric measures

	3.5.2	2	Biochemical measures	151
	3.5.	3	Wellbeing Diary Booklets (WDBs)	151
	3.5.	4	Food Diary Data: 3 and 7 day food diary records	152
	3.5.	5	Eating Behaviour Assessments	153
	3.5.	6	Body Shape Questionnaire	155
3	.6	Stu	dy measures assessed exclusively at 12 month follow-up	155
	3.6.	1	Intuitive Eating Scale	155
	3.6.2	2	Diet Satisfaction Questionnaire	155
	3.6.	3	Social Readjustment Rating Scale or Life Events Scale	156
	3.6.	4	Depression Anxiety and Stress Scales	156
	3.6.	5	Beliefs about causes of obesity	156
3	.7	Stu	dy Procedure and Study Visits	156
	3.7.	1	Screening visit (Visit 1)	156
	3.7.2	2	Inclusion Visit (Visit 2, week -1): Baseline measures	157
	3.7.3	3	Interim intervention visits (Visit 3 and 4, week 4 and 8)	158
	3.7.	4	Intervention visit (visit 5, week 12)	158
	3.7.	5	Debriefing Visit (Visit 6, week 13)	158
	3.7.	6	Early termination visit	158
	3.7.	7	Optional Follow up Visit (+1Month)	159
	3.7.	8	12 month follow-up visit	159
3	.8	Adv	verse Events (AEs)	159
3	.9	Eth	ical considerations and confidentiality	159
3	.10	Sta	tistical analysis	160
	3.10	).1	Part 1 Weight loss phase	160
	3.10	).2	Part 2 Weight maintenance phase (1 and 12 month follow-up)	.163
3	.11	Res	sults from weight loss phase –Part 1	.164
	3.11	.1	Participant Characteristics at Screening	.164
	3.11	.2	Participant Characteristics at Randomisation (week -1, Visit2)	.164
			bitual Dietary Intake during the Inclusion Phase (between screen bomisation)	•
	3.12	2.1	Dietary intake assessed by the 7 day food diary records	167
	3.12	2.2	Habitual (baseline) fibre intake	.168
	3.12	2.3	Changes in Fibre Intake during the 12-week Dietary Intervention	۱
	Pha	se		170

3.1	2.4	Changes in Dietary intake from baseline to week 12 (n=50)	173
3.13	Effe	ects of the Dietary Interventions on Body Weight (kg)	175
3.1	3.1	Body weight change (kg) from baseline to week 12	175
		Body composition assessed using Air Displacement smography (ADP, BodPod)	177
3.14	Effe	ects of the Dietary Interventions on biomarkers of health	178
3.15	Sur	nmary of Findings	180
3.16	Cha	anges in psychological measures	182
3.1	6.1	Subjective Measures of Body Shape	182
3.17	Eat	ing Behaviour Characteristics	183
		anges in subjective wellbeing symptoms in response to both die ons (Diet A and Diet B)	•
3.1	8.1	Feeling fat	185
3.1	8.2	Feeling slim	186
3.1	8.3	Feeling energetic	188
3.1	8.4	Mental alertness	189
3.1	8.5	Mental tiredness	190
3.1	8.6	Difficulty concentrating	191
3.1	8.7	Physical tiredness	192
3.1	8.8	Headaches	193
3.1	8.9	Bowel Pain	194
3.1	8.10	Constipation	195
3.1	8.11	Bloating	196
3.1	8.12	Indigestion	197
3.1	8.13	Wind	198
3.1	8.14	Breast tenderness	199
3.1	8.15	Happiness	200
3.1	8.16	Stress	201
		nmary of effects of dietary interventions on subjective wellbeing	-
		dictors of weight loss	
3.2 wei		Relationship between randomization (Visit 2) variables and boat the end of the intervention (week 12)	

3.20.2 Changes in physiological and psychological variables (V2-V5) and body weight at the end of the intervention (week 12)	
3.20.3 Relationship between baseline (randomisation, Visit 1) psychological and physiological variables and weight change during the intervention (assessed from V2-V5)	207
3.20.4 Changes in physiological and psychological variables (V2-V5) an weight change during the intervention	
3.20.5 Summary of predictors of weight loss	210
3.21 PART 2 Weight maintenance phase – 1 month follow-up	212
3.21.1 Baseline (screening) characteristics of participants who complete the 1 month follow-up	
3.21.2 Anthropometric characteristics at randomisation (week -1), week and at 1 month follow up	
3.21.3 Body weight change (kg) from randomisation (week - 1) to 1 mo follow-up	
3.21.4 Changes in fibre intake from screening to 1 month follow-up	216
3.21.5 Changes in psychological variables (BSQ, TFEQ and DEBQ measures)	218
3.21.6 Subjective measures of Body Shape	218
3.21.7 Eating Behaviour Characteristics	219
3.21.8 Summary of findings	221
3.22 Predictors of weight loss maintenance at 1 month follow-up	222
3.22.1 Relationship between randomization (week -1) variables and boweight at 1 month follow-up	•
3.22.2 Relationship between randomization (week -1) variables and weight loss maintenance (V5-1 month follow-up)	223
3.22.3 Relationship between variables at V5 (week 12) and body weigh 1 month follow-up	
3.22.4 Relationship between variables at week 5 and weight loss maintenance (V5-1 month follow-up)	225
3.22.5 Changes in physiological and psychological variables from V5 (week 12) to 1 month follow-up and body weight at 1 month follow-up	226
3.22.6 Changes physiological and psychological variables from V5 (we 12) to 1month follow-up and weight loss maintenance (V5-1 month follow up)	V-
3.22.7 Summary of predictors of weight loss maintenance (1 month folloup)	

3.23 12 month Follow-up231
3.23.1 Participant characteristics at screening and at 12 months231
3.23.2 Anthropometric characteristics at baseline (week -1), week 12 and at 12 month follow up232
3.23.3 Body weight change (kg) from baseline (week - 1) to 12 month follow up
3.23.4 Changes in fibre intake from screening to 12 month follow up234
3.23.5 Changes in psychological variables (BSQ, TFEQ and DEBQ measures)
3.23.6 Subjective measures of Body Shape238
3.23.7 Eating Behaviour Characteristics239
3.23.8 Summary of findings241
3.24 Predictors of weight loss maintenance at 12 month follow-up242
3.24.1 Relationship between randomization (week -1) variables and body weight at 12 month follow-up242
3.24.2 Relationship between randomization (week -1) variables and weight loss maintenance (V5-12 month follow-up)242
3.24.3 Relationship between variables at V5 (week 12) and body weight at 12 month follow-up
3.24.4 Relationship between variables at week 12 and weight loss maintenance (V5-12 month follow-up)243
3.24.5 Changes in physiological and psychological variables from V5 (week 12) to 12 month follow-up and body weight at 12 month follow-up 243
3.24.6 Changes in physiological and psychological variables from V5 (week 12) to 12 month follow-up and weight loss maintenance (weight change from V5 to 12 month follow-up)243
3.24.7 Changes in physiological and psychological variables from baseline (week -1) to week 12 and weight loss maintenance (weight change from V5 to 12 month follow-up)244
3.25 Psychosocial measures assessed only at 12 month follow up244
3.25.1 Relationship between psychosocial measures assessed at 12 month follow-up and body weight at 12 month follow-up244
3.25.2 Relationship between psychosocial measures assessed at 12 month follow-up and weight loss maintenance (weight change from V5 to 12 month follow-up)
3.26 Successful vs unsuccessful weight loss maintenance

3.26.1 Summary of predictors of weight loss maintenance (12 month Summary of the main findings from the two 12-week dietary 3.27.1 3.27.2 Summary of results for weight loss maintenance phase (1 and 12 month follow-up)......249 3.29 Summary of predictors of weight loss and weight loss maintenance: physiological and psychological predictors ......251 3.29.2 Weight loss maintenance phase ......251 3.31 Effects of initial body weight on weight loss and/or weight loss 3.32 Effects of biomarkers on weight loss and/or weight loss maintenance 3.33 Effects of eating behaviour characteristics on weight loss and/or weight loss maintenance......255 3.34 Effects of body shape perception on weight loss and/or weight loss 3.35 Effects of depression on weight loss and/or weight loss maintenance 259 3.36 Stressful life events as potential predictors of weight loss and/or weight 3.37 Effect of beliefs about causes of obesity on weight management......261 3.38 Effects of the dietary interventions on body weight and possible reasons for similar weight loss......262 3.39 Promotion of breakfast consumption and the effects of breakfast Why weight loss maintenance is so difficult to achieve?......266 3.41 3.44 Problems encountered when assessing predictors of weight loss and 

3.45	Ge	neralisability of the results	269
3.46	Me	thodological strengths of the present study	270
3.47	Imp	plications of the study and recommendations for future studies	271
3.48	Ov	erall Conclusions of weight loss success	272
		wards an understanding of putting the person back into weight lo	
-		An internet survey of the psychological and behavioural tics, and weight loss strategies of successful weight losers	274
4.1	Ov	erview	274
4.2	Intr	oduction	274
4.3	Me	thods	276
4.3	.1	Inclusion/exclusion criteria	276
4.3	.2	Participants	276
4.3	.3	Measures	277
4.4	Sta	itistical Analysis	279
4.5	Eth	ical Considerations	280
4.6	Re	sults	280
4.6	.1	Differences in self-monitoring and weight loss strategies	287
4.7	Su	mmary of findings	288
4.8	Dis	cussion	288
4.9	Lin	nitations of the present study	293
4.10	Co	nclusions	294
		wards an understanding of putting the person back into weight lo	
Chapte	r 5-	Factors associated with weight loss in obese and severely obes	е
adults f	ollo	wing an NHS weight management programme: a pilot study	296
5.1	Ov	erview	296
5.2	Intr	oduction	296
5.2	.1	Local rates of obesity in Yorkshire and related behaviour?	297
5.2	.2	Key features of Kirklees NHS weight management service	297
5.3	Me	thods	299
5.3	.1	Participants	299
5.3	.2	Inclusion/exclusion criteria	299
5.3	.3	Design	299

5.3	8.4	Weight management programme	299
5.4	Stu	dy Measures	302
5.4	l.1	Anthropometric measures	302
5.4	.2	Eating Behaviour Assessments	302
5.4	.3	Body Shape Questionnaire	302
5.4	l.4	Diet Satisfaction Questionnaire	302
5.4	.5	Depression and Anxiety	302
5.4	.6	Dichotomous Thinking in Eating Disorders Scale-11 (DTEDS-11	I)
			303
5.4	.7	Diet Readiness Test (DRT)	303
5.4	.8	Weight Efficacy Lifestyle Questionnaire (WEL)	303
5.4	.9	Binge eating scale (BES)	303
5.5	Pro	ocedure	304
5.5	5.1	Optional support group sessions	304
5.6	Sta	tistical Analysis Plan	304
5.7	Eth	ical Considerations	304
F 0	Ro	sults	305
5.8	IVE:	50115	000
5.8 5.8		Participants	
	8.1		305
5.8 5.8 5.8	8.1 8.2 8.3	Participants	.305 .305
5.8 5.8 5.8 am 5.8	3.1 3.2 3.3 10unt 3.4	Participants Weight loss over the 12 week weight management intervention . Differences in weight loss between participants differing in the	.305 .305 .307
5.8 5.8 3.8 am 5.8 ma 5.8	3.1 3.2 3.3 10unt 3.4 1nage 3.5	Participants Weight loss over the 12 week weight management intervention . Differences in weight loss between participants differing in the of readiness to start the weight management programme Changes in psychological measures over the 12 week weight	.305 .305 .307 .307 y
5.8 5.8 am 5.8 ma 5.8 we 5.8	3.1 3.2 3.3 100unt 3.4 100ag 3.5 100ag 3.5 100ag 3.6	Participants Weight loss over the 12 week weight management intervention . Differences in weight loss between participants differing in the of readiness to start the weight management programme Changes in psychological measures over the 12 week weight ement programme Relationship between baseline psychological variables and body	.305 .305 .307 .307 y .308 ght e
5.8 5.8 5.8 5.8 5.8 5.8 5.8 cha	3.1 3.2 3.3 100unt 3.4 100an 3.5 100an 3.5 3.6 ange 3.7	Participants Weight loss over the 12 week weight management intervention . Differences in weight loss between participants differing in the of readiness to start the weight management programme Changes in psychological measures over the 12 week weight ement programme Relationship between baseline psychological variables and body at week 12 Relationship between baseline psychological variables and weight from baseline to week 12 of the weight management programme	.305 .305 .307 .307 y .308 ght e 308 0-
5.8 5.8 5.8 5.8 5.8 5.8 0 5.8 0 5.8 0 5.8	3.1 3.2 aount 3.4 anage 3.5 ight a 3.6 ange 3.7 ek 12 3.8	Participants Weight loss over the 12 week weight management intervention . Differences in weight loss between participants differing in the of readiness to start the weight management programme Changes in psychological measures over the 12 week weight ement programme Relationship between baseline psychological variables and body at week 12 Relationship between baseline psychological variables and weight from baseline to week 12 of the weight management programme Relationship between changes in psychosocial variables (week	.305 .305 .307 .307 y .308 ght e 308 0- .309 0-
5.8 5.8 5.8 5.8 5.8 5.8 0 5.8 0 5.8 0 5.8	3.1 3.2 aount 3.4 anage 3.5 ight a 3.6 ange 3.7 ek 12 3.8 ek 12	Participants Weight loss over the 12 week weight management intervention . Differences in weight loss between participants differing in the of readiness to start the weight management programme Changes in psychological measures over the 12 week weight ement programme Relationship between baseline psychological variables and body at week 12 Relationship between baseline psychological variables and weight from baseline to week 12 of the weight management programme Relationship between changes in psychosocial variables (week 2) and body weight at week 12 Relationship between changes in psychosocial variables (week	.305 .305 .307 .307 y .308 ght e 308 0- .309 0- .309
5.8 5.8 am 5.8 ma 5.8 we 5.8 cha 5.8 we 5.8 we 5.8 we	3.1 3.2 3.3 1000000 3.4 1000000 3.5 1000000 3.5 1000000 3.5 1000000 3.7 10000000 3.7 1000000000000000000000000000000000000	Participants Weight loss over the 12 week weight management intervention . Differences in weight loss between participants differing in the of readiness to start the weight management programme Changes in psychological measures over the 12 week weight ement programme Relationship between baseline psychological variables and body at week 12 Relationship between baseline psychological variables and weight from baseline to week 12 of the weight management programme Relationship between changes in psychosocial variables (week 2) and body weight at week 12 Relationship between changes in psychosocial variables (week 2) and weight change (week 0-week 12)	.305 .305 .307 .307 y .308 ght e 308 0- .309 0- .309 .309

		.2 /ards	Potential screening tests to identify those who are more motivat behaviour change	
	5.9 ma		Lack of psychological input during the 12 week weight ment programme	.312
	5.9	.4	Group versus individual treatments for weight loss	.313
	5.9 pro		Challenges encountered when evaluating weight management mes offered within the NHS	.314
	5.9	.6	Clinical implications for primary care	.315
	5.9	.7	Strengths and limitations of the present study	.316
	5.9	.8	Future research and recommendations	.317
	5.9	.9	Conclusions	.318
			Towards an understanding of putting the person back into weight loss maintenance	
Cha	apte	r 6 –	General Discussion	.320
6	.1	Ove	erview of thesis findings	.320
-	.2 nd v		vards an understanding of putting the person back into weight los	
6	.3	Affe	ective Factors	.323
	6.3	.1	Body image	.323
	6.3	.2	Depression	.323
	6.3	.3	Stress and stressful life events	.324
	6.3	.4	Diet Satisfaction	.325
6	.4	Cog	nitive Factors	.325
	6.4	.1	Beliefs about the causes of obesity	.325
6	.5	Beh	avioural Factors	.326
	6.5	.1	Eating Behaviour	.326
	6.5	.2	Treatment adherence/attendance	.326
6	.6	Mot	ivational Factors	.327
	6.6	.1	Self-efficacy	.327
	6.6	.2	Motivation as a key factor for successful weight loss	.328
-	.7 naint	•	vsiological factors associated with weight loss and/or weight loss	
6	.8	Stra	ategies associated with weight loss	.329
6	.9	Wh	y is changing behaviour and sustaining behaviour change so	
d	ifficu			.330

	6.10	Weight stigma as a de-motivator of weight loss	
	6.11	Individual variability in weight loss and weight loss maintenance	÷333
	6.12	Group versus individual based interventions for weight loss	
	6.13	Consideration of other treatment outcomes in weight loss interv	entions
	6.14	Strengths of this thesis	
	6.1	, , , , , , , , , , , , , , , , , , , ,	
	6.15	Limitations of the present thesis	
	6.1	1 5	
		5.2 Loss to follow-up	
	6.1	5.3 Seasonal effects on weight loss	339
		5.4 Failure to control for physical activity	
	6.1	5.5 Reliance on self-reported data	341
	6.16	Future research and recommendations	341
		Conclusions	
7		ferences	
A		IDICES	
	Appe	ndix 3.1 Randomisation Schedule	
	Appe	ndix 3.2 Participant Information Sheet and Informed Consent for	m400
	Appe	ndix 3.3 Demographic Information Questionnaire (DIQ)	409
		ndix 3.4 Standard operating procedures for introducing Diet A at sion phase (week -1)	
		ndix 3.5 Standard operating procedures for introducing Diet B at	
		sion phase (week -1)	
		ndix 3.6 Fibre Intake Table	
	••	ndix 3.7 Wellbeing Diary Booklets (WDBs)	
		ndix 3.8 Dietary Instrument for Nutrition Education (DINE)	
		ndix 3.9 LWW – DINE	
	Appe	ndix 3.10 – Eating Attitudes Test -26	433
	Appe	ndix 3.11 Dutch Eating Behaviour Questionnaire (DEBQ)	435
	Appe	ndix 3.12 Three Factor Eating Questionnaire (TFEQ)	439
	Appe	ndix 3.13 Body Shape Questionnaire (BSQ-34)	446
	Appe	ndix 3.14 Intuitive Eating Scale (IES)	449
	Appe	ndix 3.15 Diet Satisfaction Questionnaire (D-SAT)	452

Appendix 3.16 Social Readjustment Rating Scale (SRRS) or Life Events Scale (LES)	456
Appendix 3.17 Depression Anxiety Stress Scales (DAAS)	
Appendix 3.18 Beliefs about the causes of obesity	460
Appendix 3.19 Study Schedule	461
Appendix 3.20 End of Study Questionnaire (Diet A)	463
Appendix 3.21 End of Study Questionnaire (Diet B)	468
Appendix 3.22 Adverse Event Report Form (AE)	474
Appendix 3.23 Ethics Certificate	475
Appendix 3.24 Predicted Probabilities (PP) by rating score for week -1 (baseline) through week 12 (end of the intervention)	476
Appendix 4.1 Ethical Approval Certificate	492
Appendix 4.2 Weight Efficacy Life-Style Questionnaire (WEL)	493
Appendix 5.1 Participant Information Sheet	495
Appendix 5.2 EAT WELL plate	500
Appendix 5.3 Hospital Anxiety and Depression Scale (HADS)	501
Appendix 5.4 Dichotomous Thinking in Eating Disorders Scale	503
Appendix 5.5 Diet Readiness Scale (DRS)	504
Appendix 5.6 Binge eating scale (BES)	505

## LIST OF TABLES

Table 2.2-1 List of search terms (\$ denotes word truncation; * permits variation)
Table 2.5-1 Predictors of weight loss following different dietary (with or without exercise) and behavioural interventions (forty-nine studies)
exercise) and/or behavioural interventions (twenty-four studies)
and/or behavioural interventions (eight studies)100 Table 2.5-4 Summary of predictors and evidence of their predictive power in weight loss and weight loss maintenance (with or without intervention input
during maintenance period) studies presented as a fraction
groups
blood parameters at randomisation (week -1)
Table 3.12-1 Dietary Intake of participants at baseline (7 day food diary records)
Table 3.12-2 Habitual fibre intake of participants at baseline
Table 3.12-4 Changes in macronutrient (g), alcohol (g/d) and fibre intake (g/d) between participants on Diet A and Diet B assessed using food diary records (n=50)
Table 3.13-1 Changes in body composition measures assessed using theBodPod178
Table 3.14-1 Mean (SE) fasting blood lipids, glucose, insulin and leptin atbaseline and at the end of the intervention
Table 3.18-1 Odds ratios with 95% confidence intervals for ratings of feeling fat
slim
energetic

Table 3.18-4 Odds ratios with 95% confidence intervals for ratings of mental Table 3.18-5 Odds ratios with 95% confidence intervals for ratings of mental Table 3.18-6 Odds ratios with 95% confidence intervals for ratings of difficulty Table 3.18-7 Odds ratios with 95% confidence intervals for ratings of physical Table 3.18-8 Odds ratios with 95% confidence intervals for ratings of Table 3.18-9 Odds ratios with 95% confidence intervals for ratings of bowel pain Table 3.18-10 Odds ratios with 95% confidence intervals for ratings of Table 3.18-11 Odds ratios with 95% confidence intervals for ratings of bloating Table 3.18-12 Odds ratios with 95% confidence intervals for ratings of indigestion......198 Table 3.18-13 Odds ratios with 95% confidence intervals for ratings of wind .199 Table 3.18-14 Odds ratios with 95% confidence intervals for ratings of breast Table 3.18-15 Odds ratios with 95% confidence intervals for ratings of Table 3.18-16 Odds ratios with 95% confidence intervals for ratings of stress Table 3.19-17 Summary of diet\*week interactions for symptoms (red indicates positive outcomes for those on Diet B) ..... Table 3.21-1 Baseline participant characteristics who completed the 1 month Table 3.21-2 Anthropometric, body composition characteristics at randomisation (week -1 of the intervention), week 12 and at 1 month follow-up (N=49) .......213 Table 3.21-3 Habitual fibre intake at screening, week 12 and at 1 month follow-Table 3.23-1 Characteristics of participants who returned for 12 month follow-Table 3.23-2 Anthropometric, body composition characteristics at baseline (week -1 of the intervention), week 12 and at 12 month follow-up (N=34) ..... 232 Table 3.23-3 Habitual fibre intake of participants who returned for follow up at screening, week 12 and at 12 month follow up (N=34) ......235 Table 3.23-4 Body shape perception and eating behaviour characteristics at Table 4.6-1 Demographic and weight history of the whole sample (N=314)...281 Table 4.6-2 Weight status and weight history of the whole sample (N=314) .. 282

Table 4.6-3 Characteristics of participants by cluster assignment (less or more	
successful at weight loss)28	34
Table 4.6-4 Weight history, current weight and BMI of participants by cluster	
assignment28	35
Table 4.6-5 Behavioural and psychological characteristics (means and standar	ď
deviations) of participants by cluster assignment28	36
Table 5.8-1 Participants' characteristics at baseline (N=22).	)5
Table 5.8-2 Psychological characteristics of participants assessed before and	
after the 12 week weight management programme (N=22)	)8
Table 6.2-1 Summary of the evidence for candidate affective, cognitive,	
pehavioural, motivational and physiological predictors of body weight loss	
assessed across the systematic review and the three studies presented in this	
hesis32	21

## LIST OF FIGURES

Figure 2.2.3-1 Study selection process60
Figure 2.28-1 Conceptual framework to illustrate different personal
characteristics linked to weight loss and weight loss maintenance
Figure 3.3-1 Schematic representation of study phases144
Figure 3.3-2 Consort figure showing the flow of participants through each phase
of the trial (pre-screening, screening, randomisation and 1 month and 12 month
follow-up147
Figure 3.12-1 Changes in DINE scores from screening to the end of the
intervention171
Figure 3.12-2 Mean (+/-SE) changes in fibre intake (g/day) assessed using the
LWW-DINE from screening to the end of the intervention
Figure 3.12-3 Mean daily fibre intake (points/day) recorded in the wellbeing
diary booklets for those following Diet B during the intervention phase
Figure 3.12-4 Mean (+/-SE) changes in fibre intake (g/day) assessed using 3
and 7-day food diary records from screening to the end of the intervention
(n=50)
Figure 3.13-1 Mean (+/-SE) body weight change assessed using the BodPod
from baseline to the end of the intervention176
Figure 3.13-2 Weight change (kg) for each participant during the 12 week
intervention according to diet group177
Figure 3.16-1 Mean (+/- SE) changes in body shape perception at baseline and
during the two dietary interventions183
Figure 3.20-1 Regression lines showing relationship between changes in fasting
leptin from week -1 (V2) to week 12 (V5) and body weight at the end of the
intervention (week 12) for both diets
Figure 3.20-2 Regression lines showing the relationship between baseline leptin
and weight loss during the intervention (V2-V5; positive value indicates weight
loss) for both diets208
Figure 3.20-3 Regression line showing the relationship between participants'
age and weight loss during the intervention (V2-V5; positive value indicates
weight loss) irrespective of diet group209
Figure 3.20-4 Regression line showing the relationship between changes in
TFEQ disinhibition during the intervention (+value indicates reduction) and
weight loss during the intervention (V2-V5; positive value indicates weight loss)
for both diet groups210
Figure 3.21-1 Mean (+/-SE) body weight change (kg) assessed using
bioimpedance from randomisation (week -1) to 1 month follow-up (N=49)214
Figure 3.21-2 Weight change (kg) for each participant who attended the 1
month follow-up during the 12 week intervention according to diet group (+
values indicate weight loss)

Figure 3.21-6 Mean (+/- SE) changes in body shape perception from baseline (week -1) to 1 month follow-up (N=49). Higher scores indicate lower body Figure 3.21-7 Mean (+/- SE) changes in TFEQ restraint (a), disinhibition (b) and Figure 3.21-8 Mean (+/- SE) changes in DEBQ restraint (a), emotional (b) and external eating (c) from baseline (week -1) to 1 month follow-up (N=49)......221 Figure 3.22-1 Regression lines showing the relationship between baseline Figure 3.22-2 Regression line showing the overall relationship between body weight at baseline (week -1) and weight loss maintenance (weight change from Figure 3.22-3 Regression lines showing the relationship between fasting insulin levels at week 12 and body weight at 1 month follow-up for doth diets...........225 Figure 3.22-4 Regression line showing the overall relationship between body weight at week 12 and weight loss maintenance (weight change from V5 to 1 Figure 3.22-5 Regression line showing the overall relationship between changes in BSQ from V5 (week 12) to 1 month follow-up and body weight at 1 Figure 3.22-6 Regression line showing the overall relationship between changes in DEBQ emotional eating from V5 (week 12) to 1 month follow-up Figure 3.22-7 Regression lines showing changes in TFEQ disinhibition from V5 (week 12) to 1 month follow-up and weight loss maintenance (weight change Figure 3.23-1 Mean (+/-SE) body weight change (kg) assessed using the BopPod from baseline (week -1) to 12 month follow up (N=34)......233 Figure 3.23-2 Weight loss (kg) for each participant from baseline (week -1) to 12 month follow up (solid lines represent weight regain and dotted lines weight loss Figure 3.23-3 Changes in DINE scores from screening to 12 month follow up (N=34).....236 Figure 3.23-4 Mean (+/-SE) changes in fibre intake (g/d) assessed using the LWW-DINE from screening to 12 month follow up (N=34)......237 Figure 3.23-5 Mean (+/- SE) changes in body shape perception from baseline (week -1) to 12 months follow-up (N=34).....239

Figure 3.23-6 Mean (+/- SE) changes in TFEQ restraint (a), disinhibition (b) and
hunger (c) from baseline (week -1) to 12 month follow-up (N=34)240
Figure 3.23-7 Mean (+/- SE) changes in DEBQ restraint (a), emotional (b) and
external eating (c) from baseline (week -1) to 12 month follow-up (N=34)241
Figure 4.3-1 Flow diagram of participants
Figure 5.8-1 Means (SE) body weight before and after the 12 week weight
management programme
Figure 5.8-2 Mean weight loss/gain achieved during the 12 week weight
Figure 5.8-2 Mean weight loss/gain achieved during the 12 week weight
Figure 5.8-2 Mean weight loss/gain achieved during the 12 week weight management programme by each participant (N=22); positive values indicate

## List of abbreviations

ADP	Air Displacement Plethysmography
AE	Adverse Event
AFA	Anti-Fat Attitudes Questionnaire
AFS	Awakening from sleep
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
AOAC	Association of Official Agricultural Chemists
BAI	Beck Anxiety Inventory
BAQ	Body Attitudes Questionnaire
BCQ	Body Cathexis Questionnaire
BDD	Balanced deficit diet
BDI	Beck Depression Inventory
BES	Binge Eating Scale
BIA	Body Image Assessment Questionnaire
BIA-O	Body Image Assessment for Obesity
BIA-Q	Body Image Avoidance Questionnaire
BITE	Bulimic Investigatory Test of Edinburgh
BHF	British Heart Foundation
BMI	Body Mass Index
BNF	British Nutrition Foundation
BPSS-R	Body Parts Satisfaction Scale
BRFS	Behavioural Risk Factor Surveillance System
BSFQ	Bristol Stool Form Scale
BSQ-34	Body Shape Questionnaire
BSRS	Brief Symptom Rating Scale
BW	Body weight

001/	
ССК	Cholecystokinin
CES-D	Center For Epidemiological Studies Depression Scale
СНО	Carbohydrate
CVD	Cardiovascular Disease
DBI	Decisional Balance Inventory
DEBQ	Dutch Eating Behaviour Questionnaire
DINE	Dietary Instrument for Nutrition Education
DIQ	Demographic Information Questionnaire
DPP	Diabetes Prevention Programme
DRT	Diet Readiness Test
DTEDS	Dichotomous Thinking in Eating Disorders Scale
EAT-24	Eating Attitudes Questionnaire
EBI	Eating Behaviour Inventory
EDE-Q	Eating Disorder Examination-Questionnaire
EDI EDI-BD	Eating Disorder Inventory Eating Disorder Inventory- Body Dissatisfaction
EE	Emotional Eating
EES	Emotional Eating Scale
EI	Eating Inventory
EPB	Exercise Perceived Barriers
EPDQ	Eating Pattern Descriptions Questionnaire
EPQ	Eating Patterns Questionnaire
ESS	Exercise Social Support
ESE	Exercise Self-Efficacy
ESES	Exercise Self-Efficacy Scale
F	Female
FF	Fermentable Fibre

xxvii

FFQ	Food Frequency Questionnaire
FIT	Fibre Intake Table
FPC	Food Preference Checklist
GCOS	General Causality Orientations Scale
GHQ	General Health Questionnaire
GI	Glycaemic Index
GLP-1	Glucagon-like peptide-1
GSI	Global Severity Index of the SCL-90
HARU	Human Appetite Research Unit
HCCQ	Health Care Climate Questionnaire
HDL	High-density lipoprotein
HSE	Health Survey for England
HF	High Fibre
НОМА	Homeostatic Model Assessment
HLOC	Health Locus of Control
HLP-II	Health-Promoting Lifestyle Profile-II
HRQL (SF-36)	Health related quality of life- Short form-36
IBS	Irritable Bowel Syndrome
IDED-IV	Interview for the Diagnosis of Eating Disorders-IV
ISEL	Interpersonal Support Evaluation List
IIP	Inventory of Interpersonal Problems
IWQOL	Impact of Weight on Quality of Life
KSP	Karolinska Scales of Personality
LCD	Low calorie diet
LDL	Low-density lipoprotein
LEI	Life Events Inventory
LGI	Leeds General Infirmary

LOPAR	Low Level Physical Activity
LOQ-UE	Larocque Obesity Questionnaire
LS	Least squares
LWW	Leeds Women's Wellbeing
Μ	Male
MAAC	Multiple Affect Adjective Check List
MAC	MacAndrews Scale
MACL	Mood Adjective Checklist
MADRS	Montgomery-Åsberg Depression Scale
MAEDS	Multiaxial Assessment of Eating Disorder Symptoms
MAQ	Modifiable Activity Questionnaire
MARS-WL	Motivation and Readiness Scale-Weight Loss
Md	Median
MBRQ	Multidimensional Body Relations Questionnaire
MBSRQ	Multidimensional Body-Self Regulations Questionnaire
MHI	Mental Health Inventory
MOS	Medical Outcomes Study;
NACNE	National Advisory Committee on Nutritional Education
NKT	Nutrition Knowledge Test
NHS	National Health Service
OBCS-Shame	Objectified Body Consciousness Scale Body-Shame
OF	Obesity Functional health Scale
OWLQOL	Obesity and Weight Loss Quality Of Life
PA	physical activity
PAQ	Physical Activity Questionnaire
PHQ-8	Personal Health Questionnaire
PIS	Participant Information Sheet

POMS	Profile of Moods Scale
PSPP	Physical Self-Perception Profile
PSQ	Perceived Stress Questionnaire
PSS	Perceived Stress Scale
PSS	Perceived Social Support
PYY	Peptide YY
QEWP-R	Questionnaire on Eating and Weight Patterns-Revised
QoL	Quality of Life
RAQ	Relapse Analysis Questionnaire
RCT	Randomised controlled trial
RMR	Resting Metabolic Rate
RSC	Rosenbaum Self-control Schedule
RSE	Rosenberg Self-Esteem Scale
SCID-II	Structured Clinical Interview for the Diagnostic and Statistical Manual
SCL-90-R	Symptom Checklist for general psychopathology
SE	Standard error
SE	Self-efficacy
SEE	Solf officeou for Exercise
SEF	Self-efficacy for Exercise
SEF	Self-efficacy Form
SF	
	Self-efficacy Form
SF	Self-efficacy Form Soluble Fibre
SF SF-36	Self-efficacy Form Soluble Fibre Short form quality of life
SF SF-36 SIAB-EX	Self-efficacy Form Soluble Fibre Short form quality of life Structured Interview for Anorexia and Bulimia Nervosa
SF SF-36 SIAB-EX SIP	Self-efficacy Form Soluble Fibre Short form quality of life Structured Interview for Anorexia and Bulimia Nervosa Sickness Impact Profile

SPAS Social Physique Anxiety Scale

SRQ-E	Exercise Self-Regulation Questionnaire;
STAI	State-Trait Anxiety Inventory
TAS-20	Toronto Alexithymia Scale
SMI	Self- Motivation Inventory
SOC	Sense of Coherence
ТСІ	Temperament and Character Inventory
T2DM	Type 2 Diabetes Mellitus
TEFQ	Three Factor Eating Questionnaire
TMD	Total Mood Disturbance
TREMORE	Treatment Motivation Readiness Test
TSRQ	Treatment Self-Regulation Questionnaire
VLCD	Very Low Calorie Diet
VLED	Very low energy diet
WALI	Weight and Lifestyle Inventory
WBIS	Weight Bias Internalisation Scale
WEL	Weight Efficacy Lifestyle
WDB	Wellbeing Diary Booklet
WDH	Weight and Diet History Questionnaire
WHO	World Health Organisation
WL	Weight loss
WLM	Weight loss maintenance
WLRT	Weight Loss Readiness Tool
WPEQ	Weight Perception Evaluation Questionnaire
WRSM	Weight Related Symptom Measure
YFAD	Yale Food Addiction Scale
Yrs	Years

## Chapter 1 – General Introduction & Thesis Aims

#### 1.1 Background

Overweight and obesity are amongst the most prevalent non-communicable diseases in our society (Elfhag & Rössner, 2005). Obesity is linked with increased risk of cardiovascular disease (CVD), hypertension, type 2 diabetes and certain types of cancer (Hollis et al., 2008; Lang & Froelicher, 2006). Scarborough et al. (2011) reported an update of cost estimates of obesity highlighting that the largest economic burden to the NHS is poor diet and overweight/obesity, which increased from £3.2 to £5.1 billion per year to the National Health System (NHS).

Modest weight loss of 5-10% of initial body weight (considered a successful weight change by many professionals), significantly improves CVD risk factors, lowers blood pressure and lowers blood glucose in diabetic and non-diabetic people (Hollis et al., 2008; Westerterp, 2004). However, although overweight or obese individuals might be successful in weight loss in the short term, they find it extremely difficult to keep weight off for a period greater than 2 years (Gage, 2012). Hence improving a person's ability to maintain weight loss in the long term and to prevent weight gain remains a major challenge in the treatment and management of obesity and overweight (Lang & Froelicher, 2006). Current weight loss interventions are not very effective over the long term with most people following programmes of weight loss via diet (with or without physical activity) and/or behavioural modification regaining all of their weight loss within 5 years (Wing & Phelan, 2005a). Relapse in obesity is attributed to people's failure to adhere to weight loss behaviours, such as the continuation of a healthy eating diet or increased physical activity (Byrne, 2002; Byrne, Cooper, & Fairburn, 2003). Different physiological, environmental and psychological factors are likely to interact, contributing to post intervention weight gain (Lang & Froelicher, 2006). Although success in weight loss maintenance has improved, more research is needed to elucidate the factors that help individuals to sustain changes in their food choices necessary for successful weight maintenance (Anderson, Konz,

Frederich, & Wood, 2001). In addition, there is a lack of research investigating the factors that are associated with weight loss and/or weight loss maintenance and relapse in obesity (Byrne et al., 2003). Hence the identification of factors affecting weight loss and/or weight loss maintenance may enhance our understanding of the behaviours that are crucial in weight management (Elfhag & Rössner, 2005).

#### 1.2 Causes of obesity

Obesity is mainly caused by excess energy consumption (dietary intake) relative to energy expenditure (energy loss via metabolic and physical activity) (Wright & Aronne, 2012). However, the aetiology of obesity is highly complex and includes several other factors such as genetic. physiological. environmental. psychological, social, economic, and even political factors that interact in varying degrees to promote the development of obesity (Wright & Aronne, 2012). A systematic review of narrative and systematic review articles that examined causes of obesity concluded that there is no agreement between studies regarding the factors that contribute to the obesity epidemic in both adults and children (Ross, Flynn, & Pate, 2015). Keith et al. (2006) examined the relationship between obesity and a variety of factors, including physical activity, diet, sleep, endocrine disruptors, ambient temperature, decreased smoking, use of medication. distribution of ethnicity and maternal age, age, intrauterine/intergeneration effects, reproductive fitness (yielding obesity predisposing genes) and assortative mating (i.e. the non-random mating of individuals with respect to phenotype and cultural factors). They concluded that although the effect of these individual factors may be small, their combined effect may be of great importance (Keith et al., 2006). Stubbs and Lee (2004) also reviewed studies from the USA, Australia and Europe, to determine the cause of obesity in adults. They suggested that an increase in food resources and subsequent consumption, combined with decreases in physical activity, are the main causes of obesity.

## 1.3 Definition of successful weight loss and/or weight loss maintenance

There is no agreement on the definition of weight loss maintenance in adults, making comparison between studies difficult (Stevens, Truesdale, McClain, & Cai, 2006). Various definitions of weight loss maintenance have been used across a range of studies with some studies(Field et al., 2001; M R Lowe, Foster, Kerzhnerman, Swain, & Wadden, 2001) using more than one definition in a single study and justification of the definition rarely being stated (Stevens et al., 2006). The Clinical Guidelines on the Evaluation and Treatment of Obesity in adults defined weight loss maintenance as a weight regain less than 3kg in 2 years plus a sustained reduction in waist circumference of at least 4cm (National Heart, Lung, and Blood Institute [NHLBI] Guidelines, 2000). The Institute of Medicine defined weight loss maintenance as losing at least 5% of body weight and maintaining it for at least one year (Institute of Medicine, National Academy of Sciences, 1995).

In some studies, weight loss maintenance has been defined as losing at least 5% of baseline body weight between baseline and follow up and maintaining that weight for an additional two years (Crawford, Jeffery, & French, 2000). However, this definition has been criticized, since a weight change of at least 5% leading to clinically relevant changes, does not necessarily imply that a change of less than 5% has no clinical relevance. Stevens et al. (2006) conducted a review of studies with a follow up of at least one year and examined definitions of weight maintenance. After taking into account expert opinions, public health and clinical applications, different body sizes, measurement error, weight fluctuations (e.g. fluid retention, menstrual cycle) and biological relevance, they suggested that long term weight maintenance in adults should be defined as a weight change of less than 3% of body weight (Stevens et al., 2006). They also recommended that weight changes of between 3% and 5% should be considered small weight fluctuations and changes of 5% or greater as clinically relevant (Stevens et al., 2006). However, other studies have suggested that intentionality should be added to the definition of successful weight maintenance, as unintentional weight

loss might occur with different frequencies for different reasons and lead to different consequences than intentional weight loss.

In a recent review of 22 intervention studies (involving dietary and physical activity strategies), Barte et al. (2010) aimed to explore the relationship between weight loss and weight maintenance after at least one year of unsupervised follow up. They found that maintenance rates were not different between interventions which achieved 5-10% and >10% weight loss, but mean weight loss differed between these categories (3.7% vs 7% respectively). Overall, mean percentage maintenance 1 year after interventions was 54%, similar to other reviews (J W Anderson et al., 2001; Curioni & Lourenco, 2005) which reported a 50% maintenance at 1 year follow up and 44% maintenance at 2 year follow up (Barte et al., 2010). Barte et al. (2010) suggested that a weight loss of 10% or more should be encouraged above lower initial weight loss (Barte et al., 2010). Weiss et al. (2007) showed that a greater weight loss was associated with greater weight regain. Those with a greater percentage of maximum weight lost (more than 20%) had double the risk of regaining this weight compared with those who lost 10-15% of their maximum weight (Weiss, Galuska, Kettel Khan, Gillespie, & Serdula, 2007). If people who lose more weight during any intervention are at a higher risk of regaining this weight later on, then the definition of successful weight loss and/or weight maintenance needs to be revisited. It might be more beneficial for people to lose less weight and remain weight stable than to lose more but to regain it. In particular, weight cycling has been suggested might have negative effects on psychological factors such as health and wellbeing, binge eating, eating self-efficacy and depression (Foster, Sarwer, & Wadden, 1997; Petroni et al., 2007), which in turn could exacerbate further weight regain (Barte et al., 2010).

Huberman (2012) suggested a new individual-centred definition of successful weight loss. Based on this definition, successful weight loss is accomplished not only when people have lost and maintained a significant amount of weight following any weight management intervention, but also when they are able to make changes in their life (Huberman, 2012). Overweight and obese people might want to lose weight for many different reasons. For some, weight loss is desired for health improvement, whilst for others positive changes on a personal

and social level are sought. The significant weight loss that might occur is often the first step in a much longer process toward achieving other life goals. From the individuals' perspective, successful weight loss is not measured only in terms of weight loss or improvements in daily functioning, but also in terms of what they feel they can achieve as a result of the weight loss (Huberman, 2012).

Taking these issues into account, the estimates of weight loss maintenance obtained from studies may be unreliable, since they each use different definitions of weight loss and weight loss maintenance. Therefore, it is important that researchers reach a consensus on the definition of weight loss/maintenance and the period on which the estimate is based, so comparability across studies is made possible.

# 1.4 Different types of interventions for weight management

Different approaches have been used to treat obesity with inconsistent evidence regarding the effectiveness of each. Dietary and/or physical exercise interventions, meal replacements, pharmacotherapy, surgery or other behavioural interventions are amongst the most common methods used for weight management. Studies also differ in terms of whether or not the intervention or support continued during the maintenance phase, leading to different conclusions and making comparisons between studies difficult. The following sections discuss the effects of different weight management interventions and where available for weight loss maintenance.

#### 1.5 Dietary interventions

Weight loss and subsequent weight maintenance is difficult for obese people despite the variety of treatments available. Different dietary interventions have been shown to lead to varying amounts of weight loss and weight maintenance (Abete, Astrup, Martínez, Thorsdottir, & Zulet, 2010). Most people are unable to maintain weight loss for a long period either due to increased hunger levels and/or lack of variety in foods consumed (Abete et al., 2010). Although findings from dietary intervention studies suggest that a low-carbohydrate dietary pattern may be most effective in inducing weight loss in the short term, there is no conclusive evidence that one diet is superior to another in the long term (Wu, Gao, Chen, &

van Dam, 2009). Alternative dietary strategies including meal replacement products have, however, been shown to improve compliance with a low calorie restricted diet (Abete et al., 2010).

Anderson et al. (2001) conducted a meta-analysis of 29 observational studies examining the effects of structured weight loss programmes on long term weight loss maintenance for up to 5 years. Thirteen studies used very low energy density diets (VLED), 14 studies used hypoenergetic balanced diets (HBD) and two studies used a combination of both. The length of treatment in these studies ranged from 8 to 30 weeks. When all studies were included, 67% of initial weight loss was maintained at 1 year and 21% at 5 years (J W Anderson et al., 2001). Percentage weight loss maintenance was higher after VLEDs than after HBDs, but the differences were significant only at 1 year. Between 3 and 5 years follow up, those following VLEDs did not show significant weight regain, whilst those following HBDs showed continued weight gain. However, Anderson et al.'s (2001) findings were from observational studies rather than randomised controlled trials (RCTs) and the studies reviewed did not provide information on dietary changes during the weight loss and the follow up phase.

Tobias et al. (2016) conducted a systematic review and meta-analysis of 53 RCTs comparing the long-term effect ( $\geq$ 1 year) of low-fat and higher-fat (i.e. low-carbohydrate) dietary interventions on weight loss. They found that low-carbohydrate interventions resulted to significantly greater weight loss than low-fat interventions when groups differed by more than 5% of calories obtained from fat at follow-up (Tobias et al., 2016). Low-fat interventions were no more successful than low-carbohydrate interventions in achieving and maintaining weight loss and they only resulted to a greater weight loss when compared with usual diet. Similarly, Sackner-Bernstein, Kanter and Kaul (2015) conducted a meta-analysis of RCTs with  $\geq$ 8 weeks follow up, comparing low carbohydrate ( $\leq$ 120gm carbohydrates/day) and low fat diet ( $\leq$ 30% energy from fat/day). They found that both low-carbohydrate diets predicted lower risk of atherosclerotic cardiovascular disease events (Sackner-Bernstein, Kanter, & Kaul, 2015).

In conclusion, there is ongoing debate about what types of diet are most effective for treating overweight or obesity. Several studies showed that low-carbohydrate, high-protein diets resulted in more weight loss over the course of 3 to 6 months than conventional high-carbohydrate, low-fat diets, (Foster et al., 2003; Yancy, Olsen, Guyton, Bakst, & Westman, 2004) but other studies did not show this effect (Das et al., 2007; Noakes, Keogh, Foster, & Clifton, 2005). Studies that extended the follow-up to 1 year did not show that low-carbohydrate, high-protein diets were superior to high-carbohydrate, low-fat diets (Dansinger, Gleason, Griffith, Selker, & Schaefer, 2005). In general, dietary interventions result in clinically meaningful weight loss regardless of which macronutrients they emphasize.

#### **1.6 Physical activity interventions**

Interventions that focus on physical activity alone as a method of weight management have found modest effects, with slightly better outcomes following interventions that combined both exercise and diet strategies (Catenacci & Wyatt, 2007; Franz et al., 2007). It appears that the effectiveness of physical activity interventions depends on the level of participants' engagement with the intervention (Jakicic, Marcus, Lang, & Janney, 2008). Despite the low effectiveness of exercise interventions when used alone, it is recommended that physical activity should be endorsed as part of a healthy lifestyle since physical activity has important positive effects on lipid levels, insulin sensitivity and CVD mortality (Franz et al., 2007).

Physical activity might not be a good predictor of initial weight loss but it is argued that it is critical for weight loss maintenance (Stubbs & Lavin, 2013). However, it is important that a gradual increase in activity behaviours is promoted since the majority of the people engaging in physical activity interventions are initially sedentary, which can result to poor compliance (Stubbs & Lavin, 2013). Physical activity introduced during the maintenance phase of a behavioural weight loss study did not lead to less weight regain as compared to a weight focused maintenance group (weight loss maintenance was based on therapist-led group problem-solving and not exercise) (Leermakers, Perri, Shigaki, & Fuller, 1999). Results suggested that poor adherence to physical activity might account for the poor relationship between physical activity and weight maintenance (Turk et al.,

2009). Weinsier et al. (2002) found that 77–80 minutes per day of moderate intensity activity was necessary in order to prevent weight regain following weight loss.

### 1.7 Pharmacotherapy

Lifestyle interventions including both diet and exercise modifications are essential for both prevention and management of obesity. However, pharmacotherapy is considered if such interventions are ineffective for individuals with a body mass index (BMI)  $\geq$ 30 kg/m<sup>2</sup> or for those with a BMI  $\geq$ 27 kg/m<sup>2</sup> when co-morbidities, such as hypertension or type 2 diabetes mellitus are present (Kang & Park, 2012). Different anti-obesity drugs have been approved for the treatment of obesity; however, some of them (sibutramine, amphetamine and rimonabant) have been withdrawn from the market because of their adverse effects (i.e. high risk of psychiatric disorders and non-fatal myocardial infarction or stroke) (Kang & Park, 2012).

Glazer (2001), in a review of the effectiveness and safety of pharmacotherapy for the treatment of obesity, reported that in trials of 36 to 52 weeks, people receiving sibutramine (a serotonin/noradrenaline reuptake inhibitor) had a mean weight loss of 4.3 kg and those receiving orlistat (a gastrointestinal lipase inhibitor preventing dietary fat absorption by 30%) 3.4 kg. In Franz et al.'s review (2007), individuals taking orlistat experienced a mean weight loss of 3.3 kg more than individuals following lifestyle interventions at 6 months, 3.7 kg more on average at 12 months, and approximately 3 kg more on average at 24, 26, and 48 months. Those taking sibutramine experienced a mean weight loss of 3.9 kg more than lifestyle controls at 6 months, 4.9 kg and 6.1 kg at 12 and 24 months, respectively. Continuous treatment with orlistat and higher doses were associated with less weight regain (Turk et al., 2009). Although these medications might be useful in weight loss/maintenance, their use is linked with adverse side effects. Sibutramine is linked with increased blood pressure and heart rate and orlistat is associated with gastrointestinal side effects (Turk et al., 2009). Additionally, these medications are only approved for a maximum of two years continuous use and weight regain occurs after stopping the medication (Turk et al., 2009).

Yanovski and Yanovski (2014) conducted a systematic review of the efficacy of medications used to treat obesity in adults in USA. Obesity drugs approved for long-term obesity treatment, resulted in additional weight loss relative to placebo, when used as an adjunct to lifestyle intervention, ranging from approximately 3% of initial weight for orlistat and lorcaserin (selective serotonin 2C (5-HT2C) receptor agonist that reduces body weight by reducing food intake) to 9% for top-dose (15/92mg) phentermine/topiramate-Extended Release (ER) (combination drug of low-dose phentermine with a non-standard dose of the antiepileptic medication topiramate-ER) at 1 year. The proportion of patients achieving clinically-meaningful (≥5%) weight loss ranges from 37–47% for lorcaserin, 35–73% for orlistat and 67–70% for top-dose phentermine/topiramate-ER at 1 year. The FDA suggests that both lorcaserin and phentermine–topiramate should be discontinued after 12 weeks of treatment if the patient has not lost at least 5% or 3% respectively of the baseline body weight.

Obesity drugs might be a useful alternative to weight management for certain type of patients. The guidelines for approval and market withdrawal are considerable barriers to the development of new obesity drugs. More studies are needed to determine the long-term safety and health effects of obesity medications in large and diverse patient populations and how they can be combined with diet/exercise interventions.

#### **1.8 Bariatric surgery**

Bariatric surgery is another strategy for managing obesity, considered as an easy and quick method to lose excess weight (Madura & Dibaise, 2012). It is mainly adopted by severely obese people, after many unsuccessful attempts to lose weight using different weight loss methods. Research has shown that weight loss surgery is the most effective intervention for weight loss for those with a BMI greater than 40 kg/m<sup>2</sup> (Hollywood, Ogden, & Pring, 2012). A review and metaanalysis by Gloy et al. (2013) showed that bariatric surgery leads to greater body weight loss than non-surgical treatments and higher remission rates of type 2 diabetes and metabolic syndrome. However, data is available for only two years of follow-up and based on a small number of studies and individuals (Gloy et al., 2013). Weight loss outcomes following surgery vary across patients and by type of surgery (Parker, O'Brien, & Brennan, 2014) with some patients either not achieving the desired weight loss or regaining weight at follow up (Hollywood et al., 2012).. The most commonly used bariatric surgery techniques are Roux-en-Y gastric bypass, sleeve gastrectomy, and laparoscopic adjustable gastric banding. Chang et al. (2014) conducted a systematic review and meta-analysis of 164 studies examining the effectiveness and risks of bariatric surgery. They found that gastric bypass was more effective in weight loss but associated with more complications (Chang et al., 2014). Adjustable gastric banding was associated with lower mortality and complication rates and less weight loss than gastric bypass. Sleeve gastrectomy appeared to be more effective in weight loss than adjustable gastric banding and similar to gastric bypass (Chang et al., 2014).

Bariatric surgery has become an effective intervention for moderately to severely obese patients. The benefits of surgery include not only significant weight loss and metabolic improvements, but also enhanced quality of life for most patients, although some will face pre- and postoperative psychosocial challenges (Bagdade & Grothe, 2012). Psychological issues related to diet, self-esteem, coping, emotional eating and adverse psychological states before and after surgery are rarely addressed and future interventions should aim to address these issues.

#### **1.9 Behavioural interventions**

Behavioural interventions refer to the techniques and skills that people have to learn in order to change their behaviours and habits. Abraham and Mitchie (2008) developed taxonomies in order to identify and characterise specific behavioural change techniques, which could help researchers identify the active ingredient in the interventions and assist them in the implementation of the intervention. Mitchie et al. (2011) revised the 26-item initial taxonomy, which led to the CALO-RE taxonomy, a list of 40 behavioural change techniques. These techniques include self-monitoring, problem solving, goal setting, stress management, cognitive restructuring and prevention training, with little evidence that any one technique is superior to others (Lang & Froelicher, 2006).

Behavioural interventions can be used alone or in conjunction with other diet or physical activity interventions and have been found to be effective (Lang & Froelicher, 2006). Johns et al. (2014) conducted a systematic review and meta-

analysis examining the effectiveness of eight RCTs of combined (including both diet and physical activity) behavioural weight management programs (BWMPs) targeting weight loss in comparison to single component programmes (diet-only or physical activity-only), with at least 12 months of follow-up. They found no significant differences in weight loss from baseline or at 3 to 6 months between the BWMPs and diet-only arms, but at 12 months, significantly greater weight-loss was achieved with the combined BWMPs (Johns, Hartmann-Boyce, Jebb, & Aveyard, 2014). Combined behavioural weight management programmes were more effective at weight loss both in the short and long term when compared with physical activity interventions alone. However, evaluation of the evidence regarding behavioural interventions is difficult, since the terms "behavioural", "lifestyle" and/or "multicomponent" are used interchangeably in the literature to describe either interventions that incorporate both dietary changes and different behavioural techniques mentioned earlier or interventions that used only behavioural changes.

A problem with behavioural interventions is that it is difficult to identify which aspects of the intervention are more important than others for weight loss and/or weight loss maintenance. Hartmann-Boyce et al. (2014) conducted a systematic review, meta-analysis and meta-regression of 37 RCTs to examine the effectiveness of multicomponent behavioural interventions and to examine which characteristics of the interventions were associated with weight change at 12 months. They found that most behavioural weight loss interventions were effective, with the more effective ones resulting in an average weight loss of 8kg in 12 months (Hartmann-Boyce et al., 2014). Counting calories, contact between participants with a dietitian during the intervention and the use of behaviour change techniques that involved comparing a participant's behaviour with that of others were the characteristics which were associated with greater weight loss. Moreover, these authors highlighted the great heterogeneity amongst interventions, making comparisons between studies difficult and conclusions difficult to draw (Hartmann-Boyce et al., 2014).

In summary, behavioural weight loss programmes are effective for short and long term weight loss. However, identifying the key aspects of the interventions that lead to greater effectiveness is still a challenge.

#### **1.10Commercial programmes**

Commercial diets are an increasingly popular option for weight management. Despite the large amount of money spent on popular commercial diets and the plethora of choices provided to consumers, data on their comparative efficacy is limited and conflicting (Truby et al., 2006). Weight Watchers (WW), which has dominated the UK market has circa one million members (Gudzune et al., 2015). Truby et al. (2006) examined the effectiveness of four commercial weight loss diets (Atkins' diet, Slim-Fast plan, WW' points programme, and Rosemary Conley's plan) provided to adults in the UK. WW is based on a food, physical activity and behaviour modification plan that uses a personalized points system to encourage diet restriction accompanied by weekly group sessions. Atkin's is a 4-phase diet based on very low carbohydrate intake, with unlimited protein and fat consumption. The first phase (induction) includes consumption of >20 grams of carbs per day for 2 weeks and high-fat, high-protein, diet. The second phase (balancing) involves adding more nuts, low-carb vegetables and small amounts of fruit in the diet. The third phase (fine-tuning), which more carbohydrates are added in the diet as individuals approach their goal weight and fourth phase (maintenance), whereas unlimited healthy carbs are allowed. Rosemary Conley is a low fat diet including a weekly group exercise class and Slim-Fast is a mealreplacement plan. A control group was also included in which participants were asked to maintain their current diet and physical activity. The study was a six month multicentre randomised unblinded controlled trial consisting of otherwise healthy overweight and obese adults. All diets resulted in significant weight loss over six months (Truby et al., 2006). There were no significant differences between groups, but weight loss was greater in all groups when compared with the control group. The Atkins diet resulted in a significantly greater weight loss during the first four weeks, but by six months it was no more effective than the other diets.

Atallah et al. (2014) conducted a systematic review of 26 randomised controlled trials (RTCs), which examined the effect of Atkins, South Beach (SB), Zone, or WW on weight loss and cardiovascular risk factors. Zone is a low-carbohydrate diet suggesting the consumption of low-fat proteins, low-glycaemic load carbohydrates and small amounts of "good" fat such as olive oil. SB is a 3-phase modified low-carbohydrate high-protein diet. The first phase involves lowcarbohydrate, high protein diet with healthy, unsaturated fats. In the second phase 2, foods which were prohibited in the first phase are slowly added until the goal weight has been reached. The third phase is a maintenance phase whereas all types of food are allowed in moderation following the principles, which were introduced in the previous phases. These diets were chosen as a representative sample of popular commercial diets used by North Americans. Atallah et al. (2014) argued that evidence for the efficacy of popular commercial diets is limited and heterogeneous. They argued that Atkins, WW, and Zone achieve modest and similar long-term weight loss, as well as similar effects on cardiovascular risk factors (Atallah et al., 2014). Johnston et al. (2014) conducted a network metaanalysis (a rigorous methodological approach in which multiple treatments are being compared using both direct comparisons of interventions within randomized controlled trials and indirect comparisons across trials based on a common comparator) to examine the efficacy of major commercial diets at 6 and 12 months weight loss. They concluded that low-carbohydrate (e.g. Atkins) and low-fat (e.g. Ornish) dietary programmes were associated with the greatest weight loss, with minor weight loss differences between them at 6 month followup (Johnston, Kanters, Bandayrel, & Al, 2014).

Gudzune et al. (2015) reviewed 45 studies (39 RCTs) to examine the efficacy of commercial or proprietary weight-loss programmes compared with control/education or behavioural counselling in overweight and obese adults. They concluded that both WW and Jenny Craig (low calorie meal replacement plan) were more effective at long term weight loss than both control/education and counseling interventions, whereas the evidence for Nutrisystem (low calorie meal replacement with exercise plans) was inconclusive and limited (Gudzune et al., 2015). They also acknowledged WW as one of the lowest-cost programme compared with other commercial programmes although estimates do not include

cost of food. A common limitation with most of the studies included in these reviews was the failure to report adherence, engagement, or adverse outcomes.

In summary, most calorie-reducing diets result in clinically important weight loss as long as the diet is maintained (Johnston et al., 2014). Different commercial diets offer considerable weight loss benefits and people may choose, among those associated with the largest weight loss, the diet that gives them the least challenges with adherence.

# 1.11 Weight management programmes provided within the UK National Health Service (NHS)

In the UK, national guidelines recommend multicomponent weight management programmes involving calorie deficient diets, physical activity and behavioural components for the management of patients who are either overweight or obese (National Institute for Health and Clinical Excellence; NICE, 2006). Despite these recommendations, the provision of weight management services across the UK remains patchy and there is limited published evidence of the effectiveness of such interventions within the National Health Service (NHS).

The Counterweight Programme was a prospective, evidence- and theory-based intervention for weight management, evaluated in 56 general practices from seven UK regions (Ross et al., 2008). The Counterweight Programme was delivered in primary care settings with training of primary care staff provided by a specialist team. The mean baseline BMI of participants was  $37(\pm 6)$ kg/m<sup>2</sup>.The Counterweight Programme report showed that 31% of patients who completed the programme achieved  $\geq 5\%$  weight loss but this rate of success was reduced to 13.9% when all patients were included, suggesting high-drop-out rates. However, this report was an audit rather than an evaluation and there were no available measured or self-reported weight data for those who dropped out.

Jebb et al. (2011) compared the efficacy of primary care referral to a commercial programme (WW) with standard care on weight and associated risk factors at 12 months post referral in overweight and obese adults. Participants were recruited from primary care practices in Germany, in Australia, and in the UK. It was found

that participants who were referred to the community-based commercial programme lost more weight than those who received standard care in all three countries (Jebb et al., 2011). Furthermore, a recent evaluation of primary-care based interventions concluded that weight management programmes provided by the NHS were ineffective (Jolly et al., 2011). Jolly et al. (2011) investigated the effectiveness of several pragmatic interventions in primary care patients recruited from the NHS. These included random allocation to a number of weight management providers including commercial, pharmacy and primary care services. They found that commercial programmes (Weight Watchers and Rosemary Conley) resulted in significantly greater weight loss than did the primary care programmes at 12 weeks, which were also the most costly to provide. However, one major limitation of this study was that where direct body weight measurement was unavailable due to non-attendance, final body weight was self-reported.

Logue et al. (2014) evaluated the efficacy of NHS Greater Glasgow and Clyde Weight Management Service (GCWMS) over 12 months, an integrated service across primary and secondary care for patients with severe obesity and obesityrelated comorbidities, which included a large number of patients from areas of high socioeconomic deprivation. NHS GCWMS resulted in 24% of participants losing 5% of their body weight, when last observation carried forward (LOCF) analysis was used. When complete cases were considered, 54% of participants achieved at least 5 kg weight loss at 12 months (Logue, Allardice, Gillies, Forde, & Morrison, 2014). Overall, men achieved greater weight loss than women. Those with very high initial weight (>150 kg) also did well with 48% of women and 41% of men losing 5 kg or more (38% and 26%, respectively losing 5%). The major strength of this work was that findings came from a very large NHS service specifically targeting severe and complex obesity (Logue et al., 2014). While there are many NHS weight management programmes across the UK, the majority are poorly evaluated or have not been at all, making their effectiveness difficult to ascertain. This results in a lack of evidence for the commissioning and decommissioning of these services and does not help in building arguments for investment in such services at times of financial constraint. However, the major limitation of weight management service evaluation was the lack of baseline

characteristics and comprehensive recording of changes in clinical risk factors (e.g., blood pressure, lipids and glycaemic control) or change in medications. This is due to the data being from a real-life NHS service rather than a study population. Therefore, it is essential that a standard methodology is adopted for the evaluation, analysis and follow-up in weight management programmes in order to make comparisons between studies easier to assist health authorities to make informed choices when commissioning weight management services.

#### 1.12 Internet-based interventions

The recent increase in access to online services has led to a growth in the use of the Internet as a platform for weight loss programmes. The Internet has the potential to overcome limitations associated with traditional weight-loss interventions (Manzoni, Pagnini, Corti, Molinari, & Castelnuovo, 2011). In addition to being a source for health information that is accessible 24 hours a day, it offers a number of novel opportunities for self-help programmes and also allows healthcare professionals to access and maintain long term contact with large numbers of individuals in a timesaving and cost-effective manner (Manzoni et al., 2011).

Neve et al. (2010) carried out a review of 18 studies to examine the effectiveness of web-based interventions on weight loss and maintenance and identify which features of web-based interventions are associated with greater weight change and low attrition rates. Four meta-analyses (each including two or three studies) suggested that web-based interventions achieve similar weight loss to control or minimal intervention groups, and web-based interventions with additional features resulted in greater weight loss than those with education alone. Greater weight change was observed in web-based weight loss maintenance interventions as compared with controls (i.e usual care) (Neve, Morgan, Jones, & Collins, 2010). However, results should be treated with caution due to heterogeneity of designs and the limited number of comparable studies.

Manzoni et al. (2011) conducted a review examining the efficacy of web-based interventions in weight loss and/or weight loss maintenance in obese or overweight individuals. This review was an update to the previous review

published by Neve et al. (2010). Manzoni et al. (2011) included 8 studies in addition to the 18 studies included in Neve's (2009) review, but was unable to perform a meta-analysis due to the heterogeneity amongst the studies. Nevertheless, behavioural internet-based interventions, which included professional feedback and counselling appeared to be more effective in promoting weight loss than education only web-site programmes (Manzoni et al., 2011).

Arem and Irwin (2011) reviewed only RCTs (n=9), which examined the efficacy of Internet-based weight loss and maintenance programmes on weight change. All studies included were common to Neve's (2010) and Manzoni' reviews (2011). The reviewed studies showed results ranging from no weight loss to an average weight loss of 4.7 kg (based on intention-to-treat analysis) (Arem & Irwin, 2011) . Conclusions on the potential impact of Internet-based weight loss programmes were not feasible due to highly variable study methods between studies, low adherence rates, minimal use of internet resources and lack of inclusion of a control group in many studies.

Tang et al. (2014) conducted a systematic review of reviews of the efficacy of self-directed interventions (including interactive websites, smartphone applications, and text messaging) on weight loss and weight loss maintenance in adults. They found that self-directed interventions promoted weight loss. Individualised feedback, email counselling and online social support were some of the features which appeared to enhance their effectiveness (Tang, Abraham, Greaves, & Yates, 2014).

Self-monitoring and peer social support are two features of internet-based weight loss programmes that have been associated with weight loss (Johnston et al., 2014). Self-monitoring of weight has been consistently reported as an important tool for weight control (Lasikiewicz, Myrissa, Hoyland, & Lawton, 2014). Keeping food or exercise diary records is also associated with successful weight loss and weight maintenance (Krukowski, Harvey-Berino, Ashikaga, Thomas, & Micco, 2008). It appears to be the act of self-monitoring, which might be related to an increase in the sense of autonomy (Lasikiewicz et al., 2014), rather than the exact approach that affects weight loss outcomes (Johnson & Wardle, 2011). There is little effect of recording method, for example electronic versus paper diaries (Yon et al., 2006), the degree of detail recorded (Helsel, Jakicic, & Otto, 2007) or whether participants receive training in recording or not (Lowe et al., 2008). Peer social support is perceived to be valuable by many of those using Internet weight loss programmes and may enhance outcomes and commitment to the programme (Johnson & Wardle, 2011; Krukowski et al., 2008). However, active involvement in peer chatrooms and message forums has been reported to be low (Binks & van Mierlo, 2010) with women using them more than men (Johnson & Wardle, 2011).

Although the Internet is a novel, feasible delivery tool for weight loss and weight loss maintenance interventions, it has been relatively underutilized and under evaluated (Neve et al., 2010). Additionally, the evidence of its effectiveness is modest due to mixed results, heterogeneity of designs and low generalisability of findings (Manzoni et al., 2011). Future research in the area should prioritise well-designed trials that could determine, which features of internet-based interventions are critical to achieve success in weight loss and weight loss maintenance.

## 1.13 Comparison amongst different weight loss interventions

Different approaches have been used to enhance weight loss and weight loss maintenance with mixed findings, and better outcomes are indicated following interventions that used multiple intervention methods. Extended contact following the end of the intervention also seems to also produce better long term outcomes and improve people's adherence to eating and/or exercise plans.

Franz et al. (2007) in a review of 80 studies found that interventions that used diet alone or in combination with exercise and meal replacements resulted in a mean weight loss of 5 to 8.5kg over a period of 6 months. Weight loss of 3 to 4kg was maintained at 24, 36, and 48 months. Similar weight loss was observed with diet and exercise interventions as was observed with weight loss medications, but at 24 months the weight maintained with weight loss medications was 2 to 5kg more than with diet and exercise interventions (Franz et al., 2007).

Interventions that focused only on exercise or provided advice by means of booklets and/or weight loss manuals were not very effective in achieving and maintaining weight loss (Franz et al., 2007). Exercise alone interventions resulted in a mean 2.4 kg (2.7%) weight loss at 6 months and a mean weight loss of 1.0 kg (1.0%) at 24 months.

Curioni and Lourenco (2005) reported similar findings to Franz et al. (2007). Mean weight loss achieved was 9.9kg with diet only interventions and 13 kg with diet and exercise interventions (Curioni and Lourenco, 2005). Although, after one year, individuals in the diet and exercise groups maintained a mean weight loss of 6.7 kg compared to 4.5 kg for those in the diet only groups. Furthermore, in both types of intervention half of the initial weight loss was regained (Curioni and Lourenco, 2005). In a later review of 18 RCTs, including interventions that had a follow up of 2 years or more, it was found that interventions including a combined diet and exercise programme resulted in greater long term weight loss than interventions with a diet only programme (Wu et al., 2009). The pooled mean weight loss was 1.14 kg greater for the diet plus exercise group as compared to the diet only group (Wu et al., 2009).

Douketis et al. (2005) examined weight loss data following dietary/lifestyle interventions (with 2 to 4 years follow up) and pharmacological studies (with a one year follow up) and found that the former interventions resulted in less than 5 kg weight loss, whilst the latter achieved between 5 to 10kg weight loss (Douketis, Macie, Thabane, & Williamson, 2005). These findings are in agreement with those of Franz et al. (2007).

In conclusion, research has demonstrated that interventions, which included combined diet (with or without exercise) and or behavioural modification resulted in greater long-term weight loss than interventions that only included diet and/or physical activity programmes. This difference in weight loss appears to be greater for interventions with a duration longer than 1 year than that for shorter interventions.

## 1.14 Factors associated with weight loss and/or weight loss maintenance and relapse

Maintaining an optimum body weight after weight loss interventions requires long term behavioural changes such as moderate exercise, lower fat intake, increased consumption of fruit and vegetables, breakfast consumption and social support (Lang & Froelicher, 2006). Unfortunately after an intervention or a treatment ends people tend to relapse and often regain all of their lost weight within 1 to 5 years (Lang & Froelicher, 2006). The low achievement rates in maintaining weight loss among dieters could be partially due to ineffective dieting strategies or inability to adhere to these strategies in the long term or inability to maintain behavioural changes (Knauper, Cheema, Rabiau, & Borten, 2005).

Evidence from retrospective studies suggests that different factors such as having unrealistic goals, poor coping or solving skills and low self-efficacy may contribute to the fact that people are unable to maintain their weight loss in the long term (Byrne et al, 2003). However, results from retrospective studies have been inconsistent and criticised as having poor scope and design (Byrne et al., 2003).

The list of potential predictors of weight loss and/or weight loss maintenance is long and inconclusive. Genetic, physiological, psychosocial, behavioural and socioeconomic factors have been reported to predict weight loss and/or weight loss maintenance with mixed findings (Stubbs et al., 2011). The most recent review of predictors of weight loss was published by Teixeira and colleagues in 2005. They reviewed psychosocial pre-treatment predictors of short- and longterm (one year or more) weight loss. Fewer previous weight loss attempts and an autonomous, self-motivated cognitive style were the best predictors of successful weight management (Teixeira, Going, Sardinha, & Lohman, 2005). Binge eating, eating disinhibition, dietary restraint and depression/mood were not significant predictors of weight loss. Evidence for other factors such as eating self-efficacy, body image, self-esteem, outcome expectancies, weight-specific quality of life and variables related to exercise was inconsistent or limited. Wimmelmann, Dela and Mortensen (2014) reviewed the literature on psychological predictors of weight loss following bariatric surgery and identified pre-surgical cognitive dysfunction (>1.5 SD below normative data), personality, more psychiatric

disorders and higher binge eating to be associated with poor post-surgical weight loss outcomes (Wimmelmann, Dela, & Mortensen, 2014).

In summary, individual physiological and psychological factors, often influenced by genetic factors, interact with social and environmental factors, resulting in a plethora of individual responses to both the amount and rate of weight loss (Karlsen, Søhagen, & Hjelmesæth, 2013). There is no evidence that a single factor strongly predicts weight loss, rather different factors interact. This highlights the need for the development of more sophisticated approaches and statistical models that can take into account the interdependencies among these factors. (See Chapters 2 and 3 for more detailed information).

### 1.15 Barriers to the prediction of weight loss success

A key problem in predicting successful weight loss and maintenance is the fact that weight loss is characterised by large intra and inter subject variability (Stubbs et al., 2011). Weight changes during interventions vary across individuals and/or time making causal relationships difficult to establish using conventional analytical approaches (Stubbs et al., 2011). Another problem with poor prediction of weight loss is the heterogeneity amongst treatments, populations studied and the measures taken (Stubbs et al., 2011). Evaluation of the efficacy of different interventions for weight loss and weight loss maintenance is mostly based on clinical trials conducted either in university or clinical settings, using population groups that are not representative of the general overweight/obese population.

Appropriate statistical analysis is also needed as, for example, per protocol analysis which ignores dropouts is problematic and lacks ecological validity to real weight loss situations. Missing data are frequently encountered in the statistical analysis of weight management studies, which raises various methodological issues that must be addressed for valid causal inference (Imai, 2007). There is a need for more sophisticated analysis and the development of studies that can account for the complexity of factors involved in weight loss (Stubbs et al., 2011). More qualitative research could also assist in exploring people's explanations for their success and/or relapse during weight loss interventions.

#### **1.16 Current Statistical Analysis Approaches**

Current approaches to data gathered in studies of effects of different interventions on weight loss and/or weight loss maintenance are mainly based on general linear model (GLM) approaches. In the most sophisticated GLM approaches (used only in a few studies), baseline covariates are included to take into account the way in which pre intervention factors influence response to intervention. Current analytical approaches do not permit researchers to identify which individuals might best adapt to each weight management programme or the way in which different baseline variables might influence adherence response and weight loss outcomes in response to intervention. The analytical methods currently available to researchers in this field do not do justice to the richness and complexity of the data which are collected in carefully controlled yet highly ecologically valid environments and which are of greater relevance in terms of the growing problems of obesity which face our society. There is an urgent need to define consistent analytical methods amongst studies, including how missing data should be treated. Figure 1 Theoretical framework of individual factors linked to weight loss and weight loss maintenance.

Affective factors include depression, anxiety, stress and body image satisfaction. These factors have all been linked with weight loss and weight loss maintenance with mixed results between studies and less evidence for their predictive value for weight loss maintenance. Cognitive factors include dichotomous thinking which has received less attention in empirical studies. It has been suggested that an 'all or- nothing' approach to eating and weight control behaviours might predispose individuals to frequent lapses in dietary restraint, leading to binge eating or overeating and a failure to lose weight (Fairburn, Cooper, & Shafran, 2003). Behavioural factors include eating behaviour and self-monitoring. Both eating behaviour and self-monitoring were frequently investigated as predictors of weight loss and weight loss maintenance with supporting evidence of their predictive value. Motivation factors include eating efficacy and diet readiness. There is considerable evidence to suggest that self-efficacy is a predictor of weight loss. The evidence for weight loss maintenance is limited due to a smaller sample of studies. In addition, motivation although intuitively seem a good predictor of weight loss, the evidence is inconsistent. Many of these factors are important correlates of success, although the amount of variance they explain is either small or highly variable between different groups. This framework will be used across the thesis to explore the role of these factors in explaining weight loss and weight loss maintenance in three different samples across a number of different settings.

#### 1.17 Thesis aims

Previous research has highlighted that there are many different weight loss strategies that people might use to manage their body weight. Although the evidence for the efficacy of these methods is mixed, with some being more effective than others, even within the same intervention, some people are more successful at weight loss than others. There is great individual variability in weight loss, suggesting that there are specific characteristics that might differentiate between those who are more or less successful at losing weight. The literature has suggested different psychosocial and behavioural factors, which might predict weight loss and/or weight loss maintenance and these are discussed in detail in Chapter 2. In addition, problems in identifying predictors of weight loss and/or weight loss maintenance, poor statistical methods, different measures to assess the same psychosocial predictors which are examined in Chapter 2, 3 and 4, are methodological and substantive problems that this thesis aims to address.

Overall, the aims of this thesis are as follows;

- 1. To identify predictors of weight loss
- 2. To identify predictors of weight loss maintenance

This thesis has addressed these aims by examining physiological, psychological and behavioural predictors in a number of different settings.

- Firstly, the existing literature was systematically reviewed to identify predictors of weight loss and/or weight loss maintenance in overweight and obese individuals following different weight management strategies (Chapter 2)
- Secondly, a 12 week free living but well controlled dietary intervention study examined whether physiological and/or psychological factors and changes in these factors during the intervention predicted weight loss (during the intervention) and weight loss maintenance (at one month and one year post intervention) (Chapter 3)
- Thirdly, the psychological and behavioural characteristics associated with successful weight loss amongst free-living individuals who had attempted to lose weight using different weight loss methods/strategies was explored using an online survey (Chapter 4)
- The final aim was to make recommendations for incorporating the assessment of significant predictors of weight loss and weight loss maintenance in NHS delivered weight management programmes. To this end, a pilot study examined predictors of weight loss in a local NHS delivered, community based programme

Taken together, the evidence presented in this thesis will help to identify significant predictors of weight loss outcomes that are important for improving obesity treatment. This thesis aims to make a contribution to the understanding of individual differences in weight loss and to assist healthcare professionals in the provision of alternative treatments for those less likely to succeed, as well as to facilitate matching individuals to the most appropriate treatments. The thesis will also demonstrate the utility of advanced quantitative statistical approaches to understand the interrelations between predictors and contribute by making recommendations for the design of future studies in this area.

## Chapter 2 - Psychosocial/behavioural Predictors of Weight Loss and/or Weight Loss Maintenance: A Systematic Research Review

### 2.1 Introduction

Weight loss is difficult to achieve and maintaining lost weight is an even greater challenge. Previous research has suggested that different factors might predict weight loss to those which predict weight maintenance (Teixeira et al., 2005). Predicting weight loss is difficult due to the large number of potential factors involved and the small variance explained by some of these (Teixeira et al., 2005). There is a need to build useful predictive models of weight loss and/or weight maintenance which account for the complex interactions of the factors involved. Some argue that no further data collection is required but rather, a more sophisticated analysis of existing data (Teixeira et al., 2005).

Identifying factors affecting weight loss and/or weight loss maintenance and developing a better understanding of individual differences in behaviours that are crucial in sustaining a healthy body weight could enable the development of more targeted interventions (Elfhag & Rössner, 2005; Stubbs et al., 2011). The last systematic review of predictors of weight loss and weight loss maintenance was published by Teixeira et al. (2005) which included 29 studies and since then the number of studies investigating predictors has increased substantially. Teixeira et al. (2005) suggested that few previous weight loss attempts and an autonomous self-motivated cognitive style were the best predictors of successful weight management. Baseline binge eating, eating disinhibition and restraint, and depression/mood clearly did not predict treatment outcomes. Recently Lazzeretti et al. (2015) published a narrative review examining the most common predictors of weight management studies in the literature and the instruments used to assess these. The found that the most common psychological constructs studied were self-motivation, self-efficacy, locus of control, health related quality of life, self-esteem, self-control, body image, outcome expectations and personality traits. Authors argued that, overall studies evaluating the association between these psychological features and treatment outcome provided inconsistent results (Lazzeretti, Rotella, Pala, & Rotella, 2015). The aim of the review presented in this chapter was to systematically review the literature and provide an update on predictors of weight loss and weight loss maintenance and examine if these are separate and specific for weight loss and weight loss maintenance in order to address the first aim of the thesis (see Chapter 1, section 1.17).

## 2.2 Literature search

## 2.2.1 Search strategy and search terms

Electronic databases were searched on 10 July 2016. The databases queried were MedLine (1946-July 2016), PsycInfo (1806-July 2016), PsycArticles (1894-July 2016) and Web of Science (1965-July 2016). Table 2..2-2 provides the search terms and strings within each database. Additional search strategies involved scanning reference lists of review articles identified. This yielded three further articles. Following removal of duplicates (n 253), 350 citations were retrieved for possible inclusion in the present review.

## Table 2.2-1 List of search terms (\$ denotes word truncation; \* permitsvariation)

1 (Predictor\$ OR correlate\$ OR determinant\$) AND adults AND weight loss

2 (Predictor\$ OR correlate\$ OR determinant\$) AND adults AND weight loss maintenance

3 Psychosocial AND adults AND (predictor\$ OR correlate\$ OR determinant\$) AND weight loss

4 Psychosocial AND adults AND (predictor\$ OR correlate\$ OR determinant\$) AND weight loss maintenance

5 Behavio\*ral AND adults AND (predictor\$ OR correlate\$ OR determinant\$) AND weight loss

6 Behavio\*ral AND adults AND (predictor\$ OR correlate\$ OR determinant\$) AND weight loss maintenance

#### 2.3 Inclusion and exclusion criteria

Papers were included or excluded in this review according to the following criteria.

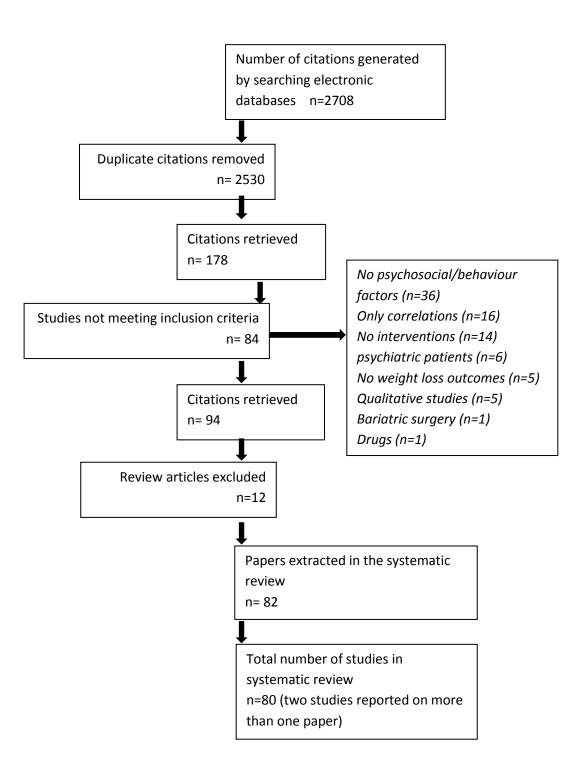
*Participants.* The target sample was adults of either gender, aged 18-75 years old, who were otherwise healthy with no concurrent disease or clinical psychopathology. Studies were excluded if they examined children, adolescents or postpartum or menopausal female samples.

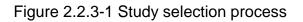
*Manipulations*. Studies which investigated psychosocial/behavioural predictors of weight loss and/or weight loss maintenance following dietary (with or without exercise) and behavioural/lifestyle interventions were included. Studies which investigated predictors of weight loss and/or weight loss maintenance following pharmacological, surgical procedures or web based interventions were excluded, unless the study included a comparative behavioural intervention. Studies utilising novel/remote techniques such as telephone, internet or postal interventions were not included. Review papers were also excluded.

Outcome measures. Studies which assessed psychosocial/behavioural factors as potential predictors of weight loss and/or weight loss maintenance using an appropriate statistical test (e.g. regression model) were included. Studies which only examined differences in psychosocial factors between successful and unsuccessful weight losers/regainers were excluded. Studies which only reported associations/correlations between psychosocial factors and weight outcomes were also excluded. This is because although studies may report correlations between psychological/psychosocial factors and weight loss and/or weight loss maintenance, unless the predictive power of these factors is tested using a regression model, there is no validity that these are predictors of weight loss and/or weight loss maintenance. Many studies reported in this review reported correlations between variables but when tested in a regression model, they were no significant predictors (e.g. Teixeira et al., 2002; Palmeira et al., 2010: Chiriboga et al., 2008). Correlation reduces a set of data to a single number that bears no direct relation to the actual data (Altman, 1991). According to Altman (1991) regression is a more useful statistical method, leading to results which are clearly related to the measurement obtained (Altman, 1991). Studies that only investigated biological, physiological or environmental factors as predictors of

weight loss and/or weight loss maintenance were excluded. Studies using a qualitative design were also excluded, unless validated questionnaires were used to assess psychosocial factors as part of the interview with appropriate statistical analysis reported.

**Study selection process.** Figure 2.1 details the stages of study selection and the number of studies excluded at each stage. Of the 178 studies retrieved, 84 exclusions were made, most commonly because the studies did not assess psychosocial and/or behavioural predictors (n=36); reported correlations only (n=16); did not include diet and/or exercise and/or behavioural interventions (n=14); included psychiatric patients (n=6); used qualitative methods (n=5), did not report weight loss outcomes (n=5), reported predictors following drug treatment or bariatric surgery (n=2); Also excluded were 12 review papers. Therefore, 82 articles were extracted providing 80 studies for review. Data from Teixeira et al. (2002) were also reported in Teixeira et al. (2004) and data from Annesi and Gorjala (2010) were also reported in Annesi and Porter (2013). Each study appears in the tables only once, irrespective of whether the data were reported in more than one paper.





## 2.4 Tabulation of Studies

Studies were categorised in terms of whether they examined psychosocial/behavioural predictors in weight loss interventions (n=49; Table 2.2), in weight loss maintenance studies with no additional intervention during the

maintenance period (n=23; Table 2.3) and in weight loss maintenance studies which included additional input during the maintenance period (n=8; Table 2.4). Gender, age, body weight and/or body mass index (means and standard deviations or standard errors (SEs)) are included where available. The nature of the intervention is documented together with the duration of treatment, measures used to assess psychosocial and behavioural predictors, statistical methods and corresponding outcomes.

#### 2.5 Results

Eighty studies were included in the present review. Forty-nine studies were weight loss interventions, which ranged from three weeks to two years. Twentythree out of eighty studies included a follow up period with no additional intervention involved and examined predictors of weight loss maintenance. Follow-up periods varied from three months to five years. Another eight studies included a weight loss maintenance period where additional intervention or advice was given during the maintenance period. The weight loss and/or maintenance interventions included in the review consisted of dietary interventions (n=14), diet and exercise interventions (n=9), exercise only (n=1)and behavioural/lifestyle interventions (n=59). Seventy-eight out of eighty studies included female subjects with 53 studies (66%) having mixed-gender samples and two studies including only male subjects (Jeffery et al., 1984; Lejeune, van Aggel-Leijssen, van Baak, & Westerterp-Plantenga, 2003). Initial mean body mass index (BMI) varied from 25 to 56.5 kg/m<sup>2</sup> and sample size ranged from 25 to 1913 participants. Participants' age ranged from 18 to 75 years old. Definition of successful weight loss and/or weight loss maintenance was only provided in 28 studies included in the review.

The following psychosocial and behavioural predictors of weight loss/ and or weight loss maintenance were identified in the papers reviewed: eating behaviour (n=27), depression (n=25), self-efficacy (n=19), physical activity (n=17), binge eating (n=17), body image (n=15), self-monitoring (n=14), motivation (n=12), social support (n=11), stress (n=9), self-esteem (n=9), mood (n=8), health related quality of life (n=8), weight loss goals/outcome expectations (n=7), previous dieting attempts (n=7), treatment attendance (n=7), personality traits (n=5), initial

weight loss (n=4), coping with stress (n=4), anxiety (n=3), weight bias/attitudes (n=2), sleep quality (n=2), dichotomous thinking style (n=2), locus of control (n=1), anger (n=1) and beliefs about causes of obesity (n=1). Table 2.5-5 shows all predictors, organised by reported frequency and separated by the type of study (weight loss interventions and weight loss maintenance studies).

Ten of the studies (Handjieva-Darlenska et al., 2010; Kiernan et al., 2012; Kong et al., 2010; Lahmann et al., 2011; Lejeune et al., 2003; Lynch et al., 2009; Martin, O'Neil, & Binks, 2002; Stotland & Larocque, 2005; Warziski, Sereika, Styn, Music, & Burke, 2008; Williamson et al., 2010) included in the review assessed only one psychological/behavioural predictor. The remaining studies assessed more than one psychological and/or behavioural predictor. The majority of the studies used multiple regression (n=51) and logistic regression (n=17) to assess predictors. One study by Williamson et al. (2010) used canonical correlation, which is used similarly to multiple regression, but when there are multiple inter-correlated outcome variables. Nine studies (Annesi & Gorjala, 2010; Poston et al., 1999; De Panfilis et al., 2007; Gripeteg, Karlsson, Torgerson, & Lindroos, 2010; Kiernan, King, Kraemer, Stefanick, & Killen, 1998; Stotland & Larocque, 2005; Teixeira et al., 2002; Wadden et al., 2011; Williams, Grow, Freedman, Ryan, & Deci, 1996a) used more than one statistical method to examine predictors of weight loss outcomes. Sixteen studies used more advanced statistical methods to assess predictors of weight loss and/or weight loss maintenance: signal detection analysis (n=2; (Kiernan et al., 1998; Kiernan et al., 2012)), linear mixed effects models (n=4; (Chiriboga et al., 2008; Sherwood, Jeffery, French, Hannan, & Murray, 2000; Warziski et al., 2008)), mediation analysis (n=2; (Annesi & Gorjala, 2010; Teixeira et al., 2010)), structural equation modelling (n=1;(Canetti, Berry, & Elizur, 2009)), partial least squares analysis (n=1:(Silva et al., 2011)), path analysis (n=2; (Choo & Kang, 2015; G. C. Williams et al., 1996a)) and multivariate regression (n=6; (Cresci et al., 2013; Gripeteg et al., 2010; Karlsen, Søhagen, & Hjelmesæth, 2013; Kong, Beresford, Alfano, et al., 2012; Niemeier, Phelan, Fava, & Wing, 2007; Presnell, Pells, Stout, & Musante, 2008).

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Abildso et al. 2012	766 overweight, obese and morbidly obese (79.6% female), age range (18- 55+yrs), BMI range (26-40 kg/m <sup>2</sup> )	USA	≥ 5% initial BW	6 months of diet and exercise community based weight management programme (Phase I: 0-3 months, Phase II:3-12 months, Phase III:13-24 months)	BRFS; Social support, programme, site and environmental factors using 17 items measured on a 7 point Likert scale	Logistic regression	Social support from friends was predictive of losing at least 5% of BW	Lack of standardised instruments to measure health outcomes; retrospective data (some participants had completed phase I up to 4 years ago)
Abildso et al. 2014	450 (81.1% females)	USA	≥ 5% initial BW	1-year community- based, public insurance benefit WMP including phase I (3 months) and phase II (9 months)	Perception of WL, effort and success; BRFSS; Frequency of self-weighing; Food management behaviours	Logistic regrssion	Self-weighing (at least once per week but not daily), limiting portions and snacking predicted WL at 1 year	Participants were still receiving intervention benefits during phase II

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Annesi & Gorjala 2010, Annesi, & Porter 2013	95 men and women (mean age = 43.5 ±10 yrs; mean BMI = 40.5 ± 3.9 kg/m <sup>2</sup> )	USA	NA	6-month exercise and nutrition treatment emphasizing self- regulatory skills	Self-regulatory skills for PA (Self- reg-PA) and self- regulation for eating (Self-reg- EAT) using adapted version of Saelens et al. scale (2000); ESE; WEL; TMD	Linear regression ; Baron and Kenny's method for assessing mediation	Changes in ESE and controlled eating (WEL) explained a significant portion of the variance in BMI change. Self- reg-EAT and fruit and vegetable intake were significant predictors of WL over both 3 and 6 months	Significant relationships between changes in Self-reg-PA and ESE, and Self-reg-EAT and WEL. The relationship between Self- reg-EAT and WEL was partially mediated by TMD changes
Anton et al. 2008	36 male (25-50 yrs) and female (25-45 yrs); M mean age (SEM)= 37.3 (1.8) yrs; F: 37.6 (1.2) yrs; M mean BMI (SEM)=27.9 (0.3) kg/m <sup>2</sup> ; F= 27.6 (0.4) kg/m <sup>2</sup>	USA	NA	6 month calorie restriction trial	BDI; EI; BSQ; MAEDS; Structured Interview for the Diagnostic and Statistical Manual (DSM-IV)(SCID- IV); IDED-IV; MARS-WL; DEBQ; GHQ; Current dieting questionnaire	Hierarchic al regression	Poor psychosocial functioning and somatic symptoms and negative mood states predicted less WL	

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Bas & Donmez 2009	96 overweight (20 men, 76 women), mean age M= 35.5±8.7 yrs, F= 34.81±9.2 yrs, mean BMI M=31.2 ±3.7 kg/m <sup>2</sup> , F= 29.1±5.1kg/m <sup>2</sup>	Turkey	NA	20 weeks behavioural WL programme	WEL; TFEQ; RSE; SPAS;STAI; BPSS-R	Multiple regression	Eating self- efficacy, social physique anxiety and social trait anxiety predicted WL	No control group; poorly written paper with lots of missing information
Batra et al. 2013	95 men and women (23 males, 72 females), mean age intervention=49.09 $\pm$ 10.12 yrs, control= 49.84 $\pm$ 10.98 yrs ; BMI intervention: 33.48 $\pm$ 6.47 kg/m <sup>2</sup> , control= 33.12 $\pm$ 6.61 kg/m <sup>2</sup>	USA	NA	6 month behavioural intervention	TFEQ; daily self-weighing records once every week used to calculate percent weight self- monitoring	Multiple regression	Decreased hunger was the strongest predictor of WL; Increased self- monitoring and a higher frequency of group meeting attendance were significant predictors of WL success	

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Bryant et al 2012	58 overweight/ obese men (n= 19) and women (n= 39), mean age = $35.57 \pm 9.78$ yrs, mean BMI = 31.83 $\pm 4.46$ kg/m <sup>2</sup>	UK	NA	12 weeks exercise intervention	Physiological measures; Energy intake; TFEQ	Stepwise multiple regression	Higher baseline disinhibition (specifically internal disinhibition), increase in flexible restraint and decrease in external disinhibition were predictors of WL	No control group
Burmeiste r et al. 2013	57 overweight/obese men and women (68.4 % women), mean age= 47.4 ±13.7 yrs, mean BMI= 38.2 ± 8.1 kg/m <sup>2</sup>	USA	NA	7 weeks behavioural WL programme	YFAD; BES; CES- D; DEBQ; ESES; WBIS; AFA; OBCS- Shame; MBSRQ	Linear regression	BES and YFAD scores were related with WL but when entered together in regression, none of them were significant predictors of WL	Food addiction and binge eating may overlap

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Byrne et al. 2012	30 adult primary care patients (25 women and 5 men); mean age = $40.9 \pm 9.4$ yrs; BMI range: 25- 39.9 kg/m <sup>2</sup> , mean BMI= $34.2\pm3.7$ kg/m <sup>2</sup>	USA	NA	12 week standard cognitive behavioural WL intervention or the same intervention with the addition of reinforcements for WL and completion of activities that promote WL	PAQ; SEE; WEL	Multiple regression	Treatment attendance and increase in ESE predicted WL	ESE was correlated with diet self- efficacy
Canetti et al. 2009	91 obese males and females (mean age= $34.2 \pm 10$ yrs, BMI= $45.1 \pm$ 7.7 kg/m <sup>2</sup> for surgery group; mean age= $42.8$ $\pm 11.5$ yrs, BMI= $35.4 \pm 7.2$ kg/m <sup>2</sup> for diet group)	Israel	NA	1 year follow up of a surgery (n=44) vs behavioural weight loss programme (n=47)	Receiving Social Support; Shapiro Control Inventory; MHI; Neuroticism NEO personality inventory; RSE; Fear of intimacy Scale; EE; SF-36	Structural equation modelling	Neuroticism and emotional eating predicted WL in both groups. Social support predicted WL only in the dieting group and not in the surgery group	The effect of neuroticism on WL was mediated by EE. Sense of control was associated with WL in the dieting group.

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Choo & Kang 2015	75 women mean age of 44.5 yrs (range: 21–64 yrs), mean BMI of 28.1 kg/m <sup>2</sup> (range: 23.2–39.2 kg/m <sup>2</sup> )	Korea	NA	3 months diet alone and 9 months diet and exercise intervention; Results are based on 6 month measures	WEL; ESES; HPLP-II	Path analysis	Increases in diet SE and health promoting behaviour were significant predictors of WL	Health- promoting behavioural change was a mediator in the path from increased diet SE to WL. Diet and ESE had significant positive effects on health promoting behaviour
Clarke et al 2007	Overweight, obese and morbidly obese women (N=119), age range:18-44 yrs (mean=27 yrs), BMI range: 25-56.5 kg/m <sup>2</sup> (mean=35 kg/m <sup>2</sup> )	USA	WL ≥ of 2.3kg	8 weeks dietary and PA programme	MBRQ; DBI;ESE; WEL;CEDS; Social Support Scale; Stress Scale; NKT	Hierarchic al regression	Only healthful eating attitude and social support change scores predicted WL	Appearance evaluation, decisional balance and the total score for the nutrition knowledge test were

								related with WL
Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Cresci et al. 2013	331 obese, overweight men and women (mean age =38.8+6.8 yrs, mean BMI= 38.8+6.8kg/m <sup>2</sup> ); (N=117 completed the programme and included in the analysis)	Italy	WL of at least 5% from baseline weight	6 months diet/exercise/educatio n programme	TREMORE	Multivariat e analysis (logistic regression )	TRE-MORE 3 and muscle mass predicted 6 months WL in completers	Completers and drop-outs differed in TREMORE 3; Lower TREMORE 3 scores (i.e. current lifestyle habits) were associated with drop-outs
Delahanty et al. 2013	274 participants from the DPP (mean age= 50.6± 11.3 yrs, 32% males, mean BW= 94.1± 20.8 kg)	USA	7% WL	6 months lifestyle intervention	WEL; 16-item Low- Fat Diet Self- efficacy Scale; ESES; PSQ; BDI; DEBQ (restraint); QEWP (5 items on binge eating); Fat- Related Diet Questionnaire; MAQ; LOPAR	Hierarchic al logistic regression	Greater baseline self- efficacy and dietary restraint predicted 6 months WL	No control group

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Delinsky et al. 2006	136 women and 25 men, mean age = 46.7 ±11.2 yrs; mean BMI=34.9 ±4.9 kg/m <sup>2</sup>	USA	NA	Continuing care provided by Trevose Behaviour Modification Programme (TBMP); WL assessed at 1 month and 12 months	EDE-Q; BDI; QEWP-R; RSE	Stepwise regression	Higher initial BMI and lower BDI scores predicted greater BMI at 12 months	BMI was negatively correlated with BDI scores and EDE shape concern
De Panfilis et al. 2007	68 obese outpatients (88.2% female and 11.8% male (mean age=38.9±12.8 yrs, and BMI 36.1±6.9 kg/m <sup>2</sup> )	Parma	WL of ≥10% of initial BW	8 months behavioural WL programme	Structured Clinical Interview for DSM- IV Axis I disorders (SCID-I/P) (22); Structural Clinical Interview for Personality Disorders (SIDPIV); Hamilton Rating Scale for Depression (Ham- D); Hamilton Rating Scale for Anxiety (Ham-A); Eating Disorders Inventory (-2); TCI; TAS-20	Logistic and stepwise regression	Obese group with an Axis I diagnosis: low scores on the TAS factor 'difficulty describing feelings' and low scores on the TCI subscale 'attachment /detachment' predicted WL; obese group without an Axis I diagnosis: low narcissisticscores predicted WL	Patients with Axis I disorders were less likely to lose weight than patients without Axis I disorder. Small sample size

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Dove et al. 2009	76 overweight/obese female mean age =46.97 $\pm$ 11.78 yrs (age range 18–68 yrs), mean BMI =35.56 $\pm$ 6.26 kg/m <sup>2</sup>	Australia	NA	12 weeks of CBT programme	BDI-II; DTEDS; EDE-Q	Multiple regression	Only depression was a significant predictor of 12 weeks WL	
Elder et al. 2012	472 men and women (83% women); mean age =55 ± 1.7 yrs, mean BMI = 37.7 ± 5.2 kg/m <sup>2</sup>	USA	NA	LIFE study: 6 months behavioural WL (phase I); those who lost at least 4.5 kg during phase I entered a WLM RCT with follow-up through 18 months post-initial study entry	ISI; PSS; Computer and TV screen time; PHQ- 8 (Depression subscale)	Logistic regression	Stress and sleep time predicted 6 months WL; changes in weight during the WL phase I were associated with changes in depression and stress	Results of WLM phase II not published yet

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Eldredge et al. 1997	47 severely obese (45 women and 2 men), mean BMI=38.6 ±9.5 kg/m <sup>2</sup> ; age not reported	USA	NA	12 or 24 week cognitive behavioural therapy followed by 12 week behavioural WL programme	Weight Perception Evaluation Questionnaire (WPEQ; designed for this study); IIP; GSI; BDI; RSE; EES; BES	Regressio n	Low levels of negative affect in response to perceived evaluation predicted greater WL at 12, 24 and 36 weeks; increases in psychopathology predicted WL at 12, 24 and 36 weeks	Negative affect and depression were related with GSI but depression and negative effect were not related
Fabricato- re et al. 2009	224 obese adults (180 female, 44 male), mean age of 43.8 ± 10.2 yrs; mean BW= 106.9±17.2 kg	USA	≥ 5% WL	52-week RCT to either (i) sibutramine (15 mg/day), (ii) lifestyle modification (iii) sibutramine (15 mg/day) plus lifestyle modification or (iv) sibutramine (1 mg/day plus brief therapy	WALI; BDI-II (Second edition)	Logistic regression	Early adherence (i.e. completion of food records) predicted WL at 1 year (sibutramine only group was not included) and lower baseline depression scores marginally predicted WL at 1 year	Early WL marginally predicted WL for lifestyle medication group but was a significant predictor of WL for all other groups

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Foster et al. 1998	223 obese women, mean age of $41.4\pm$ 8.8 yrs and BMI of 37.25 $\pm$ 5.6 kg/m <sup>2</sup>	USA	NA	5-6 months of : i) a liquid based VLCD of (400±800 kcal/d); ii) a portion controlled diet (925 kcal/d) and iii) a self-selected diet of conventional foods (1200 kcal/d)	EI; BES; BDI	Regressio n	Increases in restraint and decreases in disinhibition predicted WL	Change in disinhibition had no effect on WL after accounting for change in restraint
French et al.1994	1913 women (mean age 37.3±10.7 yrs, mean BMI: 25.1±5.5 kg/m <sup>2</sup> ) and 1639 men (mean age 39.1±9.8 yrs, mean BMI 26.6±3.9 kg/m <sup>2</sup> )	USA	NA	2 years health behaviour change programme	PA; Dietary intake; Dieting history	Mutlivaria- te linear regression	History of previous dieting and physical activity predicted weight change	
Gladis et al. 1998	118 women, mean age= 40.96 ± 8.6 yrs; BMI=36.36 ±5.3 kg/m <sup>2</sup>	USA	NA	Participants were randomly assigned to one of four 48 weeks behavioural intervention depending on the type of exercise	QEWP; BES; BDI	Stepwise multiple regression	Initial BW and presence or absence of BED accounted for 26% of the variance in WL	The study included a 1 year follow- up but no predictors of WLM were reported

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Gripeteg et al. 2010	177 women and 90 men; F mean age = $40.1 \pm 10$ yrs, mean BMI = $41.2 \pm 6.3$ kg/m <sup>2</sup> ; M mean age= $40.4 \pm 9.1$ yrs, Mean BMI= $43.1 \pm 6.5$ kg/m <sup>2</sup>	Sweden	≥ 10% WL	12 week very-low- energy diet (VLED) treatment	TFEQ-R21; SF-36; RSE; OF; MACL	Multivariat e linear and logistic regression	M: Higher perceived general health, higher social interaction and lower EE predicted WL F: Perceived physical health and obesity related phychosocial dysfunction predicted WL	
Hainer et al. 2008	67 women, mean age=48.7±12.2 yrs, mean BMI= 32.4±4.4 kg/m <sup>2</sup>	Czech Republic	NA	3 week behavioural programme	El; BDI; Hormonal parameters	Backward stepwise multiple regression	Age, initial BMI and baseline hormones involved in energy balance regulation predicted WL	Eating behaviour characteristic s and depression did not predict WL

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Hollis et al. 2008	1685 overweight/obese men and women (67% women), mean age=54.8 ± 9.1 yrs, BMI=34.3 ± 4.8 kg/m <sup>2</sup>	USA	≥ 4kg	6 month behavioural intervention	Food records kept (self-monitoring), PA	Multiple regression	Number of food records kept per week and PA predicted WL after adjusting for race, gender and initial BW	
Handjieva et al. 2010	932 obese/ overweight men and women, mean age (SEM) = 41.2 (0.21) yrs, mean BMI= 34.4 (0.16) kg/m <sup>2</sup>	Multicent re study including 8 Europea n countries	At least 10kg WL	8 week LCD	Early weight loss	Multiple regression	Early weight loss (week 1 and week 3) were predictors of 8 week WL	
Jakicic et al. 2002	104 overweight women 25–45 yrs of age; mean 37.4± 5.3 yrs, mean BMI= 32.4 ± 3.8 kg/m <sup>2</sup>	USA	NA	18 month behavioural weight loss programme	PAQ; Block Food Frequency Questionnaire; Eating Behaviour Inventory (EBI)	Multiple regression	Both EBI scores and physical activity predicted weight loss	

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Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	_
199 morbidly obese patients, 71% women, mean age 45.2 ± 11.1 yrs, BMI 42 ± 6.2 kg/m <sup>2</sup>	Norway	≥ 10%WL	12 months partly residential intensive lifestyle intervention program (ILI) comprised of 4-5 stays at the rehabilitation centre	OWLQOL questionnaire; WRSM; short form of the Medical Outcome Study (SF-36); SOC; Self-monitoring (paper based daily diary)	Multivariat e regression analysis	Keeping food diaries and frequent GP visits predicted 12 weeks WL.12 weeks WL, age, mental HRQL and employment level predicted 1 yr WL	_

Comments

Selection of

participants,

morbidly

obese

h 2013	yrs, BMI 42 ± 6.2 kg/m <sup>2</sup>			comprised of 4-5 stays at the rehabilitation centre	Outcome Study (SF-36); SOC; Self-monitoring (paper based daily diary)		weeks WL.12 weeks WL, age, mental HRQL and employment level predicted 1 yr WL	patients referred from hospitals, may have led to a biased sample
Karlsonn et al. 1994	60 moderately obese women (mean age=43 yrs, mean BMI=33 kg/m <sup>2</sup> )	Sweden	NA	Lactovegetarian diet vs low calorie diet (1300 kcal/d) for a period of 24 months	MACL;TFEQ; SIP (Sickness Impact Profile)	Stepwise multiple regression	Overall SIP score was predictor of relapse; higher baseline and end of the study disinhibition scores predicted weight regain; The more initial health-related dysfunction (SIP) the greater the weight regain	Psychologica I characteristic s did not predict overall WL; 47% completed the 2 year programme

Authors

Karlsen,

Søhagen

Hjelmesæt

&

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Kiernan et al. 2012	267 overweight/ obese women, mean BMI=32.1 ± 3.5 kg/m <sup>2</sup> , mean age 48 ± 10.8 yrs	USA	WL of 2.3kg or 2%-3% loss of initial weight	6-month, group-based behavioural WL program (RCT)	Social support (Ball & Crawford 36 item scale)	Signal detection	Support from friends for healthy eating and support from family for PA predicted WL	
Kiernan et al. 1998	177 overweight men and women (mean age= 38.4±6.2 yrs; mean BMI M= 30.7±6.2; F= 28±2.3 kg/m <sup>2</sup>	USA	WL of at least 2 units of BMI during the year	Participants were randomised to a diet only or diet and exercise WL programme	PSS; ISEL;EDI-BD; food records, self- reported binge eating; history of previous WL attempts	Signal detection methods; logistic regression	History of repeated WL and body dissatisfaction predicted WL but only for those in diet and exercise group	
Kong et al. 2010	51 men and women (65% women), mean age = 50.8 ± 12.0, BMI=109.6 ± 30.1 kg/m <sup>2</sup>	Canada	≥ 5% WL	12 month lifestyle modification program	WLRT	Univariate logistic regression	Levels of self- confidence for PA, initial weight loss (during first 6 weeks) were significant predictors of WL	Used two different populations: pre-diabetic and metabolic syndrome participants

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Kong et al. 2012	123 overweight/obese women, mean age=58.0±5.1 yrs, mean BMI= 31.3 kg/m <sup>2</sup>	USA	10% WL goal	12 months diet and exercise intervention based on the LOOK AHEAD (Action for Health in Diabetes) and Diabetes Prevention Programme (DPP)	Women's Health FFQ diet-related WL strategies; self- monitoring; items from Health Styles survey	Multivariat e regression model	Keeping food diaries predicted 12 months WL	Skipping meals and eating out more frequently were associated with less WL
Lahmann et al. 2011	54 obese outpatients (18 males, 36 females), mean age= 48.4±12.9 (21-75 yrs), mean BMI= 41.3 ±7.4 kg/m <sup>2</sup>	Germany	>15% WL	52 week behavioural Intervention (VLCD)	Inventory of Interpersonal Problems (IIP)	Stepwise linear regression	The IIP-subscale "intrusive or needy" baseline scores predicted WL at 12, 26 and 52 weeks	

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Lynch et al. 2009	Normal (N=1662), overweight (N=1119) and obese (N=741) men and women; mean BMI for normal=22.4 kg/m <sup>2</sup> , overweight=27.2, obese=35.25 kg/m <sup>2</sup>	USA	NA	Coronary Artery Risk Development in Young Adults (CARDIA) study (13 years)	Body size satisfaction (Stunkard Figure rating scale)	Multiple regression	Body size dissatisfa-ction was associated with WL in obese women (but not in obese men) and also with weight gain in men and white women of normal weight. It was not associated with WL in overweight men and women	
Martin et al. 2002	263 males and females (LCD=167 and VLCD=96), average BMI for LCD =35.93±7.24 kg/m <sup>2</sup> ; VLCD BMI= 44.48 ±7.53 kg/m <sup>2</sup>	USA	NA	10 weeks LCD vs 30 weeks VLCD lifestyle intervention; Phase I: 12 week supplement based diet, Phase II: 6-12 weeks non supplement, Phase III: 12 week structured WLM	DRT(motivation/co mmitment/effort)	Hierarchic al multiple regression	Commitment predicted programme completion and WL in LCD group; gender predicted WL in VLCD group	No predictors of WLM mentioned

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Niemeier et al. 2007	286 overweight men and women, mean age = 40.7 ± 6.6 yrs, mean baseline BMI, 31.3 ±3.0 kg/m <sup>2</sup>	USA	NA	18 month behavioural WL treatment comparing two different PA prescriptions (energy expenditure goal of 1000 kcal/wk vs. 2500 kcal/wk)	Eating Inventory: Disinhibition Scale (Internal and External Disinhibition); BDI	Multivariat e regression	Internal disinhibition predicted WL at 6 months after controlling for BDI scores and marginally predicted WL at 18 months, but not weight change at 12 months	Authors mentioned 18 months follow up, however participants were still in contact with research staff between 12 and 18 months of intervention
Oettingen & Wadden 1991	25 obese women, mean age= 39.5± 9.8 yrs, mean BMI=39.1± 6.3 kg/m <sup>2</sup>	Germany	NA	RCT: 52 weeks to either a VLCD or BDD including behavioural components	Weight goals and expectations; Weight related fantasies	Multiple regression	Negative fantasies and positive expectations were associated with increased WL at the end of the intervention	

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Presnell et al. 2008	223 females and 74 males) (mean age=47.63 ±13.66 yrs, mean BW=130.19 ± 33.13kg	USA	NA	4-week core residential weight loss treatment program (individualised restricted calorie diet combined with exercise advice and behavioural strategies)	WEL; BES; BDI-II	Multivariat e regression model	High levels of weight self- efficacy and depression predicted subsequent decreases in BMI for men, but not for women. Initial increase in binge eating predicted decreases in BMI at post-treatment for men, but only marginally for women	
Rotella et al. 2014	231 obese (76.6% women), mean age=44.7±12.7 yrs, mean BMI 39.3±6.9 kg/m <sup>2</sup>	Italy	5% WL	6 months weight management programme (monthly visits)	SCL-90-R; EDE-Q; Obesity related wellbeing; TREMORE	Stepwise logistic regression	Hypertension and somatisation scores were significant negative predictors of success	TREMORE scores were higher in men but not in women; Mean WL was small; low frequency visits

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Stotland & Larocque 2005	344 female patients with mean BMI= $33.7 \pm 64$ kg/m <sup>2</sup> , range (25.1–53.8 kg/m <sup>2</sup> ), age range from 18 to 65 yrs (mean 41.8 ± 11.3 yrs)	Canada	NA	9 months VLCD or LCD diet	LOQ-UE (eating behaviour, depression, stress response, perfectionism)	Hierarchic al linear modelling; random regression modelling	Reduction in uncontrolled eating during initial 5 weeks was predictive of future WL. Early change in depression and stress reactions predicted WL only when uncontrolled eating was not in the model	The predictive effect of the emotional factors on WL was due to a shared association with uncontrolled eating
Teixeira et al. 2002 and Teixeira et al., 2004	and obese middle- aged women (age,	Portugal	WL of ≥5%or ≥10% initial fat mass	4 month lifestyle WL program consisting of group-based behaviour therapy to improve diet and increase physical activity	Weight outcome evaluations (four items from GRWL); SF-36; BIA; BCQ; IWQOL; MOS; BDI; RSE; SMI; BSQ; BES; ESES; WEL; EI; DRT; Self- efficacy for exercise; EPB; ESS	Discrimina nt function and multiple regression	Higher baseline self-motivation, recent diet attempts, number of years at current BW, body size dissatisfa- ction and perceived barriers to exercise predicted WL	Teixeira et al. (2004) and Teixeira et al. (2002) were the same interventions but Teixeria et al. (2004) study sample was N=140

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Traverso et al. 2000	50 obese (12 males) aged 24-56 yrs (mean 40.2 years), mean BMI= 33.2 ± 3.4 kg/m <sup>2</sup>	Italy	NA	24 weeks hypoenergetic diet combined with behaviour modification programme	EI; EDI; Body Attitude Questionnaire; BSQ	Stepwise regression analysis	EDI bulimia, body dissatisfaction, interpersonal distrust and BAQ feeling fat predicted WL	Participants' exclusion criteria included only self-reported episodes of binge eating. Authors described patients as eating disordered individuals, but no further information was provided
Tseng et al. 2002	189 males and females (87.8%); mean age= 40.5 ± 12.3 yrs, mean BMI= 31.1 ± 3.8 kg/m <sup>2</sup>	Taiwan	NA	12 week hospital based weight reduction programme	Brief Symptom Rating Scale (BSRS); Bulimic Investigatory Test, Edinburgh (BITE)	Regressio n	Initial mood and binge eating did not predict WL	

Authors	Sample	Country	Definition of WL	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Wamste- ker et al. 2005	48 women and 18 men, mean age=45.9 yrs (range=23-73 yrs); mean BMI 39.4 ± 3.8 kg/m <sup>2</sup>	Netherla nds	NA	8 week very low calorie diet	Obesity Cognition Questionnaire (adapted version of IPQ); Obesity Psychosocial State Questionnaire (self-efficacy)	Multiple regression	Higher self- efficacy predicted WL	
William- son et al. 2010	683 overweight or obese men and women aged 30– 70 yrs; mean age=51±9 yrs; mean BMI=33±4 kg/m <sup>2</sup>	USA	NA	2 year RCT; 4 diets differing in their macronutrient composition: (1) Low Fat, Average Protein; (2) Moderate Fat, Average Protein; (3) Low Fat, High Protein; (4) Moderate Fat, High Protein. A behavioural programme of similar content and intensity was also provided	Frequency of submitting dietary self-monitoring records	Canonical correlation s	Greater behavioural adherence (attendance and self-monitoring) during the first 6 months predicted WL at 24 months	

85

Key: AFA: Anti-Fat Attitudes Questionnaire; BAQ: Body Attitudes Questionnaire; BCQ: Body Cathexis Questionnaire; BDD: Balanced deficit diet; BES: Binge Eating Scale; BIA: Body Image Assessment Questionnaire; BDI: Beck Depression Inventory; BITE: Bulimic Investigatory Test of Edinburgh; BPSS-R: Body Parts Satisfaction Scale; BRFS: Behavioural Risk Factor Surveillance System (Brownson, Jones, Pratt, Blanton, & Heath, 2000); BSRS: Brief Symptom Rating Scale; BSQ: Body Shape Questionnaire; BW: body weight; CES-D: Center For Epidemiological Studies Depression Scale; DBI: Decisional Balance Inventory; DEBQ: Dutch Eating Behaviour Questionnaire; DPP: Diabetes Prevention Programme; DRT: Diet Readiness Test; DTEDS: Dichotomous Thinking in Eating Disorders Scale; EBI: Eating Behaviour Inventory; EDE-Q: Eating Disorder Examination-Questionnaire; EDI: Eating Disorder Inventory; EDI-BD: Eating Disorder Inventory- Body Dissatisfaction; EE: Emotional Eating; EES: Emotional Eating Scale; EI: Eating Inventory; EPB: Exercise Perceived Barriers; ESS: Exercise Social Support; ESE: Exercise Self-Efficacy; ESES: Exercise Self-Efficacy Scale; FFQ: Food Frequency Questionnaire; GHQ: General Health Questionnaire; GSI: Global Severity Index of the SCL-90; HLP-II: Health-Promoting Lifestyle Profile-II; IDED-IV: Interview for the Diagnosis of Eating Disorders-IV; ISEL: Interpersonal Support Evaluation List; IIP: Inventory of Interpersonal Problems; IWQOL: Impact of Weight on Quality of Life; LCD: Low calorie diet; LOPAR: Low Level Physical Activity; LOQ-UE: Larocque Obesity Questionnaire; MACL: Mood Adjective Checklist; MAEDS: Multiaxial Assessment of Eating Disorder Symptoms; MAQ: Modifiable Activity Questionnaire; MARS-WL: Motivation and Readiness Scale-Weight Loss; MBRQ: Multidimensional Body Relations Questionnaire; MBSRQ: Multidimensional Body-Self Regulations Questionnaire; MHI: Mental Health Inventory; MOS: Medical Outcomes Study; NKT: Nutrition Knowledge Test; OBCS-Shame: Objectified Body Consciousness Scale Body-Shame; OF: Obesity Functional health Scale; OWLQOL: Obesity and Weight Loss Quality Of Life; PA: physical activity; PAQ: Physical Activity Questionnaire; PHQ-8: Personal Health Questionnaire; PSQ: Perceived Stress Questionnaire; PSS: Perceived Stress Scale; QEWP-R: Questionnaire on Eating and Weight Patterns-Revised; QoL: Quality of Life; RSE: Rosenberg Self-Esteem Scale; SCL-90-R: Symptom Checklist for general psychopathology; SEE: Self-efficacy for Exercise; SF-36: Short form quality of life; SIP: Sickness Impact Profile; SOC: Sense of Coherence; SPAS: Social Physique Anxiety Scale; STAI: State-Trait Anxiety Inventory; TAS-20: Toronto Alexithymia Scale; SMI: Self-Motivation Inventory; SOC: Sense of Coherence; TCI: Temperament and Character Inventory; TFEQ: Three Factor Eating Questionnaire; TMD: Total Mood Disturbance; TREMORE: Treatment Motivation Readiness Test; VLCD: Very Low Calorie Diet; VLED: Very low energy diet; WALI: Weight and Lifestyle Inventory; WBIS: Weight Bias Internalisation Scale; WEL: Weight Efficacy Lifestyle; WL: weight loss; WLRT: Weight Loss Readiness Tool; WPEQ: Weight Perception Evaluation Questionnaire; WRSM: Weight Related Symptom Measure; YFAD: Yale Food Addiction Scale; Yrs: years;

## Table 2.5-2 Predictors of weight loss and weight loss maintenance (without intervention during maintenance period) following dietary (with or without exercise) and/or behavioural interventions (twenty-four studies)

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Barnstu ble et al. 1986	40 adults (10 male,30 female), age range 22-60 yrs (mean=39 yrs), BW range 59-126 kg (mean=85.7kg)	USA	NA	10 week behavioural weight loss phase with a 6 month follow-up	Food intake and PA; RMR; Dishman Motivation Scale; POMS	Regression	Only calorie restriction predicted WL and WLM; lower RMR predicted WLM	No psychosocial predictors
Bernier & Avard, 1986	62 female, age range 21-65 yrs (mean=43.5 yrs), mean BW=79.5 ± 13.5 kg	Canada	NA	10 weeks of diet, PA and behavioural intervention with a 6 weeks and 6 months follow up	Two questionnaires assessing SE based on Bandura's SE model; EPDQ; WL goal and confidence level with a rating scale from 1 to 10	Multiple regression	Pre-treatment SE predicted WL during treatment and post- treatment SE predicted WL at 6 week and 6 month follow up	Increases in SE during treatment were unrelated to 10 weeks WL

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Bonato et al. 1988	96 women, with a mean of 48.8% overweight (SD = 23.92%); N=83 completed 1 yr follow-up	Canada	NA	10 weeks of behavioural programme with 1 year follow up	Demographic, weight history data (e.g. WL goals), weekly frequency of bingeing, daily frequency of urges to overeat and daily frequency of urges to overeat that were overcome	Regression	WL during the first week of the intervention, more past WL attempts and a larger WL goal predicted 10 weeks WL. Work status, age of onset of obesity and the ratio of urges that were overcome to total urges to overeat predicted WL from the end of treatment to 1 year follow-up	No baseline variables predicted WLM. Frequency of bingeing, frequency of urges, and demographic variables (other than age of onset and work status) were not predictive of WL at any time

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Byrne et al. 2004	54 women, mean age 42.51 ±10.12 yrs, mean BMI=37.55 ±6.58 kg/m <sup>2</sup>	Australia	10% WL	Women who had completed community slimming clubs and had lost 10% of their initial body weight were followed up for 1 yr	Leeds FFQ; DTS (16 items); Weight monitoring	Logistic regression	Dichotomous thinking style predicted 1 year WLM	Self-reported weight at follow up; Validity and reliability of DTS unknown
Chiriboga et al. 2008	572 overweight/ obese men and women, mean age= 47.9 ±12.3 yrs, mean BMI = 27.4 ± 5.5 kg/m <sup>2</sup>	USA	NA	The Seasonal Variation of Blood Cholesterol Levels (SEASONS) study- 1 year follow up	BAI; BDI, Dietary assessment; Physical activity assessment	Linear mixed model	Increased anxiety predicted weight regain only among men and not in women	Depression was not a significant predictor of WLM
Collings et al. 2008	73 women, mean age =42.3±13.2 yrs, mean BMI= 27.8 ± 6.4 kg/m <sup>2</sup>	USA	10% of BW	3 month and 12 month follow-up after diet and exercise programmes	MBSRO; BIA- O;BIAQ;CES-D; RSES	Multiple regression	Change in body image and improvement in body image avoidance predicted WLM	Self-reported measures; sample included normal weight participants too

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Hoiber et al. 1982	268 men (age 33.6 ±13.5 yrs) and 923 women (36.5 ± 13.5 yrs); initial BW or BMI were not reported	USA	NA	11 week diet and exercise programme with 1 year follow up	Questionnaire assessing history of dieting, eating behaviours , health status, feelings while dieting, food obsession, motivation to diet and PAs	Multiple Regression	Change in eating behaviour, change in health status and overweight history predicted WL and WLM. Engagement with PA predicted WLM	Inconvenient weekly meetings, transportation problems were the most frequently reason for dropouts. Women also reported lack of motivation as reason of discontinuation
Holden et al. 1992	80 women, 38 men, mean age= 46.9±11.3 yrs, mean BMI= 41.1±9.2 kg/m <sup>2</sup>	USA	NA	8 weeks VLCD with behavioural modification programme and 3.3 year follow-up	Survey: emotional states, exercise and eating habits, use of programme taught behavioural skills (e.g. problem solving, assertiveness, record keeping)	Multiple regression	Problem solving, assertiveness, record keeping predicted weight change from baseline to follow-up for exercisers. Only problem solving predicted weight change in non- exercisers	Self-reported BW. It is unknown whether WL outcomes were affected by participants' attendance to other WL programmes during the 3.3 year following VLCD

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Jeffery et al. 1984	89 obese men (mean age= 52.8 yrs, mean BW=100.24 yrs)	USA	NA	15 week behavioural intervention with follow-up at 3 months, 1 and 2 years	Eating Activity Questionnaire; Knowledge; Perceived well- being; Efficacy expectations; Self-satisfaction; Eating Attributions Questionnaire; Eating and Exercise Change Questionnaire; Perceived social support; Life events	Stepwise linear regression	Pre-treatment self- weighing was inversely related to 1 year WL; Self- weighing at 1 year predicted 2 yrs WL; Baseline situational self-efficacy was predictive of initial and 1 year WL; Self- satisfaction at 1 year predicted 2 yrs WL; Attribution of obesity to heredity predicted 15 week WL. PSS from family and friends was positively associated with WL	

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Leon 1984	47 men and women (43 females, 4 males); age range= 23-62yrs (Md 41.7); F BW range 52-117 kg (Md=80); M BW range= 84-130 kg (Md=113)	USA	NA	12 week behavioural intervention with 8 month follow-up	WDH; EPQ; SEF; RAQ;LEI;MAC; RSC	Stepwise multiple regression	Number of diets tried and emotional eating were significant predictors of WL; predictors of WLM were not analysed due to a small sample at follow-up (N=22)	Dropouts reported greater history of chronic dieting than those who completed the programme
Leib- brand & Fichter 2002	109 obese men and women (% women), mean age =37.1 ±10.8 yrs, mean BMI= 44.8 ± 8.7 kg/m <sup>2</sup>	Germany	5-10% reduction	10 week cognitive- behavioural inpatient treatment program and 18 month follow up	SIAB-EX, (3rd revision) Structured Interview for Anorexia and Bulimia Nervosa; TFEQ; BSQ; BDI; SCL-90R	Multiple regression	The only significant predictor of categorical weight outcome at the 18 month follow-up was initial BMI; no significant predictors were found when the raw reduction of BMI values were used	

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Lejeune et al. 2003	40 obese male subjects (age range= 27–50yrs, mean age = 39±7.1 yrs, BMI range 29– 35kg/m <sup>2</sup> , mean BMI= 32.3±2.3 kg/m <sup>2</sup> )	Netherlands	NA	13 week energy restriction phase and WM (53 weeks)	TFEQ	Stepwsie regression	Baseline body weight and cognitive restraint predicted weight loss; increase in cognitive restraint during WL phase predicted WLM	Authors suggested that if cognitive restraint scores approach their limit (a score of 21), because of diet frequency, subsequent WLM is reduced
Linde et al. 2004	302 women (mean age= 46.7± 8.8 yrs, mean BMI= 33.9 ± 4.3 kg/m <sup>2</sup> )	USA	NA	8 weeks cognitive intervention with 3 and 18 months follow-up	Goals and Relative Weight Questionnaire; Life Orientation test (optimism); CES-D; BES;RSES (adapted version); BIA evaluation subscale of the MBRQ; Self- efficacy; Mood- emotions Q adapted from MAAC	Multiple regression	Less realistic dream BMI predicted greater WL at 18 months. Greater attendance was significantly associated with greater BMI change at 6 months andwith greater 18 month WL	The predictive value of the other psychosocial variables on WL outcomes were not tested as this was not part of study aims and hypotheses

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Linde et al. 2006	349 women, mean age= 46.9±8.6 yrs, mean BMI=33.9±4.2 kg/m <sup>2</sup>	USA	NA	8 week cognitive- behavioural intervention with a 6 month follow-up	Eating SE and exercise SE (modified items from WEL); self- weighing	Multiple regression	Baseline eating and exercise SE predicted 8 week WL; exercise SE at week 4 predicted 8 week WL; SE at 8 weeks did not predict weight change at 6 months	The impact of baseline eating SE on weight change during treatment was mediated by eating plan adherence during WL intervention
Moore et al. 2011	311 overweight/obese women, mean age= 41±6 yrs, mean BW=85±12 kg	USA	NA	6 months WL phase including four different diets (Atkins, LEARN, Ornish and Zone) and a 6 month follow up	Outcome expectations in 15 physical and psychological domains; Outcome realisations (6 months)	Simultaneo us regression	6 month positive realisations about shape and appearance predicted WLM in the Atkins group; baseline outcome expectations and initial WL were not significant predictors of WLM	No significant correlations were found between predictors and WLM in the other three diet groups

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Nakade et al. 2012	90 middle aged men (n=44) and women (n=46); mean age = 54.85 ± 6.4 yrs, mean BMI=30.95 ± 3.9 kg/m <sup>2</sup>	Japan	Maintainin g a WL of ≥ 5% or more from initial BW for 1 year	Behavioural intervention with 1 year follow up	Diet History Questionnaire; Eating behaviour (51 items) made by Japan Society for the Study of Obesity; questionnaire about stress, obstacles, support during WL programme and confidence to continue weight control behaviours (measured at the end of the programme; yes/no responses)	Logistic regression	Higher self-efficacy, higher record keeping and self- weighing assessed at the end of the programme predicted 12 month WLM	The questionnaires were completed at the 1 year follow-up and participants already knew the amount of WL, which might have affected their answers to the questionnaires

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Phelan et al. 2010	1869 overweight/obese, mean age= 40 ±3.7 yrs (47% female). 536 out of 1869 (29%) lost at least 5% of their BW between 1995- 2000; 180 (33.5%) maintained at least 75% of their WL between 2000-2005, "weight-loss maintainers"; 356 (66.4%) lost ≥5% but regained more than 25% of their WL during 2000– 2005 "weight regainers"	USA	WL ≥ 5% of BW and maintainin g ≥75%of WL	individuals who had lost ≥ 5% of their body weight during the Coronary Artery Risk Development in Young Adults (CARDIA) Study were followed up at 5 years after the end of the intervention	PA; CES-D; SF-36; Social support; State Trait Anger Expression Inventory; Reactive Responding Measure; Sleep Disturbances	Sequential hierarchical regression model	Increased emotional support (part of social support measured using 8 items from MacArthur Network) predicted WLM	Observational study

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	
Poston et al. 1999	102 obese patients (80 females mean age=42.7 $\pm$ 10.7 yrs, 22 males, mean age =43.6 $\pm$ 12.5 yrs, mean BMI of 38.6 $\pm$ 5.6 kg/m <sup>2</sup>	USA	NA	8-week weight loss program with 12 months follow-up	KSP; SCID-II- Screen Questionnaire for Personality Disorders (modified); Depression Self- Rating Scale; MADRS)	Linear and logistic regression	KSP did not predict WL after the 8-week program. Several of the	KSP scales (Muscle Tension, Monotony Avoidance, Suspicion, and Guilt) had weak associations with 12-month relapse status
Silva et al 2011	221 overweight or mildly obese females (BMI = 31.6 ± 4.1 kg/m <sup>2</sup> age=37.6 ± 7 yrs)	Portugal	NA	RCT: 1-year behaviour change intervention and a 2-year follow-up period with no intervention	HCCQ; SRQ-E	Partial Least Squares analysis	Exercise autonomous motivation both at 1 and 2 yrs predicted WL at 3 yrs. Moderate and vigorous exercise at 2 yrs had a significant effect on WL success at 3 yrs	This study was an extension of Teixeira et al.'s study (2010) reporting 2 yr follow-up data

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Teixeira et al. 2010	225 overweight or mildly obese women (age=37.6 ± 7 yrs; BMI = 31.3 ± 4.1 kg/m <sup>2</sup> )	Portugal	5 and 10% of initial weight	RCT: 1-year behaviour change intervention and a 1-year follow-up period with no intervention	ESES; BSQ; BIA; Physical Self- Perception Profile (2 scales); Exercise perceived barriers scale; TFEQ; Intrinsic Motivation Inventory; Weight Management Efficacy Questionnaire; DEBQ	Baron and Kenny's formal steps for mediation (1986), and also using a novel procedure to evaluate total, direct, and indirect intervention effects through selected multiple mediators, as described by Shrout and Bolger (2002)	Flexible cognitive restraint Disinhibition, ESE, exercise intrinsic motivation and body dissatisfaction predicted 24-month weight change, but after controlling for group membership and 12 month weight change only ESE was a significant predictor.	Lower emotional eating, increased flexible cognitive restraint, and fewer exercise barriers mediated 12- month WL. Flexible restraint and ESE mediated 24 month WL

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Vogels et al. 2005	The Maastricht Weight Maintenance Study; 91 healthy men and women (29 men and 62 women; 18 to 65 yrs of age; mean BMI= 30.2 ± 3.1 kg/m <sup>2</sup> )	Netherlands	NA	VLCD diet with at least 2 years follow up	RMR; TFEQ	Multiple regression	Increase in dietary restraint during weight loss predicted WLM	
Williams et al. 1996	128 severely obese patients (73% females), mean age=43.4± 11.8 yrs, mean BMI=41 ± 7.3 kg/m <sup>2</sup>	USA	NA	6 months Optifast WL programme (13 weeks of VLC liquid diet) and a follow-up at 23 months	GCOS; HLOC; TSRQ; HCCQ; Exercise measures	LISREL path analysis, multiple regression	Autonomous motivation predicted WL and WLM; Perceived autonomy support predicted WL	Follow-up BW was self- reported
Warziski et al. 2008	170 (88% female), mean age = 44.1± 8.8 yrs, mean BW = 95.8 ± 14.43 kg	USA	NA	18 month behavioural weight loss programme (PREFER trial); 12 months intervention followed by 6 months maintenance period with no staff contact	WEL	Linear mixed modelling	Changes in self- efficacy predicted WL	

Key: BAI: Beck Anxiety Inventory; BDI: Beck Depression Inventory; BES: Binge Eating Scale; BIA: Body Image Appearance; BIA: Body Image Assessment Questionnaire; BIA-O: Body Image Assessment for Obesity; BIA-Q: Body Image Avoidance Questionnaire; BITE: Bulimic Investigatory Test of Edinburgh; BPSS-R: Body Parts Satisfaction Scale; BSQ: Body Shape Questionnaire; BW: body weight; CES-D: Center For Epidemiological Studies Depression Scale; DEBQ; Dutch Eating Behaviour Questionnaire; DTS: Dichotomous Thinking Scale; EPDQ: Eating Pattern Descriptions Questionnaire; EPQ: Eating Patterns Questionnaire; ESES: Exercise Self-Efficacy Questionnaire; F: Female; FFQ: Food Frequency Questionnaire; GCOS: General Causality Orientations Scale; HCCQ: Health Care Climate Questionnaire; HLOC: Health Locus of Control; KSP: Karolinska Scales of Personality; LEI: Life Events Inventory; M: Male; MAAC: the Multiple Affect Adjective Check List; MAC: MacAndrews Scale; MADRS: Montgomery-Åsberg Depression Scale; MBRQ: Multidimensional Body Relations Questionnaire; MBSRQ: Multidimensional Body-Self Regulations Questionnaire; Md: median; PA: Physical Activity; POMS: Profile of Moods Scale; PSS: Perceived Social Support; RAQ: Relapse Analysis Questionnaire; RMR: resting Metabolic Rate; RSC: Rosenbaum Self-control Schedule; RSES: Rosenberg Self-Esteem Scale; SCID-II: Structured Clinical Interview for the Diagnostic and Statistical Manual; SCL-90R: Symptom Checklist for general psychopathology; SE: Self-efficacy; SEF: Self-efficacy Form; SF-36: Short Form quality of Life; SIAB-EX: Structured Interview for Anorexia and Bulimia Nervosa , 3rd revision; SRQ-E Exercise Self-Regulation Questionnaire; TFEQ: Three Factor Eating Questionnaire; TSRQ: Treatment Self- Regulation Questionnaire; VLCD: very low calorie diet; WEL: Weight Efficacy Lifestyle; WDH: Weight and Diet History Questionnaire; WL: weight loss; WLM: weight loss maintenance; Yrs: years

Table 2.5-3 Predictors of weight loss maintenance (with intervention input during maintenance phase) following different dietary
(with or without exercise) and/or behavioural interventions (eight studies).

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Befort et al. 2008	179 males and females (65.9% females), mean age=48.7 ± 9.0 yrs, mean baseline BMI= 37.6 ± 6.5 kg/m <sup>2</sup>	USA	Maintaining a WL of at least 5% below baseline	3-month WL using either a medically monitored VLCD (500 kcal/d) or LCD (1200 kcal/ d) pre- packaged meals. WLM period of 6–21 months (structured dieting plan)	Survey assessing 14 weight control behaviours (including self- monitoring behaviours) and 8 barriers	Logistic regression model	Maximum WL during study, time since treatment, exercise 30–60 min per/day and perceived difficulty of weight management were predictive of WLM	No psychosocial predictors; self- reported weight; No differences across the two diets were reported

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Fogelhom et al. 1999	85 obese women (BMI 29±46 kg/m <sup>2</sup> , mean 34 kg/m <sup>2</sup> ), clinically healthy, premenopausal, (mean age 29 ± 46 yrs)	Finland	NA	12 weeks of WL, 40 weeks WLM following VLCD and randomised to one of three PA groups (i) control (no increase in PA) (ii) walking programme to expend 1000 kcal/w or (iii) walking programme to expend 2000 kcal/w	Anthropometric data; PA; TFEQ; BITE	Stepwise linear regression	Higher hunger and higher binge eating scores predicted less WL in the WL phase. 12 week WL predicted further weight change during WLM and lower disinhibition predicted WLM	Disinhibition was positively related with hunger and binge eating during the WLM phase; No differences between groups in terms of WLM
Gorin et al. 2007	314 participants (81% women, mean age 51.3 ±10.1 yrs; BMI 28.6 ± 4.8 kg/m <sup>2</sup> ) who lost 10% of their BW within the past 2 yrs	USA	≥10% of their BW	WLM programme delivered either face- to-face or via the Internet or to a control group (newsletters about healthy eating and PA) assessed at 0, 6, 12 and 18 months	BDI; Satisfaction with current BW; Perceived cost benefits of WL; Motivation to maintain BW; Expectations and actual benefits of WL	Hierarchical linear regression	Satisfaction with current weight and discrepancies between actual and expected weight did not predict WLM	Both the internet and face-to-face interventions were effective in reducing the proportion of participants who regained BW

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Palmeira et al. 2010	142 women (BMI = 30.2 ± 3.7 kg/m <sup>2</sup> ; age = 38.3 5.8 years; 47.7% attended college) started the 16-month University- based behavioural obesity treatment programme	Portugal	5-10% WL	4 months of the same intervention, after which participants were randomized into two maintenance programs: (a) monthly meetings; (b) monthly meetings plus two structured weekend exercise sessions; or (c) to a control group with no further contact. The duration of this second phase was 12 months	BIA; BSQ; PSPP; RSE; POMS; BDI	Multiple linear regression (stepwise)	Changes in mood and body size dissatisfaction over the 4 months of intervention predicted 0-16 months weight change	Weight change during maintenance was not different amongst the three groups
Prochaska et al. 1992	184 overweight men and women (mean age 40 yrs); average % overweight was 35% (SD = 21) and varied from 10 to 114%	USA	NA	10 week structured behavioural programme followed by 4 sessions (every other week) during maintenance period	Process of changes scale; Ways of coping checklist; Stages of change questionnaire; SSS; SE Questionnaire	Stepwise multiple regression	Social support from a friend and a spouse were the best pre-treatment predictors of WLM at the end of study	Higher action scores, lower maintenance scores, lower precontemplation scores, and less reliance on self- liberation were all associated with WLM

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Sherwood et al. 1999	Combined sample of 382 women who completed one of three behavioural WL studies; 350 (78.8%) completed 18 month follow-up; Age criteria was between the ages of 25 $\pm$ 45 y in Study 1 and 25 $\pm$ 55 y in Study 2 and Study 3	USA	NA	6 month behavioural educational programme and 18 months follow up (maintenance sessions during follow up period)	PAQ; BDI; BES; Perceived barriers to adherence	Mixed model regression with time- dependent covariance analyses	Baseline binge eating was not associated with 6 month WL, but was weakly predictive of less WL success at 18 months. Changes in BES scores were significantly associated with changes in BW, but when depression was entered in the model the association was no longer significant	There were a range of treatment variations explored in these 3 studies that produced a range of mean weight changes

Authors	Sample	Country	Definition of WLM	Design/Intervention	Measures	Statistical analysis	Findings	Comments
Svetkey et al. 2012	Overweight or obese men and women; 1,685 phase I participants, 1,032 entered phase II	USA	5% WL	6 month WL (phase I) followed by 30 months WLM (phase II); adults who lost ≥4 kg in phase I were randomized into one of three WLM interventions; (a) self-directed control condition without further intervention (b) personal counselling or (c) internet-based intervention	HRQL (SF-36); PSS; PHQ-8; Social Support and Exercise and Social Support for Eating Habits; Self-reported frequency of weighing	Multiple linear regression or logistic regression	Social support for diet and exercise was inversely associated with long term WLM. Self- reported weight monitoring was not included in the regression models but it was positively correlated with more WLM	Randomized groups were combined for this analysis as the differences between the three groups were small
Wadden et al. 2011	5145 men and women	USA	≥10% WL	RCT of intensive lifestyle intervention vs usual care for 1 yr followed by 3 yrs of maintenance intervention including contact and meetings with participants	Adherence (treatment contact); PAQ; FFQ	Linear and logistic regression	Initial WL predicted WL at 4 years and WLM; greater treatment participation, daily calorie intake predicted WL at 4 years and WLM	

Key: BES: Binge Eating Scale; BDI: Beck Depression Inventory; BIA: Body Image Assessment Questionnaire; BITE: Bulimic Investigatory Test of Edinburgh; BW; Body weight; FFQ: Food Frequency Questionnaire; HRQL (SF-36): Health related quality of life- Short form -36; LCD: low calorie diet; PA: physical activity; PAQ: Paffenbarger Activity Questionnaire; PHQ-8: Personal Health Questionnaire; POMS: Profile of Moods Scale; PSPP: Physical Self-Perception Profile; PSS: Perceived Stress Scale; RCT: randomised controlled trial; RSE: Rosenberg Self-Esteem; TFEQ: Three Factor Eating Questionnaire; VLCD: very low calorie diet; w: week; WL: weight loss; WLM: weight loss maintenance; Yrs: years

Table 2.5-4 Summary of predictors and evidence of their predictive power in weight loss and weight loss maintenance (with or without intervention input during maintenance period) studies presented as a fraction.

Predictors	No of total	Weight loss	Weight loss		
	studies	studies	maintenance studies		
Eating Behaviour	27	15/261	5/7		
Depression	25	6/22	0/9		
Self-efficacy	19	12/18	5/8		
Binge eating/Eating	17	6/22	1/3		
Disorders					
Physical activity	17	8/13	9/12		
Body image	15	4/15	2/4		
Self-monitoring	14	9/10	3/6		
Self-motivation	12	5/12	3/7		
Social support	12	8/10	2/6		
Stress	9	2/7	0/5		
Self-esteem	8	0/7	0/2		
Mood	8	1/7	1/3		
Health Related quality of Life	8	5/8	0/3		
Weight loss goals/expectations	7	2/7	1/5		
Previous weight loss attempts	7	6/7	1/2		

Predictors	No of total	Weight loss	Weight loss
	studies	studies	maintenance studies
Treatment	7	7/7	3/3
adherence/attendance			
Personality	5	3/5	0/1
Initial weight loss	4	3/4	1/2
Coping with stress	4	1/3	0/2
Anxiety	3	1/2	1/1
Weight bias/attitudes	2	1/2	0/0
Quality of Sleep	2	1/1	1/1
Dichotomous thinking	2	0/1	1/1
Locus of control	1	0/1	0/1
Anger	1	0/0	0/1
Beliefs about causes of obesity	1	0/0	0/1

<sup>1</sup>Those highlighted in italics indicate those predictors with  $\geq$  50% supporting evidence across the total number of studies

## 2.6 Eating Behaviour

Eating behaviour has been mainly investigated using the Eating Inventory (EI) also known as Three Factor Eating Questionnaire (TFEQ; (Stunkard & Messick, 1985)), measuring dietary restraint, disinhibition and hunger. Disinhibition refers to a loss of control over eating in the presence of emotional, social or cognitive cues (Ohsiek & Williams, 2011). Dietary restraint refers to monitoring and limiting dietary intake in order to avoid weight gain or promote weight loss (Ohsiek & Williams, 2011) and hunger refers to feelings of hunger and food cravings (Elfhag & Rössner, 2005). Twenty-seven studies (Anton et al., 2008; Batra et al., 2013;

Bryant, Caudwell, Hopkins, King, & Blundell, 2012; Burmeister et al., 2013; Canetti et al., 2009; Cuntz, Leibbrand, Ehrig, Shaw, & Fichter, 2001; Delahanty et al., 2013; Delinsky et al., 2006; Dove et al., 2009; Eldredge & Agras, 1996; Fogelholm et al., 1999; Foster, Wadden, Vogt, & Brewer, 1997; Gladis et al., 1998; Gripeteg et al., 2010; Hainer et al., 2008; Hoiberg et al., 1984; Jakicic et al., 2002; Karlsson, Taft, Sjostrom, Torgerson, & Sullivan, 2003; Lejeune et al., 2003; Leon & Rosenthal, 1984; Nakade et al., 2012; Niemeier et al., 2007; Stotland & Larocque, 2005; Teixeira et al., 2004; Teixeira et al., 2010; Traverso, Ravera, Lagattolla, Testa, & Adami, 2000; Vogels, Diepvens, & Westerterp-Plantenga, 2005) examined eating behaviour as a predictor of weight loss and/or weight loss maintenance. Fifteen out of 26 studies examined eating behaviour as a predictor of weight loss (Batra et al., 2013; Bryant et al., 2012; Canetti et al., 2009; Delahanty et al., 2013; Delinsky et al., 2006; Fogelholm et al., 1999; Foster et al., 1997; Gripeteg et al., 2010; Hoiberg et al., 1984; Jakicic et al., 2002; Karlsson et al., 2003; Lejeune et al., 2003; Leon & Rosenthal, 1984; Stotland & Larocque, 2005; Teixeira et al., 2010) and found that eating behaviour predicted weight loss. The majority of the studies included used the TFEQ (Stunkard & Messick, 1985) to measure eating behaviour. Other measures used were the Dutch Eating Behaviour Questionnaire (DEBQ; (van Strien, Frijters, Bergers, & Defares, 1986)) (n=3), the Eating Disorders Examination Questionnaire (EDE-Q; (Fairburn & Beglin, 1994))(n=2), the Emotional Eating Scale (EES; (Arnow, Kenardy, & Agras, 1995) (n=1)), the Eating and Weight Patterns Questionnaire (EWPQ; (Spitzer et al., 1993) (n=2), the uncontrolled eating subscale of the Larocque Obesity Questionnaire (LOQ-UE; (Stotland & Larocque, 2004)) (n=1), the Eating Behaviour Inventory (EBI; (O'Neil et al., 1979)) (n=1) and a seven-item scale developed by Canetti et al. (2009) to measure emotional eating. Seven studies (Cuntz et al., 2001; Fogelholm et al., 1999; Hoiberg et al., 1984; Lejeune et al., 2003; Nakade et al., 2012; Teixeira et al., 2010; Vogels et al., 2005) assessed eating behaviour as a predictor of weight loss maintenance and five of these studies (Fogelholm et al., 1999; Hoiberg et al., 1984; Lejeune et al., 2003; Teixeira et al., 2010; Vogels et al., 2005) found that eating behaviour predicted weight loss maintenance. Lower hunger scores predicted weight loss in two studies (Batra et al., 2013; Fogelholm et al., 1999). Higher disinhibition and higher restraint scores predicted weight loss in six studies respectively. Lower emotional

eating (eating to regulate mood and in response to emotional stress or avoidance of unpleasant thoughts) predicted weight loss in five studies (Canetti et al., 2009; Gripeteg et al., 2010; Leon & Rosenthal, 1984; Stotland & Larocque, 2005; Teixeira et al., 2010). Delahanty et al. (2013) and Teixeira et al. (2010) used more than one measure to assess eating behaviour.

Although eating behaviour seems a potential predictor of weight loss and weight loss maintenance, the evidence is mixed from weight loss studies. More studies investigating the predictive power of eating behaviours in the long term is also needed. Studies have shown that dietary restraint is negatively correlated with disinhibition suggesting that the combination of high dietary restraint and low disinhibition might be a better predictor of weight loss and/or weight loss maintenance than each of these factors alone (Vogels et al., 2005). In addition, some studies have suggested that sub-factors within the scales of disinhibition (internal and external disinhibition) and dietary restraint (flexible and rigid control) scales might be better predictors of weight loss and /or weight maintenance than the total scale scores (Elfhag & Rössner, 2005). Studies have also shown that flexible control is a better predictor of successful long term weight loss than rigid control (Westenhoefer, von Falck, Stellfeldt, & Fintelmann, 2003). More studies are needed to investigate internal and external factors of disinhibition as well as flexible and rigid control. Overall, evidence suggests that the combination of low disinhibition and low levels of hunger together with high dietary restraint is associated with weight loss and weight loss maintenance. Other eating behaviours such as intuitive eating, which is eating based on physiological hunger and satiety cues rather than external and emotional cues (Tylka, 2006) might also play a role in weight loss and/or maintenance but have received less attention.

## 2.7 Emotional states (depression, mood, anxiety, anger)

Depression has been linked with overeating and weight regain. However, many weight loss studies exclude participants with clinical depression or other psychopathologies, suggesting that this variable might not be an appropriate measure to predict weight loss, due to heterogeneity of samples and lack of variance in participants scores (Stubbs et al., 2011; Teixeira et al., 2005). Depression was assessed as a predictor of weight loss and/or weight loss

maintenance in 25 studies. Depression was assessed as a predictor of weight loss in 22 studies (Anton et al., 2008; Burmeister, Hinman, Koball, Hoffmann, & Carels, 2013; Canetti et al., 2009; Poston et al., 1999; Chiriboga et al., 2008; Clarke, Freeland-Graves, Klohe-Lehman, & Bohman, 2007; Collings, Saules, & Saad, 2008; Delahanty et al., 2013; Delinsky, Latner, & Wilson, 2006; Dove, Byrne, & Bruce, 2009; C. R. Elder et al., 2012; Eldredge & Agras, 1996; Fabricatore, Wadden, & Moore, 2010; Foster, Wadden, Vogt, & Brewer, 1997; Gladis et al., 1998; A. a Gorin et al., 2007; Hainer et al., 2008; Leibbrand & Fichter, 2002; Niemeier, Leahey, Reed, Brown, & Wing, 2012; Palmeira et al., 2010; Presnell et al., 2008; Sherwood et al., 2000; Stotland & Larocque, 2005; Svetkey et al., 2012; Teixeira et al., 2002) and as a predictor of weight loss maintenance in nine studies (Poston et al., 1999; Chiriboga et al., 2008; Collings et al., 2008; Elder et al., 2012; Gorin et al., 2007; Leibbrand & Fichter, 2002; Palmeira et al., 2010; Sherwood et al., 2000; Svetkey et al., 2012). The majority of studies reviewed assessed depression using the Beck Depression Inventory (BDI; (Beck & Steer, 1987)) (n=18). Other measures used were the Center for Epidemiological Depression Scale (CES-D; (Radloff, 1977) (n=3)), the Depression Self-rating Scale (n=1; (Poston et al., 1999)), the Montgomery Asberg Depression Scale (MADRS; (Poston et al., 1999); n=1), the Personal Health Questionnaire (PHQ-9; Depression subscale; (Kroenke, Spitzer, & Williams, 2001); (n=1), the depression subscale from the Larocque Obesity Questionnaire (LOQ-D; n=1; (Larocque & Stotland, 2000)), the Hamilton Rating Scale for Depression (Ham-D; n=1; (Hamilton, 1960)) and the Mental Health Inventory (Veit & Ware, 1983). Six out of 22 studies who examined depression as a predictor of weight loss found supporting evidence (Anton et al., 2008; Delinsky et al., 2006; Dove et al., 2009; Fabricatore et al., 2010; Presnell et al., 2008; Stotland & Larocque, 2005). Nine studies assessed depression as a predictor of weight loss maintenance (Poston et al., 1999; Chiriboga et al., 2008; Collings et al., 2008; Cuntz et al., 2001; Elder et al., 2012; Gorin et al., 2007; Palmeira et al., 2010; Sherwood et al., 2000; Svetkey et al., 2012), but none found that depression predicted weight loss in the long term.

Anxiety is a more stable construct than depression, but it has received little attention as a weight loss predictor (Teixeira et al., 2004). Three studies included

in the present review assessed anxiety (Bas & Donmez, 2009; Chiriboga et al., 2008; De Panfilis et al., 2007). Bas et al. (2009) used both the State-Trait Anxiety Inventory (STAI; (Spielberger, Gorsuch & Lushene, 1970)) and the Social Physique Anxiety Scale (SPAS; (Hart, Leary & Rejeski, 1989)) to assess anxiety related to real or perceived evaluation of others and they found that scores in both tests predicted weight loss at 20 weeks. DePanfillis et al. (2007) used the Hamilton Rating Scale for Anxiety (Ham-A; (Hamilton, 1959)) to predict weight loss but did not find supporting evidence. Chiriboga et al. (2008) used the Beck Anxiety Inventory (BAI; (Beck, Epstein, Brown & Steer, 1988)) and found that increases in anxiety scores over 1 year predicted weight gain only for men and not for women. Higher baseline depression and anxiety scores were associated with higher body weight only among women, only when depression or anxiety were considered separately in the model. However, they lost statistical significance when both were included in the model as anxiety was highly correlated with depression.

Mood was assessed in eight studies (Annesi & Gorjala, 2010; Anton et al., 2008; Barnstuble et al., 1986; Gripeteg et al., 2010; Karlsson et al., 2003; Linde et al., 2004; Palmeira et al., 2010; Tseng et al., 2002) using the Profile of Moods Scale (POMS; (McNair, Lorr & Droppleman, 1971)), the Mood Adjective Checklist (MACL; (Sjoberg, Svensson, & Persson, 1979)), the Total Mood Disturbance (aggregative scores from six subscales of POMS), the General Health Questionnaire (GHD; (Goldberg & Hillier, 1979)) and the Emotions Questionnaire (Higgins, Klein, & Strauman, 1985), a set of scales adapted from the Multiple Affect Adjective Check List ((Zuckerman, 1965). One study out of 7 found that mood predicted weight loss (Anton et al., 2008) and one (Palmeira et al., 2010) out of three studies (Barnstuble et al., 1986; Linde et al., 2004; Palmeira et al., 2010) which included a follow-up period found evidence that mood is a significant predictor of weight loss maintenance. Palmeira et al. (2010) found that changes in mood (assessed using POMS) over the first four months of the intervention predicted weight loss at 16 months and Anton et al. (2008) using the General Health Questionnaire found that negative mood states predicted less weight loss over six months.

Only one study (Phelan, Wing, Loria, Kim, & Lewis, 2010) included in the review assessed anger as a predictor of weight loss maintenance. Phelan et al. (2010) using the State Trait Anger Expression Inventory (Spielberger, 1999) failed to find evidence that anger predicted weight loss maintenance.

There was limited evidence to suggest that depression/mood is a predictor of weight loss and/or weight loss maintenance. Moderate to severe symptoms of depression were found to be a significant predictor of adherence to a dietary weight loss intervention, highlighting the possibility that depression scores might be useful for characterising, screening and allocating participants to appropriate treatments (Somerset, Graham, & Markwell, 2011a). Blaine, Rodman & Newman (2007) in a meta-analysis found that weight loss treatments resulted in reductions in depression scores and this was independent of changes in weight that occurred as a result of treatment. They argued that depression is causally prior to weight change, but nevertheless improves with psychotherapeutic attention in the context of weight loss treatment. It is likely that depression causes weight gain, perhaps through more binge eating and/or less activity, which in turn causes self-esteem decrements.

## 2.8 Self-efficacy

Self-efficacy is defined as the beliefs that people hold regarding whether they can achieve and maintain states or situations (Byrne et al., 2003). Nineteen studies (Annesi & Gorjala, 2010; Bas & Donmez, 2009; Bernier & Avard, 1986; Burmeister, Hinman, Koball, Hoffmann, & Carels, 2013; Byrne et al., 2012; Canetti et al., 2009; Choo & Kang, 2015; Clarke, Freeland-Graves, Klohe-Lehman, & Bohman, 2007; Delahanty et al., 2011; Jeffery et al., 1984; Leon & Rosenthal, 1984; Linde et al., 2006; Nakade et al., 2012; Presnell et al., 2008; Prochaska, Norcross, Fowler, Follick, & Abrams, 1992; Teixeira et al., 2008; Prochaska, Norcross, Fowler, Follick, & Abrams, 1992; Teixeira et al., 2008) included in this review assessed self-efficacy as a predictor of weight loss and/or weight loss maintenance. Twelve out of 18 studies examined weight loss (Annesi & Gorjala, 2010; Bas & Donmez, 2009; Bernier & Avard, 1986; Byrne et al., 2012; Choo & Kang, 2015; Delahanty et al., 2011; Jeffery et al., 1984; Linde et al., 2006; Presnell et al., 2008; Teixeira et al., 2008; Teixeira et al., 2008; Teixeira et al., 2010; Wamsteker et al., 2005; Warziski et al., 2006; Presnell et al., 2008; Teixeira et al., 2010; Wamsteker et al., 2005; Warziski et al., 2006; Presnell et al., 2008; Teixeira et al., 2010; Wamsteker et al., 2005; Warziski et al., 2008; Presnell et al., 2008; Teixeira et al., 2010; Wamsteker et al., 2005; Warziski et al., 2008; Presnell et al., 2008; Teixeira et al., 2010; Wamsteker et al., 2005; Warziski et al., 2008; Nerviski et al., 2010; Wamsteker et al., 2005; Warziski et al., 2008; Teixeira et al., 2010; Wamsteker et al., 2005; Warziski et al., 2008; Nerviski et al., 2010; Wamsteker et al., 2005; Warziski et al., 2008; Nerviski et al., 2008; Teixeira et al., 2010; Wamsteker et al., 2005; Warziski et al., 2008; Nerviski et al., 2008; Nervis

& Avard, 1986; Jeffery et al., 1984; Nakade et al., 2012; Teixeira et al., 2010; Warziski et al., 2008) out of eight studies (Bernier & Avard, 1986; Jeffery et al., 1984; Leon & Rosenthal, 1984; Linde et al., 2006; Nakade et al., 2012; Prochaska et al., 1992; Teixeira et al., 2010; Warziski et al., 2008) which assessed self-efficacy as a predictor of weight loss maintenance found supporting evidence. Eating self-efficacy was frequently assessed with the Eating Self-Efficacy Scale (Glynn & Ruderman, 1986) and the Weight Efficacy Life-Style Questionnaire (WEL) (Clark, Abrams, Niaura, Eaton, & Rossi, 1991), which are considered useful tools to measure self-efficacy in obesity, especially for clinicians working with weight management programmes. Other measurements used included the Self-Efficacy Form (SEF; (Leon & Rosenthal, 1984)), the Eating Behaviour Self-Efficacy scale from the Obesity Psychosocial State questionnaire (Larsen et al., 2003), the Shapiro Control Inventory (SCI; (Shapiro, 1994)) and the Exercise Self-efficacy Scale (ESES; (Sallis, Pinski, Grossman, Patterson, & Nader, 1988)). Two studies (Jeffery et al., 1984; Nakade et al., 2012) used item sets specifically designed for the studies to measure self-efficacy.

There is considerable evidence to suggest that self-efficacy is a predictor of weight loss. The evidence for weight loss maintenance is limited due to a smaller sample of studies. In addition, it is not clear whether baseline self-efficacy or changes in self-efficacy are better predictors of weight loss success. Some studies have shown that pre-treatment diet self-efficacy predicts weight loss (Prochaska et al., 1992), while others found that changes in exercise self-efficacy were more important than baseline diet and exercise self-efficacy in achieving weight loss (Byrne et al., 2012).

## 2.9 Binge eating

Binge eating is defined as a pattern of overeating episodes followed by feelings of loss of control, culpability and attempts to restrict eating to lose weight (Linde et al., 2004). Seventeen studies (Anton et al., 2008; Bonato & Boland, 1987; Burmeister et al., 2013; Delahanty et al., 2011; Delinsky et al., 2006; Dove et al., 2009; Eldredge & Agras, 1996; Foster et al., 1998; Gladis et al., 1998; Kiernan et al., 1998; Leibbrand & Fichter, 2002; Presnell et al., 2008; Rotella et al., 2014; Sherwood et al., 1999; Teixeira et al., 2002, 2004; Traverso et al., 2000; Tseng et al., 2002) included in the review assessed binge eating as a predictor of weight loss and six of these studies (Anton et al., 2008; Gladis et al., 1998; Presnell et al., 2008; Rotella et al., 2014; Sherwood et al., 1999; Traverso et al., 2000) found that binge eating predicted weight loss. Three out seventeen studies (Bonato & Boland, 1987; Leibbrand & Fichter, 2002; Sherwood et al., 1999) included a follow up and only Sherwood et al., (1999) found that binge eating was weakly associated with weight loss maintenance. Sevent studies used the Binge Eating Scale (BES) to measure binge eating. Other measures used were the Questionnaire on Eating and Weight Patterns-Revised (QEPW-R; n=3; (Spitzer & Yanovski, 1993)), the Multiaxial Assessment of Eating Disorder Symptoms (Martin, Williamson, & Thaw, 2000)), the Eating Disorder (MAEDS; n=1; Examination Questionnaire (EDE-Q; n=3; (C G Fairburn & Beglin, 1994)), the Structured Interview for Anorexia and Bulimia Nervosa, (SIAB-EX; n=1; (Fichter, Herpertz, Quadflieg, & Herpertz-Dahlmann, 1998)), the Bulimic Investigatory Test Edinburgh (BITE; n=2; (Henderson & Freeman, 1987)) and the Eating Disorder Inventory (EDI; n=1; (Garner, Olmstead, & Polivy, 1983)). Two studies assessed binge eating using self- reported measures (Bonato & Boland, 1987; Kiernan et al., 1998) and two studies assessed binge eating episodes using more than one measure (Delinsky et al., 2006; Gladis et al., 1998).

There is not enough evidence to conclude that binge eating is a good predictor of weight loss, although it is possible that obese binge eaters, respond better to some types of treatment than to others (Gladis et al., 1998). Evidence on the relationship between binge eating and weight loss maintenance is also limited (Pacanowski, Senso, Oriogun, Crain, & Sherwood, 2014). However, several studies have found that individuals who engage in binge eating regain weight faster than non-bingers (Pacanowski et al., 2014). Burmeristeir et al. (2013) suggested similarities between food addiction and binge eating. Additionally studies have shown that compared to binge eating, food addiction was more strongly related to psychological factors that may affect weight loss such as emotional eating, depression, trait impulsivity, emotion regulation, self-esteem and prevalence of mood disorders (Gearhardt et al., 2012). Gearhardt et al. (2012) argue that food addiction is an overlapping, but distinct construct from binge eating and is largely indicative of more severe eating and psychological maladjustment. In addition, it has been argued that there is a relationship between binge eating and depression and that this is more evident for women (Pacanowski et al., 2014). It has also been documented that participants who binge eat are more likely to drop out of treatment programmes, which may hinder potential relationships that exist between binge eating and weight loss outcomes (Pacanowski et al., 2014). Another issue with binge eating behaviour is that it varies over time and measurements need to be taken at multiple time points in order to capture all those experiencing symptoms (Pacanowski et al., 2014). It has also been found that assessment of binge eating status covaries with weight loss and regain (Stubbs et al., 2011).

## 2.10 Physical activity

Physical activity was assessed in seventeen studies (Barnstuble, Klesges, & Terbizan, 1986; Shannon Byrne et al., 2012; Chiriboga et al., 2008; Delahanty et al., 2013; Fogelholm, Kukkonen-Harjula, & Oja, 1999; French et al., 1994; Hoiberg, Berard, Watten, & Caine, 1984; Holden et al., 1992; Hollis et al., 2008; Jakicic, Wing, & Winters-Hart, 2002; Jeffery et al., 1984; Linde et al., 2006; Phelan et al., 2010; Sherwood, Jeffery, & Wing, 1999; Silva et al., 2011; Wadden et al., 2011; Williams, Grow, Freedman, Ryan, & Deci, 1996b). Eight (Delahanty et al., 2013; Fogelholm et al., 1999; French et al., 1994; Hollis et al., 2008; Jakicic et al., 2002; Sherwood et al., 1999; Wadden et al., 2011; G. C. Williams et al., 1996a) out of thirteen studies which assessed physical activity as a predictor of weight loss found supporting evidence. Twelve studies assessed physical activity as a predictor of weight loss maintenance (Barnstuble et al., 1986; Chiriboga et al., 2008; Fogelholm et al., 1999; Hoiberg et al., 1984; Holden et al., 1992; Jeffery et al., 1984; Linde et al., 2006; Phelan et al., 2010; Sherwood et al., 1999; Silva et al., 2011; Wadden et al., 2011; Williams et al., 1996b) and eight studies (Chiriboga et al., 2008; Fogelholm et al., 1999; Hoiberg et al., 1984; Jeffery et al., 1984; Sherwood et al., 1999; Silva et al., 2011; Wadden et al., 2011; Williams et al., 1996b) found that those who engaged in physical activity maintained their weight loss. In addition, Phelan et al. (2010) using the Cardia Physical Activity Questionnaire, reported trends for maintainers to engage in slightly less physical activity. Other measures used to assess physical activity included pedometers (Byrne et al., 2012; Fogelholm et al., 1999), daily logs/records (Barnstuble et al., 1986; Fogelholm et al., 1999; Hoiberg et al., 1984; Hollis et al., 2008; Wadden et

al., 2011), the Paffenbarger Activity Questionnaire (Jakicic et al., 2002; Linde et al., 2006; Sherwood et al., 1999; Wadden et al., 2011), Physical Activity Recall interviews, the Modifiable Activity Questionnaire (Delahanty et al., 2013), the Low Level Physical Activity questionnaire (LOPAR; (Kriska et al., 2006))(Delahanty et al., 2013), the Eating Activity Questionnaire (Jeffery et al., 1984), the Exercise Change Questionnaire (Jeffery et al., 1984) and the 7-day Physical Activity recall (Blair et al., 1985). Barriers and/or obstacles to habitual physical activity were assessed with the Exercise Perceived Barriers scale (Steinhardt & Dishman, 1989) in two studies (Teixeira et al., 2010; Teixeira et al., 2002) and they both found that fewer perceived barriers predicted weight loss.

#### 2.11 Body image

Body image is a multidimensional construct which includes cognitive, perceptual and behavioural dimensions (Teixeira et al., 2004). Different measures have been used to assess body image which has resulted in mixed findings. Fifteen studies (Traverso et al., 2000; Anton et al., 2008; Bas & Donmez, 2009; Burmeister et al., 2013; Clarke et al., 2007; Collings et al., 2008; Delinsky et al., 2006; Dove et al., 2009; Kiernan et al., 1998; Leibbrand & Fichter, 2002; Lynch et al., 2009; Palmeira et al., 2010; Rotella et al., 2014; Teixeira et al., 2010; Teixeira et al., 2002;2004) included in the present review assessed body image. Body image was assessed using the Body Shape Questionnaire (BSQ; n=7; (Cooper, Taylor, Cooper, & Fairburn, 1987)), the Eating Disorders Inventory (EDI; n=1;(Garner et al., 1983)), the Body Image Assessment guestionnaire (BIA; n=3; (Williamson, Davis, Bennett, Goreczny, Gleaves, 1989)), the Body Image Assessment for Obesity (BIA-O; n=1; (Williamson et al., 2000)), the Body Image Avoidance Questionnaire (BIAQ; n=1; (Rosen, Srebnik, Saltzberg, & Wendt, 1991)), the Multidimensional Body self-related questionnaire (MBSRQ; n=3; (Cash, 2000)), the Body Attitude Questionnaire (BAQ; n=1; (Ben-Tovim & Walker, 1991)), the Eating Disorder Examination-Questionnaire (EDE-Q; n=3; (Fairburn & Beglin, 1994)), the Stunkard Figure rating scale (n=1; (Stunkard, Sorensen & Schulsinger, 1983)), the Objectified Body Consciousness Scale-Body Shame (OBCS-Shame; n=1; (McKinley & Hyde, 1996)), the Body Parts Satisfaction Scale (BPSS-R; n=1; (Berscheid, Walster & Bohmstedt, 1973)), the Physical Self-Perception Profile (PSPP; n=1; (Fox & Corbin, 1989)) and the Body Cathexis Questionnaire (n=1; (Secord & Jourard, 1953)). Six of the studies used more than one method to assess body image (Barte et al., 2010; Burmeister et al., 2013; Collings et al., 2008; Palmeira et al., 2010; Teixeira et al., 2002; Traverso et al., 2000). Four out of fifteen studies (Collings et al., 2008; Leibbrand & Fichter, 2002; Palmeira et al., 2010; Teixeira et al., 2010) investigated body image as a predictor of weight loss maintenance and two studies found that body image was a significant predictor of weight loss maintenance (Collings et al., 2008; Palmeira et al., 2010). Four (Kiernan et al., 1998; Lynch et al., 2009; Teixeira et al., 2002; Traverso et al., 2000) out of fifteen studies which examined body image as a predictor of weight loss found evidence to support this.

Considering the diversity in the measurements used to assess body image and the complexity of the construct itself, there is not enough evidence to suggest that body image is a significant predictor of weight loss and weight loss maintenance.

## 2.12 Self-monitoring and self-weighing

Self-monitoring is the continuous observation and recording of specific behaviours, which can increase self-awareness and consequently influence eating behaviours (Burke et al., 2006). Fourteen studies included in this review, examined self-monitoring as a predictor of weight loss and/or weight loss maintenance (Abildso et al., 2014; Batra et al., 2013; Befort et al., 2008; Byrne et al., 2004; Fabricatore et al., 2010; Holden et al., 1992; Hollis et al., 2008; Jeffery et al., 1984; Karlsen et al., 2013; Kiernan et al., 1998; Kong, Beresford, Imayama, et al., 2012; Nakade et al., 2012; Svetkey et al., 2012; Williamson et al., 2010). Of these 14 studies, 10 studies examined weight loss and six studies (Befort et al., 2008; Byrne et al., 2004; Holden et al., 1992; Jeffery et al., 1984; Nakade et al., 2012; Svetkey et al., 2012) included a follow-up period. Self-monitoring was found to be a significant predictor of weight loss in nine studies (Abildso et al., 2014; Batra et al., 2013; Fabricatore et al., 2010; Hollis et al., 2008; Jeffery et al., 1984; Karlsen et al., 2013; Kiernan et al., 1998; Kong, Beresford, Alfano, et al., 2012; Williamson et al., 2010) and a significant predictor of weight loss maintenance in three out of six studies (Holden et al., 1992; Jeffery et al., 1984; Nakade et al., 2012). Self- monitoring was measured usually by the amount of food diary records completed or the frequency of self-reported self-weighing.

Self-monitoring was found to be a more consistent predictor of weight loss rather than weight loss maintenance. Self-monitoring is considered a factor that mediates weight loss rather than an important component of behavioural interventions (Burke et al., 2006). Kong et al. (2012) found that self-monitoring behaviours varied by race/ethnicity status, education and binge eating scores, supporting the hypothesis that there are differences between those who adopt self-monitoring strategies and those who do not (Kong, Beresford, Alfano, et al., 2012). Burke, Wang and Sevick, (2011) conducted a systematic review of 22 studies which reported self-monitoring of diet, physical activity and self-weighing. They found a significant association between self-monitoring and weight loss. However, Burke et al. (2011) considered the level of evidence to be weak due to methodological limitations and the use of descriptive designs with few randomised controlled trials. A further limitation was the lack of any criteria to assess self-monitoring (Burke, Wang, & Sevick, 2011). Another problem related to self-monitoring is poor adherence and people reporting behaviours long after they have engaged in them (i.e. retrospectively), which increases recall bias. Butryn et al. (2007) investigated whether frequency of self-weighing in participants from the National Weight Control Registry (NWCR) predicted weight maintenance at 1 year follow up. Those who decreased the frequency of selfweighing were more likely to show increases in fat intake, disinhibition and decreases in cognitive restraint. It is possible that frequent self-weighing might help people to address small changes in weight before they escalate and to make changes to avoid further weight gain (Butryn, Phelan, Hill, & Wing, 2007). However, the required or optimal frequency of self-monitoring and/or selfweighing to promote weight loss and/or weight loss maintenance success remains to be established.

#### 2.13 Motivation

Self-motivation is a trait-like construct conceptualized as "a behavioural tendency to persevere independently from situational reinforcements" (Lazzeretti et al., 2015, pg. 58). Twelve studies included in the review assessed motivation as a predictor of weight loss (Anton et al., 2008; Barnstuble et al., 1986; Cresci et al., 2013; Gorin et al., 2007; Hoiberg et al., 1984; Kong et al., 2010; Martin et al., 2002; Rotella et al., 2014; Silva et al., 2011; Teixeira et al., 2010; Teixeira et al.,

2002; Williams et al., 1996a). Five of these studies (Cresci et al., 2013; Martin et al., 2002; Rotella et al., 2014; Teixeira et al., 2002; Williams et al., 1996b) found evidence to support that motivation is predictive of weight loss. Seven (Barnstuble et al., 1986; Gorin et al., 2007; Hoiberg et al., 1984; Martin et al., 2002; Silva et al., 2011; Teixeira et al., 2010; Williams et al., 1996b) out of the twelve studies included both weight loss and weight loss maintenance outcomes and the remaining five assessed only weight loss outcomes. Three (Silva et al., 2011; Teixeira et al., 2010; Williams et al., 1996b) out of seven studies found that motivation was a significant predictor of weight loss maintenance. Motivation was assessed with nine different measures in the studies included. These measures included Dishman's motivation scale (Dishman & Ickes, 1981), the Motivation and Readiness scale (MARS-WL; (Drab, Greenway, Mayville, Martin & York-Crowe, 2001)), the Treatment Self-Regulation Questionnaire (Ryan, Plant, & O'Malley, 1995), the Intrinsic Motivation Inventory (IMI; (McAuley, Duncan, & Tammen, 1989)), the Exercise Self-Regulation Questionnaire (Saelens et al., 2000), the Weight Loss Readiness tool (Norcross, 2002), the Dieting Readiness Test (DRT; (Brownell, 1990)) and the Self-Motivation Inventory (SMI; (Dishman & Ickes, 1981)). Recently the Treatment Motivation and Readiness Test (TRE-MORE; (Cresci et al., 2011)) was developed and found to predict weight loss. However, in a more recent study, the same authors found that the test only seems to be capable of predicting weight loss in men. Since this questionnaire has only been published in the last few years, it has not yet been widely used or tested in populations different from those used for its validation. Further two studies (Gorin et al., 2007; Hoiberg et al., 1984) used either single or multiple non validated item(s) to assess motivation and failed to predict weight loss and weight loss maintenance.

Lazzeretti et al. (2015) suggested that self-motivation is a predictor of weight loss success with consistent evidence. However, the present findings showed a different pattern. Only half of the studies that examined motivation as a predictor of weight loss found evidence to support its predictive power. Similar findings were observed with weight loss maintenance. Furthermore, no consistent measure was used across studies. Silva et al. (2011) have, however, suggested that not all types of motivation predict long-term behavioural outcomes and that

autonomous regulations (i.e. when individuals act based on volition rather than pressure reflecting an acceptance of the personal importance and meaningfulness of one's current goals) are the critical intermediate mechanisms.

#### 2.14 Social support

Social support is considered a key component of behavioural weight-loss programmes (Kiernan et al., 2012). Given that social contexts can both help and impede weight-loss efforts, programmes frequently teach strategies to elicit support and manage interference from friends and family (Kiernan et al., 2012). Twelve studies (Abildso, Zizzi, & Fitzpatrick, 2013; Canetti et al., 2009; Clarke et al., 2007; Jeffery et al., 1984; Kiernan et al., 1998; Kiernan et al., 2012; Nakade et al., 2012; Phelan et al., 2010; Prochaska et al., 1992; Svetkey et al., 2012; Teixeira et al., 2002; Williams et al., 1996a) included in this review measured social support. Ten studies (Abildso et al., 2013; Canetti et al., 2009; Clarke et al., 2007; Jeffery et al., 1984; Kiernan et al., 1998; Kiernan et al., 2012; Prochaska et al., 1992; Svetkey et al., 2012; Teixeira et al., 2002; Williams et al., 1996a) assessed social support as a predictor of weight loss and two studies (Kiernan et al., 1998; Teixeira et al., 2002) failed to find that social support predicted weight loss. Teixeira et al. (2002; 2004) used the same questionnaire as Svetkey et al. (2012) to measure exercise social support but failed to find supportive evidence for its predictive value in weight loss. Canetti et al. (2009) found that social support was predictive of weight loss only for the dieting group but not for the surgery group, suggesting that social support could be a predictor of outcome following certain types of programmes. Williams et al. (1996a) found that perceived autonomy social support (i.e. when significant others offer choice, provide a meaningful rationale, less pressure, and acknowledge the individual's feelings and perspective) provided by the intervention team and not by family/peers was important for 6 months weight loss success. Six out of the eleven studies (Jeffery et al., 1984; Nakade et al., 2012; Phelan et al., 2010; Prochaska et al., 1992; Svetkey et al., 2012; Williams et al., 1996a) examined social support as a predictor of weight loss maintenance and two found (Phelan et al., 2010; Svetkey et al., 2012) supportive evidence, but in the opposite direction. Svetkey et al. (2012) using the social support for exercise and eating scale (Sallis, Grossman, Pinski, Patterson, & Nader, 1987) found that social

support was inversely associated with weight loss maintenance. Phelan et al. (2010) also found social support a significant predic of weight loss maintenance but in the opposite direction than Svetkey et al. (2012). They found that increased social support predicted greater weight loss maintenance. Nakade et al. (2012) who did not find that social support was predictive of weight loss maintenance assessed the concept by a single item question (yes/no response) at the end of the intervention. Other measures used to assess social support was the Social Support Scale (Mermelstein, Lichtenstein, & McIntyre, 1983; Walker, 1997), the Social Support for healthy eating and physical activity subscales (Ball & Crawford, 2006), the Receiving Social Support Scale (Abbey, Abramis & Caplan, 1985), the Perceived Social Support Scale (Kiernan 1998) the General Social Support and strain subscales (Walen & Lachman, 2000). Kiernan et al. (2012) used more than one measure to assess social support. Social support appears to be a significant predictor of weight loss, but there is not enough evidence to suggest that social support is significant predictor of weight loss maintenance. Also the type of support e.g. whether it is from family or intervention staff and whether it is promoting autonomy or control over behaviours might play a role and this needs to be investigated in future studies.

## 2.15 Stress and coping skills

Research suggests that people tend to eat in response to stressful or negative events and also eat to regulate mood (Elfhag & Rössner, 2005; Ohsiek & Williams, 2011). Stress was assessed as a predictor of weight loss and/or weight loss maintenance in nine studies (Clarke et al., 2007; Delahanty et al., 2013; Elder et al., 2012; Kiernan et al., 1998; Nakade et al., 2012; Phelan et al., 2010; Prochaska et al., 1992; Stotland & Larocque, 2005; Svetkey et al., 2012). Two (Elder et al., 2012; Stotland & Larocque, 2005) out of seven studies (Clarke et al., 2007; Delahanty et al., 2013; Elder et al., 2006; Kiernan et al., 1998; Prochaska et al., 2005; Stotland & Larocque, 2005; Svetkey et al., 2008) that examined stress as predictor of weight loss found that stress predicted weight loss. Five studies (Elder et al., 2006; Nakade et al., 2012; Phelan et al., 2010; Prochaska et al., 2004; Svetkey et al., 2008) that assessed stress as predictor of weight loss maintenance failed to find evidence to support this. Stress was

assessed by different methods such as the perceived stress scale (PSS; (Cohen, Kamarck, & Mermelstein, 1983)) (Clarke et al., 2007; Elder et al., 2006; Kiernan et al., 1998), the stress scale (Walker, 1997), the ways of coping checklist (Lazarus & DeLongis, 1983), questionnaire about stress/obstacles (two items designed for the study; (Nakade et al., 2012)), the stress response scale from LOQ (LOQ-S; (Larocque & Stotland, 2000)), the reactive responding measure (Taylor & Seeman, 1999), the Perceived Stress Questionnaire (PSQ; (Levenstein et al., 1993)) and the Sense of Coherence Scale (SOC; (Eriksson & Lindström, 2006)), which measures individual's ability to respond to stressful situations.

Four studies examined skills for coping with stress (Karlsen et al., 2013; Phelan et al., 2010; Prochaska et al., 2004; Stotland & Larocque, 2005) and only one of 3 studies that examined weight loss found that coping with stress (Stotland & Larocque, 2005) was predictive of weight loss.

The evidence for the predictive value of stress and/or coping skills was mixed. It has been suggested that the coping strategies that people use to deal with stressful events are more important than the number of the stressors or the stressors themselves (Elfhag & Rössner, 2005; Stubbs et al., 2011). Byrne et al. (2003) in a qualitative study found that weight regainers reported eating as a means of coping with stress. Stressful events such as bereavement, major illnesses, family problems or a busy schedule are amongst many life events that have been reported by weight regainers as the potential reasons for their relapse (Elfhag & Rössner, 2005). Elfthag and Rössner (Elfhag & Rössner, 2005) argued that people who manage to maintain their weight loss are those who have developed some coping skills and a support group that help them to deal with small "slips" without resorting to food for comfort. Studies have shown that maintainers, as compared to regainers, tend to seek less support from family or friends and use more effective coping strategies to deal with stressors, such as being more active, relaxation techniques or skills that they learnt during the weight loss intervention (Elfhag & Rössner, 2005). However, responses to life events might differ not only between people, but also within people at different times. For some people life events might be the reasons for behaviour change. Epiphaniou and Ogden (Epiphaniou & Ogden, 2010) argued that life events can promote behaviour change for people, when certain conditions are met. If people

feel that their choices and the function of their past unhealthy behaviours are disrupted and they believe that behavioural solutions will be effective, then behaviour change might happen (Epiphaniou & Ogden, 2010).

## 2.16 Self-esteem

Self-esteem has been defined as "a personal judgment of the worthiness that is expressed in the attitudes the individual holds towards himself" (Lazzereti et al., 2015, pg. 61). Seven studies assessed self-esteem as a predictor of weight loss and/or weight loss maintenance. Seven studies (Bas & Donmez, 2009; Canetti et al., 2009; Delinsky, Latner, & Wilson, 2006; Eldredge & Agras, 1996; Gripeteg et al., 2010; Palmeira et al., 2010; Teixeira et al., 2002; 2004) assessed the predictive value of self-esteem for weight loss. All of the studies included in the review utilised the Rosenberg Self Esteem Scale which has been used frequently to evaluate self-esteem (RSES; (Rosenberg, 1965)). RSE measures global selfesteem, whereas other instruments such as the Coopersmith Self-Esteem Inventory and the Tennessee Self-Concept scale (Coopersmith, 1967), which have been used only sporadically in obesity research, are multidimensional. They measure self-concept (of which self-esteem is just one component) and the subdomains of self-esteem (performance, social, and physical self-esteem). Two out of the seven studies (Collings et al., 2008; Palmeira et al., 2010) included a followup period. Although self-esteem has been found to be correlated with weight loss outcomes, none of the studies included found that self-esteem was a significant predictor of weight loss or weight loss maintenance.

## 2.17 Health Related Quality of Life

Health Related Quality of Life (HRQoL) refers to the psychological, physical and social areas of health, which are affected by individuals' experiences, beliefs, expectations, and perceptions (Testa & Simonson, 1996). Eight studies assessed health related quality of life (HRQoL) as a predictor of weight loss and/or weight loss maintenance (Anton et al., 2008; French et al., 1994; Gripeteg et al., 2010; Karlsen et al., 2013; Phelan et al., 2010; Rotella et al., 2014; Svetkey et al., 2012; Teixeira et al., 2004). Five (Anton et al., 2008; Gripeteg et al., 2010; Karlsen et al., 2013; Rotella et al., 2014; Teixeira et al., 2002) out of eight studies (Anton et al., 2010; Jeffery et al., 2002) out of eight studies (Anton et al., 2008; Gripeteg et al., 2013; Phelan

et al., 2010; Rotella et al., 2014; Svetkey et al., 2012; Teixeira et al., 2002) who examined quality of life (QoL) as predictor of weight loss found that HRQoL predicted weight loss. Only three studies (Jeffery et al., 1984; Phelan et al., 2010; Svetkey et al., 2012) examined HRQoL as a predictor of weight loss maintenance and they failed to confirm this. The most widely generic tool used to measure guality of life is the SF-36 (Ware, Snow & Kosinski, 1993), which measures eight non-disease-specific domains. SF-36 was used in six out of the eight studies, and two studies found evidence to support that quality of life as measured by SF-36 predicted weight loss. Karlsen et al. (2013) used both the SF-36 and the Obesity and Weight Loss Quality Of Life (OWLQOL; (Patrick, Bushnell, & Rothman, 2004)) questionnaire and found that mental HRQoL status predicted weight loss at 1 year. Gripeteg et al. (2010) used the SF-36 (Ware, Snow, Kosinsk, & Gandek, 1993), the Impact of Weight on Quality of Life (IWQOL; (Kolotkin & Crosby, 2002)), the Obesity Functional health scale (OF; (Karlsson, Sjöström, 2000)) to measure condition specific functional health and the Obesity-related Problems scale (OP; (Karlsson et al., 2003)) to measure the impact of obesity on psychosocial functioning. They found that in women, successful outcome was predicted by less obesity-related psychosocial dysfunction (OP) and better physical health (SF-36), whilst in men greater weight loss was predicted by better functioning in social interaction (OF Social interaction) and ambulation capacity (OF Ambulation capacity). Teixeira et al. (2002;2004) used the SF-36 (Ware, Snow, Kosinsk, & Gandek, 1993) and the IWQOL and found that higher weight related quality of life predicted greater weight loss. Anton et al. (2008) used the General Health Questionnaire (GHQ; (Goldberg & Hillier, 1979)) and found that higher scores predicted less weight loss at 6 months. In total, four studies (Gripeteg et al., 2010; Karlsen et al., 2013; Rotella et al., 2014; Teixeira et al., 2002) used more than one method to measure QoL. Rottella et al. (2014) used the Symptom Checklist 90-Revisited (Derogatis, 1986) and Obesity related wellbeing (Orwell 97; (Mannucci et al., 1999)) questionnaire and found that somatisation (i.e. tendency to report somatic symptoms in the absence of a medical problem) scores predicted weight loss. Overall, HRQoL tends to be a significant predictor of weight loss but the evidence is limited for weight loss maintenance.

## 2.18 Weight loss goals/expectations

Seven studies reviewed examined weight loss goals and/or expectations as predictors of weight loss and/or weight loss maintenance (Bonato & Boland, 1987; Oettingen & Wadden, 1991; Bernier & Avard, 1986; Gorin et al., 2007; Linde et al., 2004; Moore et al., 2011). In terms of weight loss, two out of seven studies (Bonato & Boland, 1987; Oettingen & Wadden, 1991) found that goal expectations predicted weight loss. Teixeira et al. (2002) found an association between unrealistic expectations and weight loss, but no significant predictors. Five of these studies included a weight maintenance period (Bernier & Avard, 1986; Bonato & Boland, 1987; Gorin et al., 2007; Linde et al., 2004; Moore et al., 2011), and only Linde et al. (2004) found that unrealistic weight loss goals were positively related to long-term weight loss success (18 months follow-up), but were not predictive of initial weight loss. In contrast, Teixeira et al. (2004) found a negative association between unrealistic weight loss at 16 months follow up.

People entering any type of behavioural intervention have high hopes, expectations and sometimes unrealistic goals. It has been suggested that people with unrealistic weight loss expectations/goals are at higher risk of regaining weight after undertaking a weight loss intervention (Ohsiek & Williams, 2011). Results from studies investigating unrealistic weight loss expectations are mixed with some studies showing an association between unrealistic expectations and weight loss maintenance (Linde et al., 2004; Teixeira et al., 2004) and others not (Ames et al., 2005; Finch et al., 2005). Although having high expectations might be a good motivator at the start of any intervention, if people feel that the outcomes do not match their initial expectations, they are more likely to discontinue with the behaviour changes needed for long term weight maintenance (Gorin et al., 2007). People who are able to achieve their desired weight loss goals are more likely to maintain weight in the long term. Gorin et al. (2007) suggested that weight loss expectations are not necessarily detrimental for weight loss maintenance. This is in agreement with Rothman's framework (2000) which differentiates between initiation and maintenance of behaviour change. According to Rothman (2000) maintenance of behaviour change depends on perceived satisfaction, whilst initiation of behavioural change

depends on favourable expectations about future outcomes. People are more likely to maintain a behaviour only if they are satisfied with what they have accomplished, which mainly depends on their expectations during behavioural initiation (Rothman, 2000). There was also limited evidence for weight loss goals expectations. Byrne et al. (2004) suggested that the reason for weight regain might not be the failure to achieve weight goals per se but rather how people perceive or interpret this failure. Therefore, an interaction between failure to meet weight goals and a dichotomous thinking style (i.e. a rigid, "all or nothing" way of thinking, for example, "If I am not a success, I am a failure" (Byrne et al., 2004) might be predictive of poorer weight loss maintenance in the long term.

## 2.19 Treatment adherence/attendance

Adherence to treatment was assessed in seven studies (Batra et al., 2013; Byrne, Barry, & Petry, 2012; Hollis et al., 2008; Jeffery et al., 1984; Wadden et al., 2011; Williamson et al., 2010, Linde et al., 2004). Greater behavioural adherence/attendance at intervention sessions was significant predictor of weight loss in all seven studies (Batra et al., 2013; Byrne et al., 2012; Hollis et al., 2008; Jeffery et al., 1984; Wadden et al., 2011; Williamson et al., 2010, Linde et al., 2004) and predicted weight loss maintenance in all three studies where this was assessed (Linde et al., 2004, Jeffery et al., 1984, Wadden et al., 2011). Linde et al. (2006) found a significant positive association between self-efficacy and programme attendance after controlling for baseline weight. However, they did not report whether the observed association between self-efficacy and attendance was related to weight loss. Prochaska et al. (1992) found that internal reasons for losing weight, percentage overweight, the amount of weight participants wanted to lose and previous weight loss attempts predicted treatment attendance. Age and marital status, were also significant pretreatment predictors of attendance. One problem with attendance outcomes is that it is not clear whether attendance predicts weight loss, or weight loss predicts attendance. It has been suggested that both factors may be influenced by increased motivation or fear (Stubbs et al., 2011).

### 2.20 Personality traits

Five studies assessed personality traits as predictors of weight loss success (Canetti et al., 2009; Poston et al., 1999; De Panfilis et al., 2007; Lahmann et al., 2011; Stotland & Larocque, 2005) and three of the studies examined weight loss outcomes (Canetti et al., 2009; De Panfilis et al., 2007; Lahmann et al., 2011). De Panfilis et al. (2007) used the Temperament and Character Inventory (TCI; (Cloninger, Svrakic, & Przybeck, 1993)), the Toronto Alexithymia Scale (TAS-20: (Bagby, Parker, & Taylor, 1994)), the Structural Clinical Interview for Personality Disorders (SIDP-IV; (Pfohl, Blum & Zimmerman, 1997)) and the Structured Clinical Interview for DSM-IV Axis I disorders (SCID-I/P; (First, Spitzer, Gibbon, Williams & 1995) to assess personality. They found that in obese patients weight loss was favoured by the presence of low narcissistic personality traits as assessed by the TCI (De Panfilis et al., 2007). Canetti et al. (2009) using the Neuroticism scale from the five factors of the NEO-Personality Inventory Revised (Costa & McCrae, 1992) found that neuroticism predicted weight loss in obese patients following a very low energy diet. Lahman et al. (2011) using the Inventory for Interpersonal problems (IPI) (Horowitz, Rosenberg, Baer, Ureno, & Villasenor, 1988) found that "intrusive or needy" baseline traits predicted weight loss at 12, 26 and 52 weeks. Poston et al. (1999) did not find that the scores on Karolinska Scales of Personality (KSP; (Schalling & Edman, 1993)) predicted initial weight loss or contributed to the prediction of 12-month relapse status. Additionally, Stotland and Laroque (2005) using the Laroque Obesity Perfectionism Scale (Larocque & Stotland, 2000) did not find that perfectionism was predictive of weight loss after nine months of very low calorie diet.

Data on personality traits were sparse and although there are some trends favouring certain personality traits further research is needed. Studies have argued that three traits, neuroticism (low self-esteem, anxious, irritable and worrying), conscientiousness (efficient, thorough, organised and hard-working) and extraversion (socially stimulated, energetic, enthusiastic and pleasure seeking) are linked to obesity (Lazzeretti et al., 2015). However, neuroticism and extraversion have been found to be both positively and negatively correlated with obesity (Sutin, Ferrucci, Zonderman, & Terracciano, 2011). Studies have also shown that conscientiousness is associated with adiposity, with high conscientiousness related to low body mass index (BMI) (Munro, Bore, Munro, & Garg, 2011). Munro et al. (2011) examined whether personality traits could be used to match individuals to two different weight management programmes (a heathy eating weight loss diet (HEWLD) for 12 weeks vs a very low energy diet (VLED) for 4 weeks) followed by 10 weeks of weight maintenance. They measured neuroticism, conscientiousness and extraversion using the Five Factor Model (FFM) model and self-control (controlling of self from undesired behavioural tendencies) using the Tangency Self Control Scale (SCS) (Tangney, Baumeister, & Boone, 2004). but only reported correlations between personality traits and weight loss. They found that neuroticism was positively correlated with weight loss and weight loss maintenance and that the conscientiousness subfactors of discipline and dutifulness were negatively correlated with weight loss. These correlations were only significant for the VLED group and not the HEWLD group. Multiple regressions were performed to examine significant interactions between groups and personality, but none were found. This study found some correlations between personality traits for one of the diet groups (VLED). However, no clear conclusions can be drawn as the two diets differed in duration, despite the authors claiming otherwise.

## 2.21 Initial weight loss/previous weight loss attempts

Initial weight loss was assessed as a predictor of weight loss and/or weight loss maintenance in four studies (Fabricatore et al., 2010; Handjieva-Darlenska et al., 2010; Moore et al., 2011; Wadden et al., 2011). Three out of four studies (Fabricatore et al., 2010; Handjieva-Darlenska et al., 2010; Wadden et al., 2011) found that larger amounts of initial weight loss (assessed at week 1 and/or week 3 of intervention) predicted greater (subsequent) weight loss. Initial weight loss was assessed as a predictor of weight loss maintenance in two studies (Wadden et al., 2011; Moore et al. 2011) and only Wadden et al. (2011) found that greater weight loss during the first year predicted greater loss at follow-up (3 years later). Previous weight loss attempts and previous participation in weight loss programmes were assessed in seven studies (Delahanty et al., 2013; French et al., 1994; Jeffery et al., 1984; Kiernan et al., 1998; Leon & Rosenthal, 1984;

Pekkarinen, Takala, & Mustajoki, 1996; Teixeira et al., 2002) and all studies apart from one (Pekkarinen et al., 1996) found that fewer previous weight loss attempts predicted greater weight loss. Previous weight loss attempts were assessed as a predictor of weight loss maintenance in two studies and only Jeffery et al. (1984) found that fewer previous dieting attempts predicted greater weight loss maintenance. Thus, most results suggest that previous participation in weight loss programmes and previous dieting attempts are predictive of worse weight loss outcomes.

## 2.22 Weight bias/attitudes

Weight related attitudes and beliefs were assessed in two studies (Burmeister et al., 2013; Eldredge & Agras, 1996). Burmeister et al. (2013) using the Weight Bias Internalisation Scale (WBIS; (Durso & Latner, 2008)) and the Anti-Fat Attitudes Questionnaire (AFA; (Crandall, 1994)). Anti-fat attitudes are negative attitudes towards other individuals who are overweight or obese and internalized weight bias is a concept which measures the degree to which individuals apply anti-fat attitudes to themselves (Burmeister et al., 2013). Burmeister et al. (2013) found that neither anti-fat attitudes nor internalised weight bias were correlated with weight loss and therefore were not tested further in a regression model. They also found that internalised weight bias and attitudes were correlated with food addiction scores. Eldredge et al. (1996) used the Weight Perception Evaluation Questionnaire (WEPQ) and found that low levels of negative affect in response to perceived evaluation were associated with greater mean weight loss. They argued that individuals who are highly distressed by internalised weight stigma attach greater emotional effort to changing their weight, which in turn might interfere with individuals' ability to comply with treatment. This is consistent with more recent research highlighting that internalized weight bias is related to psychological distress and also seen as a potential barrier to treatment adherence (Puhl, Moss-Racusin, & Schwartz, 2007). Research has also shown that internalized negative attitudes mediate the relationship between BMI and health related quality of life (Lillis, Levin, & Hayes, 2011). This highlights the need for designing weight loss interventions with food addiction components with a focus on the reduction of stigmatised beliefs and attitudes.

## 2.23 Quality of Sleep

Sleep patterns were assessed as potential predictors of weight loss and weight loss maintenance in two studies (Elder et al., 2012; Phelan, Wing, Loria, Kim, & Lewis, 2010). Elder et al. (2012) used the Insomnia Severity Index (ISI) (Bastien, Vallieres & Morin, 2001) to measure participants' perception of their sleep quality in the previous two weeks (higher scores indicate worse sleep quality) and their sleep time. They found that sleep time predicted weight loss at the end of the intervention, such that those sleeping less than 6 hours per day were less likely to lose weight (Elder et al., 2012). Phelan et al. (2010) used the Sleep Heart Health Study (Quan et al., 1997) to assess the predictive value of sleep disturbances (i.e. excessive daytime sleepiness, trouble falling asleep and frequent awakening) on weight loss maintenance, and found trends for maintainers to report less awakenings at night.

## 2.24 Dichotomous thinking style

Dichotomous thinking style (see definition in Section 2.18) is another psychological factor, which was examined as a predictor of weight loss and/or weight loss maintenance. People with a dichotomous thinking style may feel a failure if they do not reach their weight loss goals (Byrne et al., 2004). This failure leaves them feeling dissatisfied with their weight and this in turn reduces their motivation to continue with behaviour changes necessary to maintain their weight or induce further weight loss (Byrne et al., 2004). Dichotomous thinking style was examined as a potential predictor of weight loss in one study (Dove et al., 2009) and in a second study as a predictor of weight loss maintenance (Byrne et al., 2004) using the Dichotomous Thinking in Eating Disorders Scale (DTEDS; (Byrne, Allen, Dove, Watt, & Nathan, 2008)). Byrne et al. (2004) found that regainers had higher dichotomous thinking scores, were less satisfied with their weight and were more likely than maintainers to demonstrate a lack of vigilance with regard to weight control. Dove et al. (2009) investigated whether a dichotomous thinking style moderates the association of depression with BMI and the effect of dichotomous thinking and depression on weight loss during a cognitive behavioural therapy (CBT) intervention. They found that dichotomous thinking moderated the association of depression with BMI, such that depression

was positively associated with BMI among those with low dichotomous thinking, but was not associated among those with high dichotomous thinking.

Byrne et al. (2008) also suggested that dichotomous thinking may predict rigid dietary restraint and/or mediate links between restraint and binge eating. This, however, deserves further research. Future studies should test the association of dichotomous thinking with depression, obesity, binge eating and weight loss. Future studies might also use the DTEDS to investigate whether reductions in dichotomous thinking are related to weight loss and weight loss maintenance, or to reductions in disordered eating among those who binge eat. Dichotomous thinking was not predictive of weight loss during treatment in Dove et al's study (2009) suggesting that dichotomous thinking neither impedes nor assists weight loss in the short term. This finding runs contrary to the theorised inhibitory effect of dichotomous thinking on weight loss. It has been suggested that an 'all ornothing' approach to eating and weight control behaviours might predispose individuals to frequent lapses in dietary restraint, leading to binge eating or overeating and a failure to lose weight (Fairburn, Cooper, & Shafran, 2003). While dichotomous thinking might lead to overeating among some individuals, in others it might provoke a more focussed and determined approach to caloric restriction that is sustainable for at least a short period of time. Therefore, dichotomous thinking might only be disadvantageous for longer-term weight loss or maintenance and this merits further investigation.

## 2.25 Locus of control

Locus of control refers to the degree that individuals believe they can control events that are affecting them. Locus of control is one of the four dimensions of core self-evaluations along with neuroticism, self-efficacy, and self-esteem (Lazzeretti et al., 2015). Only one paper included in the present review measured locus of control (Williams et al., 1996b) using the Health Locus of Control scale (HLOC; (Wallston, Wallston, & DeVellis, 1978). HLOC scores were not predictive of weight loss and/or weight loss maintenance in this study (Williams et al., 1996b). Two studies (Adolfsson, Andersson, Elofsson, Rössner, & Undén, 2005; Nir & Neumann, 1995) found a relationship between locus of control and weight

loss, but these were not included in the present review as no regression analysis was performed to test the predictive value of locus of control. Adolfson et al. (2005) found that internal locus of control was associated with weight loss using the Rotter's I-E scale (Eisemann, Perris, Palm, Palm & Perris, 1988). In addition, Nir and Neumann (1995) using the modified form of Gurin, Gurin, Lao, and Beattie's (1973) Internal-External (I-E) scale found that an internal locus of control was related to a lower weight regain after a weight reduction program.

The evidence for locus of control is limited and further research is needed. Internal locus of control appears to have some resemblance to the concept of 'self-efficacy' (Holt, Clark, & Kreuter, 2001), which has also received much attention in weight management. Allison and Engel (1995) reported that an internal locus of control is a beneficial trait regarding weight management and suggested that health and weight specific locus of control are more predictive than more general measures (Allison & Engel, 1995). Holt et al. (2001) using the Weight Locus of Control Scale (WLOC; (Saltzer, 1982)) found that more internal control was related to having more confidence in weight loss behaviours whereas external control was related to perceiving external reasons for being overweight, perceiving several barriers to physical activity and being dissatisfied with the social support received. Saltzer (1982) using the WLOC found that WLOC scores significantly predicted womens' completion of a weight loss programme. Programme completers who were "internals" and who highly valued health or physical appearance were more successful in achieving their initial weight loss goals than programme completers who were "externals" with similar values (Saltzer, 1982).

## 2.26 Beliefs about causes of obesity

Beliefs about causes of obesity was examined as a predictor of weight loss in one study by Wamstecker et al. (2005). They found that after an 8 week of a low calorie diet using meal replacements, less weight loss was associated with the belief that one's obesity has a physical (mainly genetic) origin. Beliefs about causes of obesity were assessed using the Obesity Cognition Questionnaire, an obesity-adapted version of the Illness Perception Questionnaire (IPQ) (Larsen & Geenen, 2002). The Obesity Cognition Questionnaire items are divided in separate scales for psychological consequences, controllability, time line, and physical origin.

## 2.27 Discussion

This systematic review focused on elucidating predictors of weight loss and/or weight loss maintenance in studies which employed a behavioural and/or dietary weight loss intervention (with or without exercise) in a sample of overweight to moderately obese individuals. The present review focused on studies which assessed potential predictors of weight loss and/or weight loss maintenance using an appropriate statistical test (e.g. regression model). Studies which only reported correlations to assess predictors of weight loss and weight loss maintenance were not reported as correlation cannot infer causality and therefore the validity of the findings from these studies is questionable. Moreover, this review highlighted that although previous studies have reported that there might be different predictors of weight loss than those who weight loss maintenance, there is not enough evidence to support this. Fewer studies have examined the predictive power of psychosocial and/or behavioural factors in weight loss maintenance studies than in weight loss studies.

Of all the psychosocial/behavioural predictors which emerged from this review (26 in total), eating behaviour, depression, self-efficacy, binge eating and physical activity were those who most frequently investigated. Eating behaviour, self-monitoring, self-efficacy, physical activity, treatment adherence, previous weight loss attempts, initial weight loss, sleep quality and anxiety were the strongest predictors of weight loss and weight loss maintenance (more than half of the studies which assessed these factors found supporting evidence). However, sleep quality and anxiety were only assessed in a few studies. Self-esteem was not as significant predictor of either weight loss or weight loss maintenance as none of the studies found evidence to support its predictive power. The evidence was mixed and inconclusive for weight loss goals, stress/coping skills, depression, body image and binge eating. Social support, HRQoL and personality appeared to predict weight loss more than weight loss maintenance. However, the number of studies which included these factors in weight loss

maintenance studies was quite small (especially for personality and HRQoL). Although body image appeared to predict weight loss maintenance better than weight loss, the number of studies which examined its predictive value in the long term were less than those who assessed it in the short term. Similarly, dichotomous thinking was a significant predictor only of weight loss maintenance and since only two studies assessed its predictive power, results should be treated with caution. Furthermore, locus of control, weight related bias and beliefs about causes of obesity were assessed in a few studies and there was not enough evidence to draw any clear conclusions. Therefore the relationship between these factors and weight management is still unclear and remains to be clarified. More studies are needed to investigate their predictive power in the short and long term.

The findings of the current review are limited to a sample of otherwise healthy male and female adults. The outcomes, therefore, may not generalise to other potentially vulnerable groups and so this should be explored. It would also be of value for future research to examine gender differences in predictors of weight loss and weight loss maintenance. Studies have argued that there are gender differences in predictors of weight loss and/or weight loss maintenance. Presnell et al. (2008) found that high levels of depression predicted subsequent decreases in BMI for men, but not for women. It is also known that women are twice as likely to experience major depression than men (Aker, Harmer, & Landrø, 2014). Previous research indicates differences in coping styles for men and women; whereas men employ more active coping strategies (i.e. problem-focused or distractive strategies), women tend to use more passive and emotion-focused strategies, such as rumination and social support (Monteiro, Balogun, & Oratile, 2014). Furthermore, individuals who have experienced depression in the past have been found to employ more dysfunctional strategies such as rumination (Aker et al., 2014). Thus, depressive symptoms may elicit greater active attempts at coping and serve as a motivating factor for men, but not for women.

Other limitations that need to be taken into account are the large heterogeneity in the statistical methods and psychosocial measures used which prevented us from applying meta-analytical techniques to pool data across studies. Measures may vary in sensitivity to the construct under investigation or may emphasise one or more of its elements. This often makes comparisons between studies difficult and is particularly pertinent for measures of body image. In the current review, body image was assessed by no less than thirteen different measures in only fourteen studies in comparison to one for self-esteem and two for depression and HRQoL. It has also been argued that the psychological tools used in obese individuals are often inadequate (i.e. usually not designed specifically for obese subjects) and too heterogeneous (Lazzeretti et al., 2015). Both theory and measurement methods need to be improved for the links between psychosocial/behavioural factors and weight management behaviour to be understood.

Weight management is a process that constantly evolves and progresses; however, variables have been identified that predict outcomes. These predictors may account for only 20% to 30% of the total variance in weight loss outcomes (Stubbs et al., 2011), which suggests that many other factors play important roles. There is need for multidisciplinary studies to look at the interaction of these psychosocial and behavioural predictors as well as their interaction with environmental factors, seasonal effects, education, socioeconomic status, gender, smoking and alcohol intake. The interrelatedness of many of these predictors is highlighted in many studies (Burmeister et al., 2013; Sherwood et al., 2000, 1999). As mentioned earlier, binge eating was related to dieting history, weight cycling, depressive symptoms, perceived barriers to weight loss and attrition (Stubbs et al., 2011). Dichotomous thinking style has also been linked with dietary restraint, binge eating and depression (Stubbs et al., 2011). Other potentially important treatment variables were not considered or not properly analysed, such as treatment group size, type of exercise or diet recommendations, characteristics of maintenance programmes, level of support. Different weight management programmes are available and it is likely that any weight management programme will be beneficial for some individuals, but not for all, suggesting the need for a better matching between treatment and individuals' needs. Further research should focus on the definition and identification of specific sub-groups which demonstrate certain psychological characteristics and the identification of more reliable and comprehensive tools, which have been designed specifically for obese individuals.

134

# 2.28 Summary of psychosocial and behavioural characteristics linked to weight loss and weight loss maintenance

The systematic review reported in this chapter indicates that the extant literature highlights that, aside from physiological factors such as initial body weight, a number of personal characteristics are linked with weight loss and weight loss maintenance. These personal characteristics can be broadly conceptualised as reflecting affective, cognitive, behavioural and motivational factors. Figure 2.28-1 provides a framework showing the individual constructs within each of these four factors which emerged from the systematic review and their relationship to weight loss and weight loss maintenance. Affective factors include variables such as depression, anxiety, stress/coping with stress, anger, body image satisfaction, binge eating, mood, self-esteem, HRQoL and personality. Cognitive factors include dichotomous thinking, beliefs about causes of obesity, weight bias/attitudes and locus of control. Behavioural factors include constructs such as eating behaviour, self-monitoring, physical activity, treatment adherence, quality of sleep, social support and previous weight loss attempts. Motivational factors include eating self-efficacy and motivation. Many of these constructs are important correlates of success, although the amount of variance they explain is either small or highly variable between different groups. To understand individual variability in weight loss and weight loss maintenance the present thesis will use the framework proposed in Figure 2.28-1 to explore the role of these factors in explaining weight loss and weight loss maintenance, which could potentially guide future intervention development, in three different samples across a number of different settings.

## **Personal Characteristics**

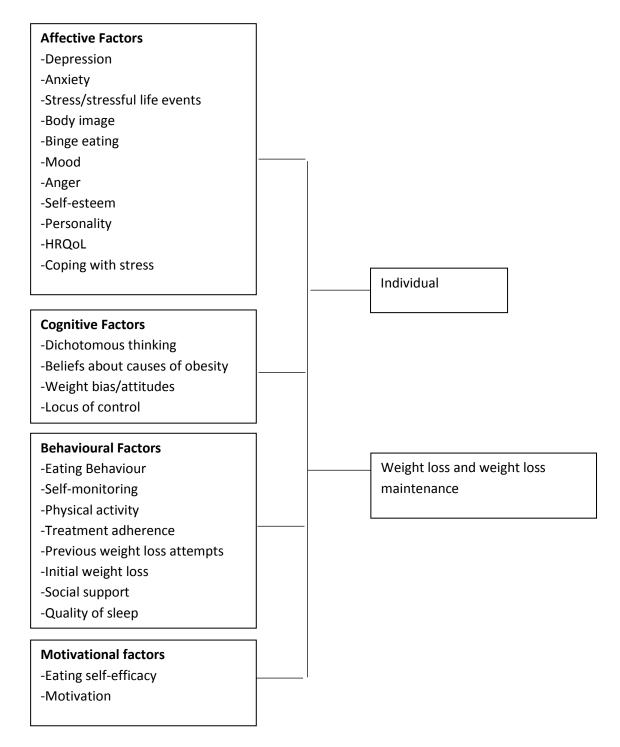


Figure 2.28-1 Conceptual framework to illustrate different personal characteristics linked to weight loss and weight loss maintenance.

#### 2.29 Conclusions

According to our review, it is not clear whether predictors are specific to weight loss and weight loss maintenance, since the number of long term studies is far less than those who assessed predictors in the short term. Behavioural factors (eating behaviour, self-monitoring, physical activity, treatment adherence, previous weight loss attempts and initial weight loss) and motivational factors (eating self-efficacy) were the most consistent predictors of weight loss and weight loss maintenance. Many of the constructs that might seem intuitively good predictors of weight loss (self- esteem, motivation, binge eating,) do not turn out to be so. It is likely that combination of these predictors is important, which highlights the need for interventions that will account for all the potential predictors discussed. Only one study reviewed investigated a substantial amount of personal characteristics and in this study the sample was too small to account for all the constructs measured. Future studies with larger samples are needed that will allow for the use of more sophisticated analyses and could account for many different factors at once.

# Chapter 3 - Physiological and psychological predictors of weight loss and weight loss maintenance following a dietary intervention – the Leeds Women's Wellbeing (LWW) Study

## 3.1 Overview

The previous chapter (Chapter 2) presented a systematic review of psychosocial/behavioural predictors of weight loss and/or weight loss maintenance following dietary (with or without exercise) and behavioural/lifestyle interventions. The review showed that different affective, cognitive, behavioural and motivational factors are associated with weight loss and weight loss maintenance. Behavioural factors (eating behaviour, self-monitoring, physical activity, treatment adherence, previous weight loss attempts and initial weight loss) and motivational factors (eating self-efficacy) were the most consistent predictors of weight loss and weight loss maintenance. The review also highlighted that it is not clear whether predictors are specific to weight loss and/or weight loss maintenance, since the number of long term studies is far fewer than those which have assessed predictors in the short term. The study reported in the present chapter examines the effects of a 12 week dietary intervention on weight loss and weight loss maintenance (1 month and 12 month follow-up) on body weight in overweight habitually low fibre consuming premenopausal female adults. The association of different personal characteristics (broadly classified as affective, cognitive, behavioural and motivational) with weight loss and weight loss maintenance is also explored.

## 3.2 Introduction

The current obesity epidemic demands effective strategies to improve both weight loss and weight maintenance. Overweight or obese individuals find it exceptionally difficult to achieve weight loss in the short term and maintain it in the long term (Ayyad & Andersen, 2000). There has been considerable interest in the potential for different dietary components to serve as a means of promoting weight loss in the short term and preventing weight gain in the long term (Abete et al., 2010). Although there is a plethora of diets available offering different

choices to people struggling with weight loss, data on their comparative efficacy is limited (Truby et al., 2006).

Dietary interventions promoting increased fibre are promising for maintenance of a healthy body weight (Joanne Slavin, 2013). A recent systematic review of prospective observational evidence suggested that comparison of the highest and lowest percentile of intake of cereal fibre, whole grains and bran/whole grains appeared to consistently lead to small but significant improvements in long-term body weight management (Cho, Qi, Fahey, & Klurfeld, 2013). In a review of successful diet strategies for weight loss and weight maintenance (24 studies), increased fibre intake was the third most important strategy after reduction of energy and fat intake (Ramage, Farmer, Apps Eccles, & McCargar, 2014). The fibre recommendations among successful studies varied from 17-20 g/ day, 17 g/1000 kcal and 5–10 g of soluble fibre/day, as well as general recommendations to increase fibre. However, evidence from randomized controlled trials of whole grain or fruit and vegetable intake and body weight across interventions of varying doses of fibre intake and time lengths have noted a consistent lack of effect (Brownlee, Chater, Pearson, & Wilcox, 2016). Fibre is a dietary component that has received substantial attention in this respect, not least because of its' effects on satiety (Slavin & Green, 2007). Reviews by several researchers indicate that dietary fibre intake is inversely related to weight gain (Anderson et al., 2009; Babio, Balanza, Basulto, Bullo, & Salas-Salvado, 2010; Slavin, 2005; Slavin & Green, 2007) Epidemiological evidence indicates that a high fibre intake is associated with a lower BMI and studies have shown that obese people consume less fibre than normal weight people (Howarth et al., 2001).

The nutritional composition of the diet may influence a range of cardiovascular disease risk factors (Threapleton et al., 2013). For example a high fibre intake, particularly from wholegrains, has been shown to be beneficial in improving insulin, glucose and lipid concentration, in addition to facilitating weight loss (Anderson et al., 2009). Although there has been a lot of research supporting the beneficial role of fibre in several diseases such as cardiovascular disease, bowel function and diabetes, the literature still leaves some unanswered and important questions regarding the association between dietary fibre and body weight (Tucker & Thomas, 2009).

#### 3.2.1 Dietary Fibre and Satiety

Many studies have examined the effects of dietary fibre on satiety, energy intake and body weight. (Slavin, 2005). Slavin (2005) reviewed published studies on the effects of dietary fibre on hunger, satiety, energy intake and body composition in healthy individuals and concluded that increasing fibre intakes is a critical step in tackling the ever increasing rate of obesity in developed countries. However, the effectiveness of different types of fibre foods in promoting energy intake regulation merits further investigation.

The majority of the intervention studies examining the effects of dietary fibre on energy intake have observed a decrease in intake during consumption of a high fibre diet, with no apparent difference between the effects of soluble versus insoluble fibres and fibre from fibre rich foods versus supplements (Lobley et al., 2013). Findings from several observational and intervention studies support a beneficial role for total dietary fibre intake in maintaining a healthy body weight (Newby et al., 2007), promoting weight loss (Birketvedt, Aaseth, Florholmen, & Ryttig, 2000) and preventing weight gain (Liu et al., 2003). However, more recent intervention studies show less convincing results. Furthermore, most of the studies included in a review by Wanders et al. (2011) did not include body weight changes as the primary endpoint. Overall, the results from intervention studies do support a role for dietary fibre in body weight management (Wanders et al., 2011). Ye et al. (2012) conducted a systematic review of longitudinal studies investigating whole-grain and fibre intake in relation to risk of type 2 diabetes (T2D), cardiovascular disease CVD and weight gain. Nine studies examined the relationship between whole-grain and fibre intake and weight gain (Ye, Chacko, Chou, Kugizaki, & Liu, 2012). Results indicated an inverse association between whole-grain and dietary fibre intakes and weight gain over time.

Different study designs have been employed to examine the effects of fibre foods or fibre supplements on body weight. Studies have shown that incorporation of fibre in diets in the form of natural foods or supplements can influence satiation and satiety. The addition of fibre to the diet can alter energy density and palatability, which can then lead to lower energy intake (Kristensen et al., 2009; Ello-Martin et al., 2007). However, a change in satiety will only be of clinical significance if it translates into weight loss or weight maintenance over time. Short term studies have the disadvantage of failure to predict food intake during subsequent days or weeks if the diet is continued. It is therefore necessary to examine the longer term effects of dietary manipulations on body weight to determine whether short term effects of foods or food components (such as dietary fibre) on satiety translate into weight loss over the longer term.

## 3.2.2 Rationale for the present study

Approaches to reduce energy intake typically focus on limiting food portions or choices, which might result in increased feelings of hunger. Conversely, a dietary strategy that helps individuals control hunger by eating satisfying amounts of food could improve adherence and increase weight loss. Obesity can have an impact on different aspects of health related quality of life domains, such as physical health, emotional wellbeing, and psychosocial functioning (Kolotkin & Crosby, 2002; Palmeira et al., 2009; Smith, 2005). There have been only a few studies which have examined the beneficial effects of weight loss on feelings of wellbeing. Although a good deal of research has investigated the effects of breakfast on physical and psychological functioning (Hoyland, Dye, & Lawton, 2009; Smith, 2011), there is a lack of information regarding the benefits of healthy eating plans using specific foods for mood and feelings of wellbeing. The Leeds Women's Wellbeing (LWW) study was, therefore, designed to compare the effects of two 12-week dietary interventions (one of which promoted dietary fibre intake) on body weight, body composition, physiological markers of health, physical and psychological wellbeing in overweight female habitual low fibre consumers.

#### 3.2.3 Aims of the present study

This chapter reports the results from 71 participants who completed the LWW study. The aim of this study was:

 to assess the relative effects of two 12-week healthy eating dietary interventions on body weight in overweight habitually low fibre consuming premenopausal female adults aged 18-48 years. Secondary aims were to examine the relative effects of both diets on body composition, fasting biomarkers of health, physical and psychological wellbeing, body shape perception and eating behaviour characteristics (reported in Part 1)

- To examine whether baseline physiological and/or psychological factors and changes in these factors during the dietary intervention predicted weight loss (reported in Part 1)
- To examine predictors of weight loss maintenance (one month and 12 month follow-up) (reported in Part 2)
- To assess differences in psychosocial factors (assessed at 12 month follow up) between successful and unsuccessful weight loss maintainers (reported in Part 2)

## 3.3 Methods

## 3.3.1 Study Design

This study design conformed to a randomised, controlled single-blind intervention trial of two diets, a healthy eating diet with (B) and without (A) extra advice to increase intake of dietary fibre. The study involved a 4 week inclusion phase followed by a 12 week dietary intervention phase where participants visited the Human Appetite Research Unit (HARU) every 4 weeks for dietary counselling and assessments. A randomisation schedule (Appendix 3.1) was produced by the consulting statistician (Quadt Consulting B.V., The Netherlands) and provided to the Principal Investigator (PI). Women were allocated a screening number at their screening visit and this number was superseded by a randomisation number, if their 7 day food diary data (see section 3.4.4) confirmed eligibility (fibre intake ≤15g/day). Following allocation of the randomisation number the researcher requested the information on diet allocation (A or B) from the PI (who did not meet the study participants). A schematic representation of the study phases and the measurements within these phases is detailed in Figure 3.3-1 below.

#### 3.3.2 Participants

Female participants were recruited using flyers, posters, email and advertisements distributed around the University and the local area. Two articles were also placed in a local newspaper (Yorkshire Evening Post, January 2011). Potential participants were directed to call the study coordinator for further information and to undergo a preliminary telephone screening interview. The telephone screening interview was used to check the main inclusion/exclusion criteria (Table 3.3-2). Women who fitted these criteria and who were willing to

consume complementary study products and breakfast cereals as part of the study were provided with the participant information sheet (PIS; Appendix 3.2) and asked to read it in their own time before deciding whether or not to take part in the study. Participants who remained interested in the study were asked to contact the research staff to arrange a screening visit at the HARU. Researchers obtained written informed consent from each volunteer at HARU prior to performing any study measures.

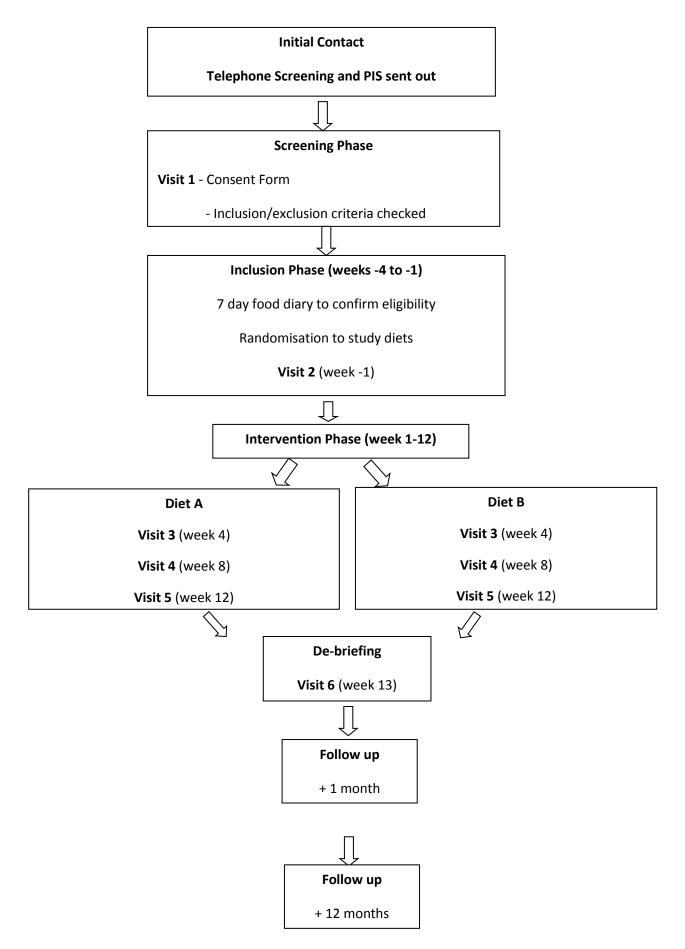


Figure 3.3-1 Schematic representation of study phases

Inclusion Criteria	Exclusion Criteria
Female	
18-24 years of age (premenopausal)	Menopausal or showing menopausal symptoms (e.g. frequent/recurrent hot flushes) at screening or taking any supplements for menopausal symptoms
Self reported good health	T2DM; Cardiac pacemaker fitted Taking medication and/or supplements known to affect appetite/body weight in the last 6 months (e.g. asthma, steroids, anti-depressants)
BMI within overweight/obese range (26-35kg/m <sup>2</sup> )	BMI outside range of 26-35 kg/m <sup>2</sup>
Willingness to consume study foods and prepared to eat breakfast cereals as part of the intervention	Food allergies or aversions to foods likely to be consumed within the study (e.g. wheat bran, nuts)
Non-smokers or given up more than 6 months ago	Smokers
Exercising no more than 4 times per week at a medium intensity	Exercising more than 4 times per week at a medium intensity
Weight stable in the last 3 months (fluctuation of no more than 3kg)	Shift work (night shifts)Pregnant or planning a pregnancy within the next year; having been pregnant or lactating within the previous 6 months
	No history of, or current eating disorders as determined using the EAT-26 (a score higher than 20)
Current fibre intake ( $\leq 15g/day$ ) according to DINE and verified by 7 day food diary (fibre points)	Current fibre intake (>15g/day according to DINE)
Ability to adequately understand verbal and written information in English	Insufficient English language skills to complete all study questionnaires

### Table 3.3-1 Inclusion and Exclusion criteria

**Key**: BMI (Body Mass Index); DINE (Dietary Instrument for Nutrition Education); EAT-26 (Eating Attitudes Test); T2DM (Type 2 Diabetes Mellitus); BMI (Body Mass Index)

Seventy one female participants (36 on Diet A and 35 on Diet B) completed all study visits from screening (Visit 1) through to week 12 (Visit 5) and attended the debriefing visit (Visit 6). Recruitment of the 71 participants whose data are reported, took place between April 20th, 2010 and March 30th, 2011. These participants were drawn from 752 women who responded to recruitment initiatives by telephone or email (Figure 3.2-2). Of these volunteers, 237 participants were considered potentially eligible on the basis of the telephone interview and were invited to attend a screening visit at HARU. 42 volunteers

failed and 195 passed screening. Of the 195 who passed screening, 27 participants dropped out between screening and inclusion and the remaining 168 entered the inclusion phase and were asked to complete a 7 day food diary record. On the basis of the dietary analysis of the 168 food diaries that were returned, 72 participants were ineligible to continue with the dietary intervention (due to a daily fibre intake >15 g/day). A further 4 participants dropped out prior to randomisation and the remaining 92 participants were randomised to either of the two intervention diets. After randomisation, 12 women dropped out before starting the intervention and the remaining 80 entered the dietary intervention phase; 40 participants were assigned to the healthy eating diet (Diet A) and 40 were assigned to the high fibre and healthy eating diet (Diet B). Four participants from Diet B (see Figure 3.3-2). A total of 49 women (26 A; 23 B) agreed to come for an optional follow up visit one month after completion of the intervention.

Women who completed one of the two 12 week healthy dietary interventions and had already indicated on their initial recruitment questionnaire that they were willing to be contacted about future studies (N=65) were invited to take part in the 12 month follow-up. Interested women were asked to contact the study team for further information and were sent the PIS by post or email. Participants who were interested in the follow up study were booked for a short (one hour) visit at the Human Appetite Research Unit (HARU), University of Leeds. Each participant provided written informed consent prior to commencing any study measures and then asked to complete a Demographic Information Questionnaire (DIQ; Appendix 3.3) to assess demographic information and general health. 51 out of 65 women responded to the letters or emails sent and 14 could not be contacted. Of the 51 women who responded, 17 women could not attend either due to pregnancy (n=1), or no time (n=8), or living overseas (n=8). Hence, a total of 34 women attended the 12 month follow up visit (19 A; 15 B).

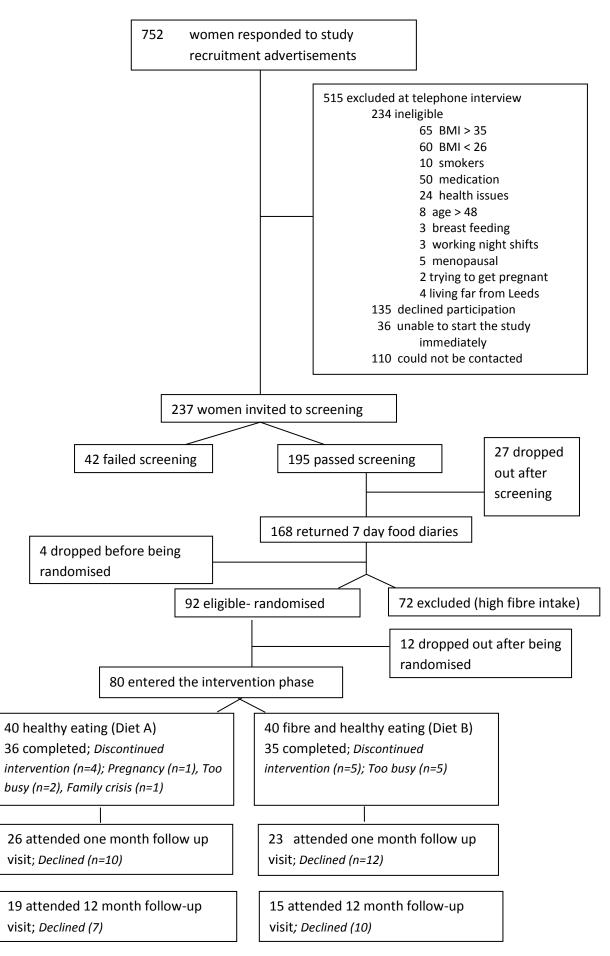


Figure 3.3-2 Consort figure showing the flow of participants through each phase of the trial (pre-screening, screening, randomisation and 1 month and 12 month follow-up)

Participants were randomly assigned to one of the two dietary intervention diets (A or B). Table 3.3-3 describes the dietary advice that was given to the participants in the Diet A and Diet B intervention groups and describes the types of complimentary food products that were provided to them.

Table 3.3-2 Dietary advice for participants in Diet A and Diet B intervention
groups

Diet A (healthy eating without extra	Diet B (healthy eating with extra
advice to increase dietary fibre intake)	advice to increase dietary fibre intake)
Participants were provided with the British Heart Foundation booklet: 'Food Should Be Fun And Healthy'*	Participants were provided with the British Heart Foundation booklet: 'Food Should Be Fun And Healthy'*
No emphasis was placed on increasing fibre intake Participants were encouraged to eat breakfast cereals and were provided with complementary cereals appropriate to Diet A	Participants were trained to increase their fibre intake to a minimum of 25g per day using a points-based system**. Participants were encouraged to eat high fibre breakfast cereals and to incorporate wheat bran fibre in other meals. Complementary high fibre cereals were provided
Participants were be provided with a commercially available recipe book to encourage preparation of meals 'from scratch'	Participants were given information on the benefits and importance of fibre and told which foods in the diet are good sources of fibre. They were also provided with a selection of high fibre recipes to help compliance with the diet whilst also encouraging the preparation of meals 'from scratch'.
Participants were provided with a selection of complementary snack food products low in fibre	Participants were provided with a selection of complementary snack food products high in cereal fibre

\*According to the British Heart Foundation (BHF) booklet, a healthy balanced diet should contain plenty of fruit, vegetables and starchy foods (wholegrains), meat, fish, eggs, pulses, milk and dairy foods. Intake of saturated fat should be avoided and intakes of sugar and salt should be reduced (<6g per day). The benefits of eating a healthy diet in order to reduce the risk of developing heart disease, some cancers, obesity, diabetes, arthritis and high blood pressure are also highlighted. The booklet contains sample

eating plans, advice on shopping and cooking together with a selection of healthy eating recipes.

\*\*Those on Diet B (high fibre and healthy eating) were provided with a recipe book which contained recipes and ideas to support them to increase their amount of fibre intake. Participants had to keep records of their daily fibre intake based on a fibre points system that was described and explained in the recipe book. In this system, 1 fibre point equalled 1 gram of fibre. Each recipe and food portion in the recipe book was allocated a fibre points value to help participants to keep track of how much fibre they were eating. For typical UK foods, fibre points were also provided per standard portion size (g; based on food portion sizes, Food Standards Agency, 2002) and per 100g. Participants were also given instructions on how to report fibre intake based on food manufacturer's nutritional information (on food packaging) by the study dietitian.

Participants were given the choice to select food products to take home. Those on Diet A were given 4 boxes of low fibre breakfast cereal while those on Diet B were given 5 boxes of high fibre breakfast cereal (an extra box of cereal was provided to encourage participants to use the recipes including this ingredient). Both groups were also given cereal snacks (a total of 40) appropriate to their diet. Participants were only given information about the diet to which they were assigned. This information was delivered by the research dietitian following standard operating procedures (SOPs) for Diet A and B. (Appendix 3.4 and 3.5). Participants were asked to refrain from discussing their diet with other participants. However, at the end of the study they were offered full information on the diet they did not follow (to give them the opportunity to try the alternative diet). Women allocated to Diet B (high fibre and healthy eating) were informed that they might experience an increase in flatulence and were advised that they should drink more water. In order to minimise this and other possible adverse events, the high fibre intervention was gradually introduced based on baseline fibre intake, according to a Fibre Intake Table (FIT; Appendix 3.6) under individual supervision of the research dietitian.

# 3.4 Compliance with dietary advice and recommendations

Several methods were implemented to assist compliance with the study diets. These included provision of the British Heart Foundation booklet: 'Food Should Be Fun And Healthy', together with complementary (commercially available) food products (breakfast cereals and snacks) and recipes appropriate to each diet group (A or B). Participants were also provided with an electronic food weighing scale, measuring spoons and cups. These were provided alongside the HARU based nutrition and dietetic advice and support.

Over the intervention period (a total of 12 weeks), participants attended the HARU every 4 weeks for anthropometric measures (section 3.5.1) and to complete study questionnaires (section 3.5.5 & 3.5.6). During these visits, the dietitian met with each participant to discuss any questions or difficulties in following the assigned diet and to provide advice to enhance dietary compliance. Participants were also contacted by phone or email on a weekly basis by the dietitian in order to further assist compliance. Three day food diary records were completed at weeks 1, 5, 9 and 12 of the intervention to evaluate compliance with dietary instructions and to assess dietary changes across the intervention.

## 3.5 Study Measures

The following measures were assessed during the inclusion phase to give baseline (pre-intervention) values. They were then repeated during the intervention phase as detailed below to evaluate how they changed as a result of both dietary interventions.

### 3.5.1 Anthropometric measures

Height and weight were measured initially at screening in order to accurately calculate BMI (kg/m<sup>2</sup>). Height was measured to the nearest 0.1cm using a free standing height measuring unit (Seca, Leicester Height Measure, Birmingham, Ltd) with participants barefoot. Body weight was measured without shoes on a calibrated electronic weighing scale to the nearest 0.1kg (MSP200P, Adam Equipment Co.Ltd.). Waist circumference was measured at the midway between the lower rib margin and the iliac crest (Van der Kooy and Seidell, 1993). Measurement of waist circumference was repeated at each subsequent study visit (weeks 4, 8 and 12). Body composition was measured three times using Air

Displacement Plethysmography (ADP; Life Measurement, Inc., BodPod, Concord, CA, USA), once during the week before the intervention started (week -1), during the last week of the intervention (week 12) and at 12 month follow-up. Body composition was also measured six times using bioimpedance (Tanita, Illinois, USA), once during the inclusion phase (week -1) and then again during weeks 4, 8, 12 of the intervention, at one month and 12 month follow-up. Measurements of body composition using each technique were taken according to standard procedures described in detail elsewhere (Fields et al., 2002; Ginde et al., 2003; Jebb et al., 2000). Both the BodPod and Tanita Systems provided a measure of body weight.

#### 3.5.2 Biochemical measures

Fasting blood samples were collected during the inclusion phase (week -1) and in the last week of the dietary intervention (week 12). These samples were collected at the phlebotomy outpatient clinic at Leeds General Infirmary (LGI) and were assayed for glucose, insulin, cholesterol (total, HDL and LDL), triglycerides and leptin. Homeostatic Model Assessment (HOMA) estimates of insulin resistance (Matthews et al., 1985) were calculated based on single fasting insulin and glucose levels sampled pre and post intervention. Fasting plasma glucose, total cholesterol, HDL cholesterol and plasma triglycerides were measured by enzymatic methods (Siemens Healthcare Diagnostics Inc, Tarrytown, NY). LDL was calculated from subtraction of total cholesterol, HDL cholesterol and triglycerides using the equation of Fiedewald et al. (1972). Plasma concentrations of insulin were measured with the ADVIA Centaur Insulin Assay using two antibodies (Lite Reagent and Solid Phase) (Siemens Medical Solutions Diagnostics, Tarrytown, NY). Plasma concentrations of leptin were measured by enzyme immunoassay technique (R & D Systems Europe, Ltd., Abingdon, UK).

### 3.5.3 Wellbeing Diary Booklets (WDBs)

Participants completed Wellbeing Diary Booklets (WDBs, Appendix 3.7) throughout the inclusion and intervention study phases. At the end of each day, before retiring, women completed a symptom checklist which asked them to rate a range of symptoms on a five point Likert scale from 0 (none) to 4 (extreme). The checklist comprised symptoms relating to women's physiological and psychological wellbeing (e.g. feelings of bloating, mood and alertness). Sixteen

wellbeing symptoms (subjective ratings of feeling slim, feeling fat, feeling happy, stress, difficulty concentrating, mental alertness, mental tiredness, physical tiredness, feeling energetic, breast tenderness, constipation, wind, indigestion, bowel pain, bloating and headaches) are reported and analysed. A blank section on each WDB was provided for women to record any adverse events or other information they wished to report. During the intervention phase (but not the inclusion phase), the Diet B group recorded the amount of fibre consumed each day using a points-based system. This measure of fibre consumption was also used as a measure of compliance.

#### 3.5.4 Food Diary Data: 3 and 7 day food diary records

A 7 day food intake diary (self-reported food intake using household measures) was completed during the first week of the inclusion phase to allow an assessment of usual fibre intake. Participants were given thorough verbal and written instructions on how to fill out the 7 day food diary by the HARU research dietitian. Additionally, 3 day food intake diaries (self-reported food intake using household measures on 2 weekdays and 1 weekend day) were completed during study weeks 1, 5, 9 and 12 of the dietary intervention to evaluate potential differences in usual dietary intake as a result of the intervention. This allowed an assessment of any changes in habitual diet as a result of following Diet A or Diet B. The food diary that was used in this project was specially designed for the purposes of human appetite research and was first used in the Leeds Intervention Snacking Study (Lawton et al., 1998). At the front of the diary, detailed information on how to record food and drink consumed using common household measures is provided. The diary itself is split up into various time periods across the day in order to assist subjects in recording intake between meals etc., thus reducing participants' forgetting to record food and drink consumed between meals. The diary also provides a space for participants to record their activity level throughout the day and to indicate whether they had felt well. This information is useful in order to ascertain whether anything particularly unusual has occurred during the day that might have had an impact on any participant's appetite and food intake (e.g. if the participant had been ill). When completing the food diary records, participants are instructed to record everything they eat and drink. Food diary records were returned to HARU as soon as possible after completion and reviewed by the study dietitian. Dietary records were analysed using nutritional analysis software (Windiets, Research Version, 2010). In order to obtain AOAC measures for fibre intake from the food diary data, foods were analysed using different databases/sources. All non fibre containing foods were analysed using the UK food tables (FSA, 2002 McCance and Widdowson's The Composition of Foods integrated dataset (CoF IDS)). Fibre containing foods were analysed using the USA food tables (AOAC fibre calculations (USDA National Nutrient Databank for Food Composition)). Manufacturer's nutritional information (which reports AOAC fibre calculations) from food packets/wrappers (supplied by volunteers) was entered into the Windiets supplementary database and these data were used as appropriate.

#### 3.5.5 Eating Behaviour Assessments

Participants completed the Dietary Instrument for Nutrition Education (DINE; Roe et al., 1994, Appendix 3.8) four times; once at screening in order to screen out those with an obvious high fibre intake, during the last week of the intervention (week 12) in order to determine differences in fibre intake in response to the intervention, at one month and 12 month follow-up. The DINE is a short food frequency questionnaire that provides a simple and quick assessment of habitual fat and fibre intake. Specific foods are included in the questionnaire because they account for around 70% of the fat and fibre in the typical UK diet. The scores are weighted by the frequency of consumption using five categories which range from 'none' to 'six times a week or more'; more frequently eaten foods are categorised on a daily basis. The scores for each food item are added together to give a total fibre score. A score less than 30 represents a dietary fibre intake of 20g/day or less and a score higher than 40 corresponds to more than 30g/day (amount proposed by the National Advisory Committee on Nutritional Education, NACNE, 1983). An adapted Leeds Women's Wellbeing DINE (LWW-DINE) was created to gain more accurate (quantitative) information on dietary fibre intake since the original DINE only permits classification into low, medium and high fibre categories (Appendix 3.9). The LWW version of the DINE used a scoring system based on the AOAC fibre content of common foods (g fibre/portion) to give an average daily fibre intake (g). Participants also completed the Eating Attitudes Test (EAT-26; Garner et al., 1982, Appendix 3.10) during the screening visit to

ensure they did not have a history of/or current eating disorder/s (reflected by a score >20). The EAT-26 (Garner et al., 1982) is a shortened version of the original 40 item test (EAT-40) previously described by Garner and Garfinkel (1979). EAT-26 has been described as a reliable, valid and objective measure of the symptoms of anorexia nervosa (Garner et al., 1982). However, later studies have suggested that the questionnaire remains a suboptimal screening instrument of anorexia rervosa in non-clinical settings (Rivas, Bersabe, Jimenez and Berrocal, 2010). This questionnaire was used to identify any subjects with eating disturbances. The majority of individuals from non-clinical groups who score highly on the EAT have been identified as experiencing abnormal eating patterns which interfere with normal psychosocial functioning (Button and Whitehouse, 1981; Garner and Garfinkel 1979, 1980). This does not, however, mean that they necessarily satisfy the diagnostic criteria for anorexia nervosa. The Dutch Eating Behaviour Questionnaire (DEBQ; van Strien et al., 1986, Appendix 3.11) and the Three Factor Eating Questionnaire (TFEQ; Stunkard and Messick, 1985, Appendix 3.12) were completed four times; once during the inclusion phase (week -1), during the last week of the intervention (week 12) to provide measures of eating behaviour and to determine any changes in these behaviours during the intervention, at one month and 12 month follow-up. The TFEQ is a validated instrument incorporating measures of restraint (21 items), disinhibition (16 items), and hunger (14 items). Responses are based on a yes/no response format and scored 0 or 1. Restraint refers to cognitive dietary restraint, that is, conscious control over food intake in order to influence body weight and body shape. Disinhibition measures episodes of loss of control over eating, while the hunger scale measures subjective feelings of hunger and food cravings (Stunkard and Messick, 1985). The DEBQ (van Strien et. al., 1986) is a 33-item, selfassessment scale for assessing three eating behaviour domains: restraint (10 items), emotional eating (13 items) and external eating (10 items). Respondents are required to rate each item on a 5-point Likert scale ranging from 1 (seldom) to 5 (very often). The restrained eating scale in this questionnaire is highly correlated with that of the TFEQ (Laessle et al. 1989).

## 3.5.6 Body Shape Questionnaire

Participants were asked to complete the Body Shape Questionnaire (BSQ-34; Cooper et al, 1987; Appendix 3.13) during the inclusion phase (week -1), weeks 4, 8, 12 of the intervention phase, at one month and 12 month follow-up. These were used to allow an assessment of any changes in body shape perception during the intervention and maintenance period for both diet groups. The BSQ is a 34-item self-report questionnaire that measures the degree of body shape dissatisfaction. It provides a means of investigating the role of concerns about body shape in the development, maintenance, and treatment of anorexia nervosa and bulimia nervosa (Cooper et al., 1987).

# 3.6 Study measures assessed exclusively at 12 month follow-up

### 3.6.1 Intuitive Eating Scale

Participants were asked to complete the Intuitive Eating Scale (IES; Tylka, 2006; Appendix 3.14) in order to measure the levels of intuitive eating behaviour and cognitions, present in individuals' eating styles. The IES is a 21-item self-assessment scale for assessing three eating behaviour domains: unconditional permission to eat (9 items), eating for physical rather than emotional reasons (6 items) and reliance on internal hunger/satiety cues (6 items). Respondents are required to rate each item on a 5 point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Higher scores indicate higher levels of intuitive eating.

### 3.6.2 Diet Satisfaction Questionnaire

Participants were asked to complete a diet satisfaction questionnaire (D-SAT; Ello-Martin et al., 2004; Appendix 3.15) to assess their satisfaction with their current diet. This 45 item questionnaire evaluates 7 factors which might affect diet satisfaction: family dynamics, cost, preparation, convenience, healthy lifestyle, negative aspects and preoccupation with food. The questionnaire provides a score for each of the factors as well as a score for overall diet satisfaction. Items are coded so that a higher score indicates greater satisfaction or perceived benefit. The available responses to questions were arranged on a 5-point Likert scale from 1 ("strongly disagree") to 5 ("strongly agree") (Ello-Martin et al., 2007).

## 3.6.3 Social Readjustment Rating Scale or Life Events Scale

Participants were asked to complete the Social Readjustment Rating Scale (SRRS) or Life Events Scale (SRRS/LES; Holmes and Rahe, 1967; Appendix 3.16) in order to assess stressful events that they might have experienced over the previous 12 months and to explore how this might differ between successful and unsuccessful weight maintainers/gainers.

## 3.6.4 Depression Anxiety and Stress Scales

Participants were asked to complete the Depression Anxiety Stress Scales (DASS42; Lovibond and Lovibond, 1995; Appendix 3.17) in order to assess symptoms of depression, anxiety and stress. The reliabilities of the DASS scales, as measured by Cronbach's alpha, were .90 for anxiety, .95 for depression, .93 for stress and .97 for the total (Lovibond and Lovibond, 1995). The questionnaire incorporates three scales and each of the scale contains 14 items. Participants were asked to use a 4 point severity/frequency scale to rate the extent to which they have experienced each state over the past week.

## 3.6.5 Beliefs about causes of obesity

Participants rated a series of a statements relating to the causes of obesity (Ogden et al., 2001) on five point Likert scales ranging from 'not at all' (1) to 'totally' (5) (Appendix 3.18).

## 3.7 Study Procedure and Study Visits

A full study schedule is provided in Appendix 3.19. This displays the study weeks/visits during which each aspect of the study took place.

## 3.7.1 Screening visit (Visit 1)

Participants who appeared to be eligible on the basis of the preliminary telephone interview were asked to attend the HARU for a screening visit. During this visit:

- the researcher checked that volunteers had read and understood the PIS
- written informed consent was taken (Appendix 3.3)
- the inclusion / exclusion criteria were checked verbally and via completion of a Demographic Information Questionnaire (DIQ, Appendix 3.3)
- women completed the DINE, LWW-DINE and the EAT-26 Height and weight were measured to enable the accurate calculation of BMI

If women did not remain eligible to participate in the study after the inclusion/exclusion criteria had been checked (including the DINE, LWW-DINE and EAT-26 scores), they were informed of this and thanked for their time. Women who remained eligible to continue in the study were provided with a 7day food diary (and freepost envelope for its return) and asked to complete and return this booklet as soon as possible. They were also provided with a pack of WDBs (and freepost envelopes) and asked to begin the first of these on the same day as they began the 7-day food diary and to continue completing one WDB each week thereafter. The first day of completing the 7-day food diary and the WDB marked the beginning of the inclusion phase. Women's eligibility to continue with the study was assessed after the analysis of the 7-day food diary on the basis of their average daily fibre intake using fibre points. Women were considered ineligible to continue with the study if they had an average fibre intake >15g/day. Ineligible women were informed of this by telephone, thanked for their time and sent a small honorarium to compensate them for the time and effort that they had invested in the study (£10 gift voucher).

Women were eligible to continue onto the intervention phase of the study if their 7-day food diary showed that they had an average daily fibre intake  $\leq$  15g/day. These women were contacted to arrange their next study visit and contacted 2-3 days before this to remind them to attend after an overnight fast.

## 3.7.2 Inclusion Visit (Visit 2, week -1): Baseline measures

Inclusion and exclusion criteria were re-checked at this visit and at every subsequent visit. During this visit participants:

- had a fasting blood sample taken to assess glucose, cholesterol (total, HDL and LDL), insulin, triglycerides and leptin at LGI
- had anthropometric measures taken: body composition via ADP and bioimpedance, weight and waist circumference
- received a 3-day food diary that was clearly labelled with the study week in which it was to be completed and reminded to complete this diary on 2 weekdays and 1 weekend day during the following week.

- received a pack of WDBs to complete during weeks 1-4 and freepost envelopes for their return
- completed the DEBQ, TFEQ and BSQ-34

At this visit, participants met with the study dietitian and received eating advice in line with the treatment arm to which they had been assigned and complimentary study food products appropriate to Diet A or B to take home. Women were asked to attend three further intervention study visits during the intervention phase (weeks 4, 8 and 12). Women were telephoned 2-3 days before these visits were due to remind them to attend and also to remind them to fast overnight prior to the visit in week 12.

### 3.7.3 Interim intervention visits (Visit 3 and 4, week 4 and 8)

During these visits inclusion/exclusion criteria were rechecked. Participants' weight was measured to enable accurate measurement of their BMI (using height previously measured at screening). Waist circumference and body composition (via bioimpedance) measurements were also taken. Women also completed the BSQ-34. They had a meeting with the study dietitian and received complementary study food products appropriate to their diet (A or B) to take home, 4 WDBs and a 3-day food diary to be completed on 2 weekdays and 1 weekend day during the following week and to be returned as soon as possible.

### 3.7.4 Intervention visit (visit 5, week 12)

The same procedure was followed as at visit 2 (week -1) but women were also asked to complete the DINE and LWW-DINE questionnaires. If required, a final WDB was provided. Participants were asked to complete this up until they finished completing their final food diary record (provided at the previous visit).

## 3.7.5 Debriefing Visit (Visit 6, week 13)

During this visit women were asked to return any outstanding study paperwork (questionnaires, food diaries, WBDs) and to complete an end of study questionnaire appropriate to their diet (Appendix 3.20 and 3.21). Their honorarium was processed after this visit.

## 3.7.6 Early termination visit

Participants who dropped out prior to completing the study were invited to an optional early termination visit at which final body weight, waist circumference

and body composition (via bioimpedance) were measured. Of the 4 participants who did not complete the study only 1 participant agreed to attend this visit.

## 3.7.7 Optional Follow up Visit (+1Month)

All women who completed the intervention were invited to an optional follow up visit (one month after Visit 6) where they had their body weight, body composition (via bioimpedance) and waist circumference measured. They were also asked to complete the DINE, LWW-DINE, DEBQ, TFEQ and BSQ-34.

## 3.7.8 12 month follow-up visit

All women who completed the intervention were invited to a 12 month follow up visit where they had their body weight, body composition (via bioimpedance and BodPod) and waist circumference measured. They were also asked to complete the DINE, LWW-DINE, DEBQ, TFEQ, BSQ-34, IES, D-SAT, SRSS and DAAS-42. They were also asked to indicate the extent to which they thought that their current weight was due to medical, psychological, behavioural and social causes (Ogden et al., 2001).

## 3.8 Adverse Events (AEs)

Any Adverse events (AEs) reported or observed during the study were documented by research staff at the time they were reported/observed using a standard adverse event report form (see Appendix 3.22). As this was a low risk study, only information on AEs generated spontaneously by participants was documented. For AEs occurring away from the University, participants were advised to seek help for the AEs in the usual way through their general practitioner (GP).

## 3.9 Ethical considerations and confidentiality

Ethical approval was obtained from the South Humber NHS Research Ethics Committee (Reference number: 10/H1305/6). Participants were informed of the study requirements and gave their written consent before taking part in the study. Any records identifying the participants (e.g. DIQ) and all the information that was collected from participants during the course of the research were kept strictly confidential. Participants were given a unique study ID number (unique screening number) on entry to the study. Participants who were randomised were allocated a unique randomisation number and all study paperwork was coded by screening or randomisation numbers rather than participant names (with the exception of the DIQ and signed consent forms).

An honorarium of £120 (taxable) was paid to each participant following completion of the 12 week intervention and on receipt of their debriefing questionnaire. Participants who dropped out during the study received payment for completed visits on a sliding (pro-rata) scale.

For the 12 month follow-up, ethical approval was obtained from the Institute of Psychological Sciences, Research Ethics Committee, University of Leeds (IPS REC Reference number 11-0224; Appendix 3.23). Participants were informed of the study requirements and gave their written consent before taking part in the study. Participants were given a unique study ID number (unique screening number) on entry to the LWW study and this number was used throughout the follow-up study. All study paperwork was coded by this unique study ID code rather than participant names. A £10 love to shop voucher was given to each participant following completion of the follow-up visit to compensate for their time and effort.

## 3.10 Statistical analysis

All data were entered, processed and checked in Excel. Analysis was performed using SPSS 20.0 (SPSS, Inc, Chicago, IL) where complete data were available, SAS 9.1.3 (SAS, Institute Inc., Cary, NC) and R (R Core Team, 2013) where missing data occurred, in which case missing values were not imputed. All data were examined for outliers and relevant assumptions were checked for each inferential analysis.

## 3.10.1 Part 1 Weight loss phase

The primary outcome variable was body weight change (kg) over the 12 week intervention. Secondary physiological endpoints included anthropometric measures, habitual fibre intake and biomarkers of health. Secondary psychological endpoints included eating behaviour characteristics, body shape perceptions and daily wellbeing symptoms reported in the WDBs.

Baseline characteristics were compared at screening and randomisation using independent t-tests or Chi-squared tests as appropriate. Change in outcome

variables as a result of the intervention were analysed using 2x2 mixed ANOVAs with diet as the between subjects factor and time as the within subjects factor. Changes in body weight were reported based on ADP data as it is the most sensitive measure employed. Hence data based on bioimpedance are not reported. Where Mauchley's test of sphericity was significant, Greenhouse Geisser's (GG) correction was applied and "GG adjusted p" is used to indicate this. Levene's test was used to examine the homogeneity of variance of the between-subjects factors. When Levene's test was significant, degrees of freedom (df) were adjusted and original df are reported. Post hoc comparisons were performed using the Bonferroni correction. Correspondence between body weight, and food intake measures, using different equipment/techniques was assessed using Pearson's Product Moment correlation coefficients.

Wellbeing diaries were completed on a daily basis for at least 13 weeks. Sixteen wellbeing symptoms (subjective ratings of feeling slim, feeling fat, feeling happy, stress, difficulty concentrating, mental alertness, mental tiredness, physical tiredness, feeling energetic, breast tenderness, constipation, wind, indigestion, bowel pain, bloating and headaches) were scored on a 0 to 4 Likert scale (0=none, 1=minimal, 2=moderate, 3=a lot/very, 4=extreme). Likert scale data are ordinal data (i.e. data that can be ranked in order but the distance between them is unknown) and hence the most appropriate analysis is ordinal logistic regression (OLR). OLR is suitable for dichotomous comparisons, such as being on Diet A or Diet B. The results of OLR are expressed as odds ratios. These indicate the predicted likelihood that an individual with a particular symptom score was on Diet B as opposed to Diet A. In OLR, Diet A is used as the reference category and week -1 (baseline, pre-intervention) is the reference value against which the 12 weeks of the intervention are compared. Hence a significant effect of a particular week would indicate that the pattern of scores in this week differed from baseline. This analysis also permits the estimation of the interaction of diet with the week of the intervention relative to the baseline week. Multiple OLRs were performed using R to model the relationship between ratings of different symptoms and being on Diet A or Diet B during each week of the 12 week dietary intervention. The likelihood ratio test was<sup>1</sup> used to examine model fit. A significant (p<0.05) change in the test statistic between the baseline model (overall effect of

Diet B compared with Diet A) and the final model (effect of Diet B compared to Diet A according to week of intervention) demonstrates that the predictors were significant. All ordinal regression models showed a highly significant change in score (smallest  $\chi^2$ =38, df=25, p<0.05). A significant  $\chi^2$  indicates that the model gives a statistically significant improvement over the baseline intercept-only model. The test of parallel lines was examined to determine whether the proportional odds assumption was satisfied (Fullerton and Xu, 2012; Aki and Yildiz, 2014). The proportional odds assumption (also known as parallel regression assumption) for modelling ordinal data suggests that the coefficients that describe the relationship between, the lowest versus all higher categories of the response variable are the same as those that describe the relationship between the next lowest category and all higher categories (Fullerton and Xu, 2012; Aki and Yildiz, 2014).

The relationship between change in body weight during the intervention and changes in physiological and/or psychological factors were assessed using Pearson's Product Moment correlations coefficients. Data were checked for outliers, multicollinearity, homoscedasticity and linearity prior conducting multiple The inter-correlations between predictor variables regression analyses. produced as part of the multiple regression analyses indicated that none of the predictor variables were strongly correlated which would be indicative of multicollinearity (coefficients  $> \pm 0.9$ ; Tabachnick & Fidell, 2007). Cases were considered outliers when standardised residuals exceeded ±3.3 and were removed from the analysis. Cook's Distance values indicated that no values were >1 suggesting that no cases were particularly influential (Cook Distance min: 0.00 max: 0.06). Following each regression analysis, a graphical examination of the residuals indicated no departure from normality confirming the data were suitable for regression analysis. Residual scatterplots of standardised residuals against standardised predicted residuals indicated that the assumptions of homoscedasticity and linearity were met. Multiple regression models were conducted in order to predict weight loss from baseline physiological and/or psychological variables and from changes in variables during the intervention using R. Multiple regressions were conducted in R (R Core Team, 2013) using the (Im) function. R uses stepwise method with joint forward, backward and both as a default. Akaike's Information Criterion (AIC) was used for model selection as it minimises the expected Kullback–Leibler divergence, also called discrimination information (i.e. measure of the difference between two probability distributions of the fitting model and the truth), where a smaller AIC value indicates a better model. The minimum AIC criterion produces a selected model, which is close to the best possible choice (Hurvich and Tsai, 1989; Burnham and Anderson, 2002). Both raw AIC values and changes in AIC ( $\Delta$ AIC= AIC<sub>best</sub> -AIC<sub>min</sub>) are reported. Akaike's weights (the probabilities of one model being better than another) were also checked as a continuous measure of strength of evidence (Burnham and Anderson, 2002)

#### 3.10.2 Part 2 Weight maintenance phase (1 and 12 month follow-up)

The relationship between change in body weight during the intervention and at follow-up (1 month and 12 month) and changes in physiological and/or psychological factors were assessed using Pearson's Product Moment correlations coefficients. The relevant assumptions were tested and confirmed as described in part 1. Multiple regression models were conducted in order to predict weight loss maintenance from baseline physiological and/or psychological variables and from changes in variables over time following the same procedure as in part 1. Binary logistic regression was performed in order to examine the effects of continuous variables assessed at 12 month follow-up in predicting a dichotomous variable (successful weight loss maintenance or not).

<sup>&</sup>lt;sup>1</sup> The likelihood test indicates that the model as a whole is statistically significant, as compared to the null model with no predictors

## 3.11 Results from weight loss phase –Part 1

#### 3.11.1 Participant Characteristics at Screening

Table 3.11-1 summarises the baseline characteristics of participants at screening. At screening, there were no significant differences between participants subsequently assigned to Diet A and Diet B with respect to age, body weight, height or BMI. There were also no significant differences between the groups in terms of eating behaviour; frequency of regular breakfast consumption, EAT-26 scores, or fibre intake assessed by the DINE and LWW-DINE (largest t=-0.76, df=69, p=0.45).

### 3.11.2 Participant Characteristics at Randomisation (week -1, Visit2)

Participant characteristics at randomisation (week-1) are presented in Table 3.11 -2 (anthropometric and physiological characteristics) and table 3.11-3 (psychological characteristics). There were no significant differences between participants allocated to Diet A and Diet B at randomisation (week-1) in terms of anthropometric characteristics (weight, BMI and body composition variables assessed by ADP and bioimpedance; largest t=0.91, df=69, p=0.37) or fasting blood parameters (glucose, total cholesterol, HDL, LDL, triglycerides, leptin, insulin and HOMA). However, participants allocated to Diet A (t =-1.96, df=69, p=0.054, largest t for all comparisons in Table 3.10-2). Furthermore, there were no significant differences (see Table 3.10-3) between these groups in terms of psychological characteristics (BSQ, TFEQ and DEBQ eating behaviour traits).

		Whole sample (n=71)	Diet A (n=36)	Diet B (n=35)
		Mean (SE)	Mean (SE)	Mean (SE)
		(Min, Max)	(Min, Max)	(Min, Max)
Demographics				
Age (y)		34.45 (1.21)	33.61 (1.72)	35.31 (1.71)
		(18, 48)	(20, 48)	(18, 48)
Body weight (kg)		84.21 (1.37)	84.33 (2.02)	84.08 (1.87)
		(61.3, 116.4)	(64.3, 116.4)	(61.3, 112.9)
Height (m)		1.65 (0.01)	1.64 (0.01)	1.65 (0.01)
		(1.52,1.82)	(1.53, 1.78)	(1.52, 1.82)
BMI (kg/m²)		31.02 (0.38)	31.09 (0.55)	30.9 (0.54)
		(26, 38.9)	(26, 38.9)	(26.4, 37.9)
Employment	FT	28(39%)	15 (42%)	13 (37%)
	PT	18 (25%)	10 (28%)	8 (23%)
	S	19(27%)	10 (28%)	9 (26%)
	н	2 (3%)	0	2 (6%)
	UN	4 (5%)	1 (3%)	3 (8%)
Eating Behaviour				
BF regular consumption	Y	59 (83%)	31 (86%)	28 (80%)
	Ν	12 (17%)	5 (14%)	7 (20%)
BF cereal consumption	Y	46 (65%)	23 (64%)	23 (66%)
	Ν	25 (35%)	13 (36%)	12 (34%)
EAT- 26		6.48 (0.57)	6.31 (0.78)	6.66 (0.85)
		(0, 19)	(0, 19)	(0, 19)
DINE		27.41 (1.2)	26.83 (1.73)	28 (1.68)
		(5, 59)	(9, 59)	(5, 48)
LWW-DINE		10.99 (0.4)	10.99 (0.58)	10.99 (0.56)
		(4.8, 19.5)	(4.4, 18)	(5.7, 19.5)

Table 3.11-1 Participant Characteristics at Screening (n=71)<sup>1</sup>

Key: BF: breakfast; FT: full time; PT: part time; S: student; H: housewife; UN: unemployed; Y: Yes; N: No

<sup>1</sup>Data were examined across the whole sample (n=71). The subsequent diet groups were also compared to determine any differences at screening. Values are means and standard errors (SEs) or number of participants (percentages). Independent t-tests were used to compare characteristics between the two diet groups. The Chi-square test was used to test any difference in the frequency of regular breakfast consumption between the two diet groups.

There were no significant differences in terms of demographic or eating behaviour characteristics between the Diet A and Diet B groups at screening

e (n=71)	Diet A (n=36)	Diet B (n=35)
E)	Mean (SE)	Mean (SE)
(xr	(Min,Max)	(Min, Max)
41)	83.87 (2.09)	83.81 (1.94)
7.4)	(61.3, 117.4)	(61.3, 112.3)
8)	30.03 (1)	30.98 (0.58)
13)	(25.44, 37.9)	(25.97, 38.13)
39)	83.17 (2.02)	82.87 (1.94)
6)	(61.7, 116)	(59.8, 111.3)
9)	30.56 (0.53)	30.64 (0.58)
3)	(25, 37.4)	(25.7, 37.8)
05)	36.6 (1.57)	36.11 (1.4)
3)	(21.5, 61.3)	(20.5, 52.2)
67)	43.55 (1.04)	43.02 (0.84)
9)	(32, 56.9)	(30.1, 54.6)
67)	46.57 (0.99)	47.03 (0.9)
5)	(35, 61.5)	(37.1, 61.6)
1)	84.23 (2.05)	83.97 (1.94)
7.5)	(62.8, 117.5)	(61.4, 112.5)
39)	30.95 (0.53)	31.03 (0.58)
2)	(25.5, 37.9)	(26, 38,2)
94)	34.31 (1.36)	34.35 (1.33)
3)	(21.1, 56.3)	(21.7, 51.3)
5)	40.28 (0.71)	40.47 (0.73)
6)	(31.7, 50.4)	(31.5, 50.6)
57)	49.93 (0.85)	49.63 (0.77)
7)	(39.4, 61.3)	(39.7, 62.7)
5)	4.88 (0.07)	4.93 (0.08)
)	(3.9, 5.8)	(4.1, 6)
.2)	4.83 (0.16)	5.04 (0.17)
	(3.3, 6.8)	(3.4, 7)
5)	1.56 (0.08)	1.43 (0.06)
3)	(1, 2.8)	(0.7, 2.2)
1)	2.88 (0.13)	3.11 (0.14)
3)	(1.4, 4.8)	(1.8, 4.7)
<i>,</i> )6)	0.91 (0.06)	1.14 (0.11)*
, ))	(0.3, 1.9)	(0.5, 2.9)
, 25)	15.24 (1.68)	14.52 (1.88)
		(4.2, 59.49)
	, , ,	32.94 (2.62)
		(11.2, 77.7)
		1.83 (0.22)
		(0.5, 4.7)
2	99) 888) 7) 5)	88)       36.89 (2.7)         7)       (6.4, 75.8)         5)       1.94 (0.21)

## Table 3.11-2 Anthropometric, body composition characteristics and fasting blood parameters at randomisation (week -1)

\*p=0.054 (B>A); <sup>1</sup>Data for these ADP variables were available for 70 participants (36A, 34B) due to a technical problem with the BodPod. All other variables were examined across the whole sample (n=71). The diet groups were also compared to determine any differences at randomisation. Values are means and standard errors (SEs). Independent t-tests were used to compare characteristics between the two diet groups. IR=insulin resistance.

	Whole sample (n=71)	Diet A (n=36)	Diet B (n=35)
	Mean (SE)	Mean (SE)	Mean (SE)
	(Min, Max)	(Min ,Max)	(Min, Max)
BSQ	112.8 (3.97)	120.31 (4.91)	105.09 (6.07)
	(40, 180)	(61, 177)	(40, 180)
TFEQ outcomes			
Restraint	7.58 (0.5)	8.17 (0.77)	6.97 (0.63)
	(0, 17)	(1, 17)	(0, 14)
Disinhibition	9.52 (0.41)	9.44 (0.58)	9.6 (0.59)
	(0, 15)	(3, 14)	(0, 15)
Hunger	6.2 (0.44)	6.86 (0.67)	5.51 (0.54)
	(1, 14)	(1, 14)	(1, 12)
DEBQ outcomes			
Restraint	2.54 (0.08)	2.54 (0.12)	2.54 (0.11)
	(1.1, 4.3)	(1.1, 3.8)	(1.4, 4.3)
Emotional eating	2.9 (0.1)	2.89 (0.16)	2.92 (0.12)
	(1.2, 5)	(1.2, 4.7)	(1.7, 5)
External eating	2.89 (0.06)	2.92 (0.09)	2.86 (0.09)
	(1.9, 4.3)	(1.9, 4.3)	(2, 4.2)

Table 3.11-3 Psychological characteristics at randomisation (week -1)
continued (updated)

<sup>1</sup>Data were examined across the whole sample (n=71). The diet groups were also compared to determine any differences at randomisation. Values are means and standard errors (SEs). Independent t-tests were used to compare characteristics between the two diet groups.

# 3.12 Habitual Dietary Intake during the Inclusion Phase (between screening and randomisation)

### 3.12.1 Dietary intake assessed by the 7 day food diary records

The 7 day food diary records (n=70) were analysed using Windiets software and the resulting dietary intakes are shown in Table 3.12-1. One 7-day food diary was lost and could not, therefore, be analysed. In terms of energy (kcal) macronutrient (g), alcohol (g) and fibre (g) intake there were no significant differences between the participants subsequently randomised to Diet A and Diet B during the

inclusion phase (largest t=-1.15, df=68, p=0.14). Average fibre intake was confirmed as <15g/day for both Diet A and Diet B groups.

Under-reporting and/or under-eating between participants randomised to Diet A and Diet B at screening was estimated using Schofield equations (Schofield, 1985). The mean difference between reported (food diary) and calculated energy intakes (using Schofield equations) was in the region of 450kcals and suggests that participants were underreporting (or undereating) by about 20%. There were no significant differences in degree of under-reporting between participants on Diet A (mean=451.82, SE=70.07) and those on Diet B (mean=446.67, SE=61.24) during screening (t=0.06, df=68, p=0.95).

Table 3.12-1 Dietary Intake of participants at baseline (7 day food diary records)

	Whole sample (n=70)	Diet A (n=35*)	Diet B (n=35)
	Mean (SE)	Mean (SE)	Mean (SE)
Energy (Kcal/d)	1809.79 (39.81)	1806.85 (58.04)	1812.72 (55.35)
Protein (g/d)	75.42 (1.69)	77.56 (2.15)	73.29 (2.58)
Carbohydrates (g/d)	210.46 (5.68)	213.05 (8.84)	207.87 (7.25)
Fat (g/d)	68.69 (2.1)	65.55 (2.82)	71.84 (3.06)
Alcohol (g/d)	10.44 (1.52)	11.22 (2.44)	9.66 (1.83)
Dietary Fibre (g/d)	14.28 (0.25)	14.18 (0.35)	14.37 (0.37)

### 3.12.2 Habitual (baseline) fibre intake

Habitual fibre intake was initially assessed using the DINE (see section 3.4.5). This measure of fibre intake was compared with that yielded by the LWW-DINE (described in section 3.4.5) and corroborated by fibre intake (points/day using the points-based system, see section 3.4.4) assessed from the 7-day food diary records completed during the inclusion phase. Low fibre intakes assessed using this points system were later confirmed by the full food diary data analysis using Windiets (grams/day), shown in Table 3.12-1. Table 3.12-2 shows the baseline fibre intake of participants assessed using all 4 methods. No significant differences were observed between the 2 diet groups in terms of their habitual fibre intake (assessed using 4 methods) at the beginning of the study; largest t=-0.76, df=69, p=0.45). These data also confirmed that all participants were low fibre consumers.

	Whole sample (n=71)	Diet A (n=36)	Diet B (n=35)
	Mean (SE)	Mean (SE)	Mean (SE)
	(Min, Max)	(Min, Max)	(Min, Max)
DINE (score)	27.41 (1.2)	26.83 (1.73)	28 (1.68)
	(5, 59)	( <i>9, 59</i> )	(5, 48)
LWW DINE (g/d)	10.99 (0.4)	10.99 (0.58)	10.99 (0.56)
	(4.8, 19.5)	(4.8, 18)	(5.7, 19.5)
7 day food diary	13.4 (0.24)	13.31 (0.35)	13.49 (0.32)
(points/d)	(8.5, 16.4)	(8.5 <i>,</i> 16.4)	(9.2, 16.4)
7 day food diary*	14.28 (0.25)	14.18 (0.35)	14.37 (0.37)
(g/d)	(7.93, 17.77)	(9.39, 17.6)	(7.93, 17.77)

Table 3.12-2 Habitual fibre intake of participants at baseline

\*Data are based on n=70 food diaries (35A; 35B)

The relationships between fibre intake assessed using the DINE (fibre score), LWW-DINE (fibre g/day) and the 7day food diary records (fibre points/day and g/day) were investigated using Pearson Product Moment correlation coefficients. Preliminary analyses were performed to ensure no violations of the assumptions of normality, linearity and homoscedasticity. Results are presented in Table 3.12-3.

 Table 3.12-3 Pearson's product moment correlations across the different

 methods used to assess fibre intake

	DINE	LWW-DINE	Fibre	Fibre g/d <sup>1</sup>
			points/d <sup>1</sup>	
DINE	_	0.69**	0.25*	0.33**
LWW-DINE	_	_	0.28*	0.37 **
Fibre	_	_	_	0.74**
points/d <sup>1</sup>				
Fibre g/d <sup>1</sup>	_	_	_	_

<sup>1</sup> Fibre intake calculated from 7 day food diaries. Significant correlations are denoted by \*p<0.05; \*\*p<0.01

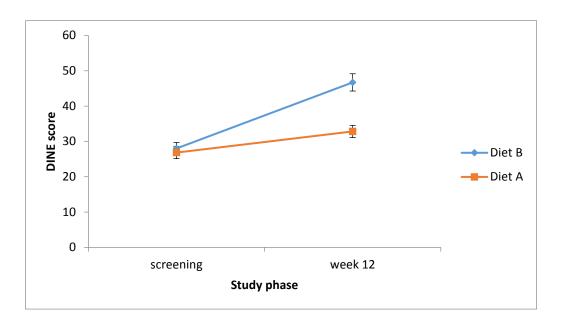
There was a strong positive correlation between fibre intake assessed by the DINE and LWW-DINE. There was a significant moderate correlation between fibre intake assessed using both the LWW-DINE and DINE and that assessed by the 7-day food diary records using the points system (points/day). There was a

significant moderate positive correlation between fibre intake assessed using both the LWW-DINE and DINE and that assessed from the 7-day food diary records using Windiets (g/day). Additionally, there was a strong positive correlation between fibre intake assessed using both measures from the 7-day food diary records (points/day and g/day, see Table 3.12-3). It is understandable that DINE and LWW-DINE were significantly correlated since they are both retrospective measures of habitual fibre intake (participants reporting intake of fibre containing foods eaten in a typical week) whereas the 7-day food diary (points/day and g/day) shows prospectively reported fibre intake (participants reporting what they eat as they eat it).

## 3.12.3 Changes in Fibre Intake during the 12-week Dietary Intervention Phase

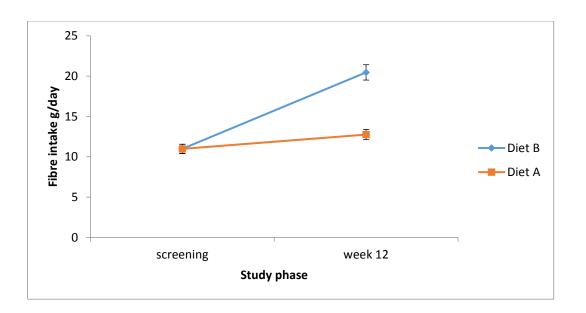
Changes in dietary fibre intake during the 12-week intervention phase were assessed using 3 different methods. Changes in fibre intake were calculated using the DINE (score), LWW-DINE (fibre points/d) and fibre g/d calculated from 7-day food diaries completed at baseline and 3-day food diaries completed at week 12. In order to ensure that the food diary data collected at baseline (7 days) and week 12 (3 days) were comparable the following strategy was adopted; The average fibre intake (g/day) from 3 consecutive days (2 weekdays and one weekend day) within the 7-day food diary records completed at baseline was compared with average fibre intake (g/day) from the 3-day food diaries completed at week 12.

A 2x2 ANOVA was performed to evaluate changes in DINE scores in response to the intervention. There was a significant main effect of time (F (1, 69) = 44.65, GG adjusted p<0.001) and diet (F (1, 69) =9.55, p<0.01) on DINE scores. There was also a significant diet\*time interaction (F (1, 69) =13.37, GG adjusted p<0.001). A post hoc t-test at week 12 revealed that DINE scores were significantly higher for participants on Diet B than those on Diet A (t=-4.06, df=69, p<0.001; Figure 3.12-1).



## Figure 3.12-1 Changes in DINE scores from screening to the end of the intervention

Changes in fibre intake (g/day) assessed using the LWW-DINE for both diets are presented in Figure 3. A 2x2 ANOVA revealed that there was a significant main effect of time (F (1, 69) =94.34, GG adjusted p<0.001) and a significant main effect of diet (F (1, 69) = 23.37, p<0.001) on fibre intake. The diet\*time interaction (shown in Figure 3) was also significant (F (1, 69) = 44.32, GG adjusted p<0.001). Participants who followed Diet B showed a significant increase in their fibre intake from baseline (screening) to the end of the intervention (week 12) whereas those who followed Diet A did not significantly increase their fibre intake during this period. Fibre (g/d) assessed using LWW-DINE increased by 9.5 (SE=0.97) for those who followed Diet B while it increased by 1.77 (SE=0.64) for those who followed Diet A. A post hoc t-test revealed significant differences between diet groups at week 12 (t=-6.74, df = 59.54, p<0.001). Those who followed Diet B had a higher fibre intake (g/d) than those who followed Diet A at week 12.



## Figure 3.12-2 Mean (+/-SE) changes in fibre intake (g/day) assessed using the LWW-DINE from screening to the end of the intervention

Participants on Diet B were also asked to record daily fibre intake using the points system (see section 3.4.3). Figure 3.12-3 shows that participants following Diet B gradually increased their daily fibre intake and that they reached 25g/d by about week 3. Although fibre intake fluctuated over time, it generally remained above 23g/d until week 12 (1point= 1g of fibre).

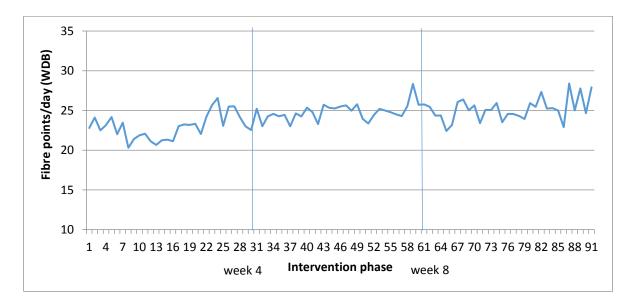


Figure 3.12-3 Mean daily fibre intake (points/day) recorded in the wellbeing diary booklets for those following Diet B during the intervention phase

## 3.12.4 Changes in Dietary intake from baseline to week 12 (n=50)

A total of 50 participants provided food diary data at both the baseline and week 12 time points. Changes in macronutrient, alcohol and fibre intake between participants randomised to Diet A (n=27) and Diet B (n=23) from baseline to the end of the intervention were assessed using the 7 day diary records from the baseline inclusion phase and the 3 day diary records (n=50) at week 12 (Table 3.12-4). Within this subsample of all study completers, there were no significant differences in macronutrient, alcohol and fibre intake between the participants randomised to Diet A (n=27) and those randomised to Diet B (n=23) during the inclusion phase (largest t=1.28, df=48, ns). Furthermore, there were no significant differences between under-reporting estimated in the participants randomised to Diet A (mean=350.78, SE=76.92) and those randomised to Diet B (mean=415.27, SE=74.06) at baseline (t=-0.6, df=48, p=0.55).

	Baseline (inclusion phase)		Interventi			
	Diet A (n=27)	Diet B (n=23)	Total (n=50)	Diet A (n=27)	Diet B (n=23)	Total (n=50)
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)
Energy (Kcal/d)	1905.9 (71.95)	1897(84.04)	1902.22 (54.24)	1594.43 (71.78)	1761.48 (80.38)	1671.27 (54.33)
Protein (g/d)	83.07 (3.65)	76.5 (3.55)	80.04 (2.57)	75.44 (1.9)	79.51 (3.6)	77.31 (1.95)
Carbohydrates (g/d)	220.69 (10.7)	217.1 (10.45)	219.04 (7.45)	196.28 (9.22)	220.45 (10.86)	207.4 (7.19)
Fat (g/d)	68.13 (3.83)	74.36 (4.58)	71 (2.96)	53.23 (4.57)	58 (4.22)	55.42 (3.13)
Alcohol (g/d)	15.18 (3.63)	11.74 (2.58)	13.6 (2.28)	7.92 (2.45)	8.71 (2.62)	8.28 (1.77)
Dietary Fibre (g/d)	14.08 (0.52)	14.51 (0.59)	14.28 (0.39)	17.65 (0.76)	25.17 (1.45)	21.11 (0.94)

Table 3.12-4 Changes in macronutrient (g), alcohol (g/d) and fibre intake (g/d) between participants on Diet A and Diet B assessed using food diary records (n=50)

Changes in fibre intake (g/day) assessed using 3 consecutive days from the 7 day (baseline) and 3 day (week 12) food diary records for both diets are presented in Figure 3.12-4.

A 2x2 mixed ANOVA was performed to evaluate under-reporting and/or undereating during the intervention as a function of time and diet. There was a significant effect of time for under-reporting (F (1, 48) = 8.5, p<0.01). However, there was no significant effect of diet (F (1, 48) =0.28, ns) or significant diet\*time interaction (F (1, 48) = 3.22, p=0.08) for under-reporting. Participants irrespective of diet group showed more under-reporting (or undereating, reduced energy intake) at week 12 than at screening.

A 2x2 mixed ANOVA was performed to evaluate changes in fibre intake (g/day) during the intervention in response to the diets. The diet\*time interaction was significant (F (1, 48) =17.67, p<0.001). Participants who followed Diet B showed a significant increase in their fibre intake from baseline (inclusion phase) to the end of the intervention (week 12) whereas those who followed Diet A did not significantly increase their fibre intake. A post hoc t-test revealed significant differences between diet groups at week 12 (t=-4.79, df=48, p<0.001). Figure 5 shows that fibre intake increased by 3.58 g/d for those who followed Diet A and increased by an average of 10.66 g/d for those who followed Diet B. There was a significant main effect of time (F (1, 48) =71.39, p<0.001) and a significant main effect of diet (F (1, 48) =19.01, p<0.001) for fibre intake.

All 3 measures used to assess changes in fibre intake (DINE, LWW DINE and the food diary records) showed that participants who followed Diet B increased their fibre intake during the 12-week intervention. This is further supported by an increase in daily fibre intake (points/day) as shown in Figure 3.11.4-1 using the fibre points records from the WDBs.

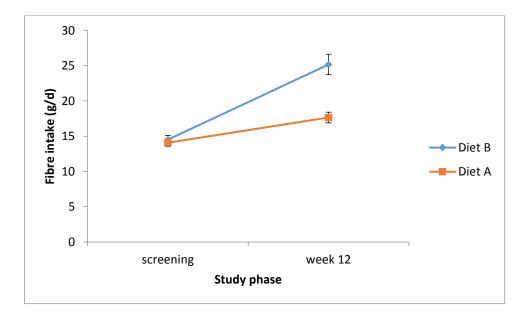


Figure 3.12-4 Mean (+/-SE) changes in fibre intake (g/day) assessed using 3 and 7-day food diary records from screening to the end of the intervention (n=50)

A 2x2 mixed ANOVA revealed that there was a significant main effect of time (F (1, 48) =10.7, p<0.01) for energy intake (kcal/d). Participants on both diets reduced their energy intake (kcal/d) from baseline to the end of the intervention. However, there was no significant diet\*time interaction (F (1, 48) = 3.56, p=0.21) and no significant main effect of diet (F (1, 48) =0.89, ns) for energy intake (kcal/d).

A 2x2 mixed ANOVA revealed that there was a significant main effect of time (F (1, 48) = 15.83, p<0.001) for fat intake (g/d). Participants on both diets reduced their fat intake (g/d) from baseline to the end of the intervention. However, there was no significant effect of diet (F (1, 48) = 1.37, ns) for fat intake (g/d) and no significant diet\*time interaction (F (1, 48) = 0.03, ns).

A 2x2 mixed ANOVA revealed that there was no significant main effect of time (F (1, 48) = 0.58, ns) or diet (F (1, 48) = 0.14, ns) for protein intake (g/d). There was no significant diet\*time interaction (F (1, 48) = 3.07, p=0.09).

A 2x2 mixed ANOVA was performed to evaluate changes in CHO intake (g/d) in response to the dietary interventions. There was no significant main effect of time (F (1, 48) =1.74, ns) or diet (F (1, 48) =0.71, ns) for CHO intake (g/d). There was also no significant diet\*time interaction (F (1, 48) =3.02, p=0.09).

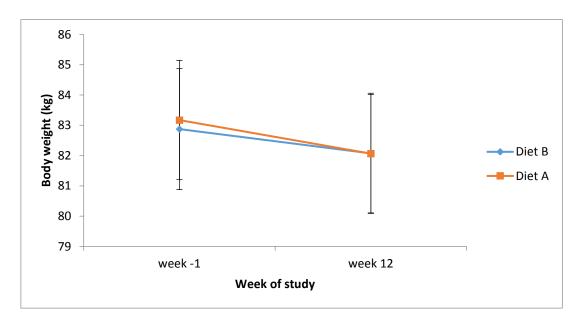
A 2x2 mixed ANOVA revealed that there was no significant main effect of time (F (1, 48) = 3.68, ns) or diet (F (1, 48) = 0.16, ns) for alcohol intake (g/d) and no significant diet\*time interaction (F (1, 48) = 0.73, ns).

# 3.13 Effects of the Dietary Interventions on Body Weight (kg)

## 3.13.1 Body weight change (kg) from baseline to week 12

Body weight was measured using three different techniques described (see section 3.4.1). Body weight change from baseline (week -1) to the end of the intervention (week 12) is reported based on the data collected using the BodPod (ADP) equipment because this technique measures body weight with minimal clothing and the BodPod weighing scale is calibrated before every use. There were no differences between Diet groups with respect to body weight at baseline (week -1).

A 2x2 mixed ANOVA was employed to examine the effects of the two 12-week dietary interventions (Diet A and Diet B) on body weight measured using ADP (Bodpod). Figure 6 shows that across both dietary interventions (all participants) there was significant weight loss from week -1 to week 12 (main effect of time (F (1, 69) = 12.28, p < 0.01) irrespective of diet group. However, the diet\*time interaction was not significant (F (1, 69) = 0.32, ns). In addition, there was no main effect of diet on body weight (F (1, 69) = 0.003, ns). Figure 3.12.1-1 shows that body weight decreased by a similar proportion in response to both diets. Those on Diet A lost an average of 1.11kg (SE=0.39) whereas those on Diet B lost an average of 0.8kg (SE=0.38). This weight loss was not significantly different between Diet groups.



## Figure 3.13-1 Mean (+/-SE) body weight change assessed using the BodPod from baseline to the end of the intervention

However, weight loss across diet groups and between participants varied considerably. This is illustrated in Figure 3.13-2 which shows individual weight changes in each diet group. There was considerable individual variability in the amount of body weight lost, with participants following Diet B losing up to 6.2 kg and gaining up to 3.9 kg over the 12 week intervention. A similar pattern of weight loss/gain was observed for participants following Diet A, with some of them losing up to 5.8kg and others gaining up to 2.9kg over the 12 week intervention. Hence the pattern of individual weight changes within both diet groups was very similar.

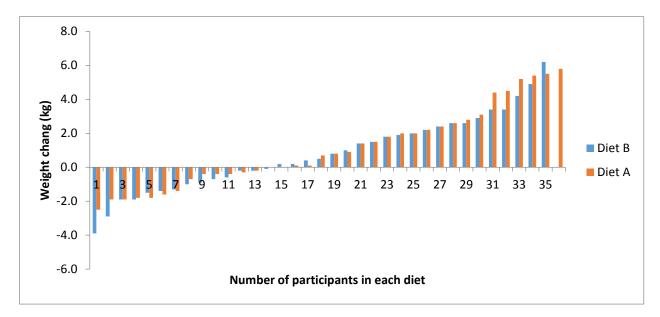


Figure 3.13-2 Weight change (kg) for each participant during the 12 week intervention according to diet group

## 3.13.2 Body composition assessed using Air Displacement Plesthysmography (ADP, BodPod)

Table 3.13-1 illustrates mean (SE) body composition measures assessed using the BodPod at baseline (week -1) and at the end of the intervention (week 12). Mixed 2x2 ANOVAs were performed to examine the effect of the two 12-week interventions on fat mass (kg), fat percent and lean mass (kg). There was a significant main effect of time on fat mass, lean mass and fat percent (smallest F (1, 68) =7.67, GG adjusted p<0.01). Fat mass decreased by 1.5g (SE=0.34) for Diet A and by 1.34g (SE=0.44) for those on Diet B. Fat percent decreased by 1.22 (SE=0.26) for Diet A and by 1.19 (SE=0.39) for those on Diet B. Lean mass increased by 0.38g (SE=0.18) for Diet A and by 0.47g (SE=0.25) for those on Diet B. There was no main effect of diet (largest F (1, 68) =0.14, p=0.71) for any of these measures and no diet\*time interaction (largest F (1, 68) =0.9, p=0.76).

	Baseline (week -1)			Inte	ervention (week	: 12)
	<b>Diet A (n=36)</b> Mean (SE)	<b>Diet B (n=34)</b> Mean (SE)	<b>Total (n=70)</b> Mean (SE)	<b>Diet A (n=36)</b> Mean (SE)	<b>Diet B (n=35)</b> Mean (SE)	<b>Total (n=71)</b> Mean (SE)
Fat mass (kg)	36.6 (1.57)	36.11 (1.4)	36.35 (1.05)	35.1 (1.52)	34.59 (1.36)	34.85 (1.02)**
Fat %	43.55 (1.04)	43.02 (0.84)	43.29 (0.67)	42.33 (1.03)	41.75 (0.9)	42.04 (0.68)**
Lean mass (kg)	46.57 (0.99)	47.03 (0.9)	46.79 (0.67)	46.95 (1.02)	47.49 (0.9)	47.22 (0.68)*

Table 3.13-1 Changes in body composition measures assessed using the BodPod

Significant differences between week -1 and week 12, irrespective of diet, are indicated as follows: \*\*p<0.001, \*p<0.01

## 3.14 Effects of the Dietary Interventions on biomarkers of health

Participants attended the LGI phlebotomy unit twice (at baseline, week -1 and at the end of the intervention, week 12) to have fasting blood samples taken. All assays were run immediately with the exception of insulin and leptin which were analysed in batches from frozen plasma/serum. Although all 71 women attended for blood sampling at both time points some errors occurred at the LGI phlebotomy unit such that some assays were not performed on all samples. Table 3.14-1 summarizes the fasting blood results at baseline (week -1) and at the end of the intervention (week 12).

	Baseline (wk-1)			Intervention (wk 12)		
	Diet A	Diet B	Total	Diet A	Diet B	Total
Plasma Glucose (mmol/L)	4.88 (0.07)	4.93 (0.08)	4.9 (0.05)	4.84 (0.08)	4.91 (0.09)	4.87 (0.06)
	n=35	n=35	n=70	n=35	n=32	n=67
Total Cholesterol (mmol/L)	4.83 (0.16)	5.04 (0.17)	4.93 (0.12)	4.82 (0.15)	4.88 (0.15)	4.85 (0.1)
	n=36	n=35	n=71	n=35	n=33	n=68
HDL (mmol/L)	1.56 (0.08)	1.43 (0.06)	1.5 (0.05)	1.49 (0.06)	1.38 (0.05)	1.44 (0.04)
	n=36	n=35	n=71	n=35	n=33	n=68
LDL (mmol/L)	2.88 (0.13)	3.11 (0.14)	2.99 (0.1)	2.91 (0.12)	2.98 (0.12)	2.94 (0.09)
	n=36	n=35	n=71	n=35	n=33	n=68
Triglycerides (mmol/L)	0.91 (0.06)	1.14 (0.11)	1.02 (0.06)	0.98 (0.06)	1.21 (0.13)	1.09 (0.07)
	n=36	n=35	n=71	n=35	n=33	n=68
Insulin (mU/L)	15.24 (1.68)	14.52 (1.88)	14.88 (1.25)	12.99 (1.55)	14.55 (1.74)	13.76 (1.16)
	n=36	n=35	n=71	n=35	n=34	n=69
Leptin (ng/mL)	36.89 (2.7)	32.94 (2.62)	35 (1.88)	33.23 (2.55)	32.28 (2.84)	32.76 (1.89)
	n=36	n=34	n=70	n=35	n=34	n=69
HOMA (IR)	1.94 (0.21)	1.83 (0.22)	1.88 (0.15)	1.57 (0.2)	1.83 (0.23)	1.69 (0.15)
	n=35	n=35	n=70	n=35	n=32	n=67

Table 3.14-1 Mean (SE) fasting blood lipids, glucose, insulin and leptin at baseline and at the end of the intervention

To examine the effect of the 12 week dietary interventions on fasting plasma glucose, total cholesterol, HDL, LDL, triglycerides, fasting insulin and leptin separate 2x2 mixed ANOVAs were performed. There were no significant main effects of diet on fasting glucose levels, total cholesterol, HDL and LDL cholesterol (largest F (1, 66) =1.81, p=0.18). Furthermore, there were no significant main effects of time (largest F (1, 64) = 1.3, p=0.26) and no significant diet\*time interactions (largest F (1, 66) =1.3 p=0.26) for any of these biomarkers. However, for HDL, a significant main effect of time was found (F (1, 66) = 5.16, p=0.026). Fasting HDL levels were significantly reduced at the end of the intervention compared to levels at baseline. There was no significant main effect of diet (F (1, 66) = 1.81, ns) or diet\*time interaction (F (1, 66) = 0.04, ns) for HDL. For triglycerides, there was no significant main effect of time (F (1, 66) = 2.02, ns) or diet\*interaction (F (1, 66) =0.14, ns), but a significant main effect of diet was found (F (1, 66) = 3.92, p=0.05). A post hoc t-test, showed that there were no significant differences in fasting triglyceride levels between participants allocated to Diet B and those allocated to Diet A at week 12 (t=-1.64, df=45.84, ns). However, triglycerides value levels were significantly different at randomisation,

with those following Diet B having higher fasting triglyceride levels than those following Diet A.

HOMA was calculated using a single fasting insulin and glucose measure at baseline (week -1) and at the end of the intervention (week 12). A 2x2 way ANOVA indicated that there was no significant main effect of time (F (1, 64) = 2.62, ns) or diet (F (1, 64) = 0.1, ns) for HOMA. Similarly there was no significant diet\*time interaction found (F (1, 64) = 1.07, ns) for HOMA.

## 3.15 Summary of Findings Inclusion Phase (Baseline)

- There were no significant diet group differences in participant characteristics at screening with respect to age, body weight, height or BMI. There were also no significant diet group differences in terms of eating behaviour, frequency of regular breakfast consumption, EAT-26 scores, or fibre intake assessed by the DINE and LWW-DINE
- There were no significant diet group differences in participant characteristics at randomisation in terms of body weight, body composition and fasting blood measures (insulin, leptin, glucose, total cholesterol, HDL and LDL)
- There was an almost significant difference (p=0.054) in participants' triglyceride levels at randomization (higher triglyceride levels for those on Diet A than those on Diet B)
- There were no significant diet group differences at screening or randomization in terms of body weight (kg)
- There were no significant diet group differences in terms of energy (kcal) macronutrient(g), alcohol(g) and fibre(g) intake at baseline
- There was a strong positive correlation between baseline fibre intake assessed by the DINE and LWW-DINE (p<0.01)
- There was a positive correlation between baseline fibre intake assessed by the DINE and that assessed by the 7-day food diary records using the points system (points/d, p<0.05)</li>

- There was a positive correlation between baseline fibre intake assessed using the LWW-DINE and that assessed by the 7-day food diary records using the points system (points/d, p<0.05)
- There was a moderate positive correlation between baseline fibre intake (g/d) assessed using the LWW-DINE and fibre intake (g/d) assessed from the 7 day food diary records (p<0.01)</li>
- There was a moderate positive correlation between baseline fibre intake assessed using the DINE and fibre intake (g/d) assessed by the 7 day food diary records (p<0.01)
- There was a strong positive correlation between baseline fibre intake (g/d) and fibre intake (points/day) assessed from the 7 day food diary records (p<0.01)

#### Dietary Intervention Phase

#### Dietary Changes

- All 3 measurement tools used to assess changes in fibre intake (DINE, LWW-DINE and the 3-day food diary records [g/d]) showed that participants who followed Diet B significantly increased their fibre intake during the 12-week intervention whereas those following Diet A did not (diet\*time interactions).
- Participants on both diets significantly reduced their daily energy intake (kcal/d), fat intake (g/d) and alcohol intake (g/d) during the 12-week intervention.
- There were no significant changes in CHO (g/d) or protein intake (g/d) in either diet group during the 12 week intervention.

#### Physiological Changes

 Body weight assessed using ADP decreased significantly over the 12-week intervention phase in both diet groups. Those who followed Diet A reduced their body weight by an average of 1.11kg (SE=0.39) and those who followed Diet B reduced their body weight by an average of 0.8 kg (SE= 0.38). There was no significant difference in the average weight lost by both Diet groups

- Body fat mass and fat percent assessed using ADP, decreased significantly over the 12-week intervention phase in both diet groups (p<0.001)</li>
- Lean mass assessed using ADP, increased significantly over the 12-week intervention phase in both diet groups (p<0.01)</li>
- There were no significant diet group differences in terms of the change in both body fat percentage and lean mass assessed using ADP during the 12-week intervention.
- There were no significant differences between the two diet groups in terms of fasting total cholesterol, LDL, HDL, glucose and HOMA (IR) during the 12-week intervention. Total cholesterol, LDL, triglycerides and glucose levels did not change significantly over time, irrespective of diet group
- There was a significant difference in average fasting triglyceride levels between the two diet groups over the 12-week intervention (on average, those on Diet B had a significantly higher fasting triglyceride level than those on Diet A; main effect of diet when data were pooled across both time points).
- There was a significant main effect of time for fasting HDL; both diet groups showed a reduction in fasting HDL levels from baseline to week 12

#### 3.16 Changes in psychological measures

Different psychological measures were assessed during this study (see sections 3.4.5 and 3.4.6) to examine any effects of the two dietary interventions on these parameters. Effects on Body Shape Questionnaire (BSQ), Three Factor Eating Questionnaire (TFEQ), Dutch Eating Behaviour Questionnaire (DEBQ) scores and WBDs are presented in this thesis.

#### 3.16.1 Subjective Measures of Body Shape

Participants completed the BSQ (described in section 3.4.6) at baseline (week - 1) and then at monthly intervals (weeks 4, 8 and 12 of the intervention) and scores

were used to evaluate any changes in body shape perception over time. Participants randomised to Diet A tended to have higher body shape perception scores at baseline than those randomised to Diet B. A repeated measures ANCOVA with body shape perception score at week -1 as the covariate was employed to examine the effect of the two dietary interventions on body shape perception measured across the intervention. Baseline scores of body shape perception significantly predicted subsequent body shape perception scores during the intervention period (F(1, 68)=88.81, p<0.001). There was no significant main effect of diet (F(1, 68)=1.56, ns) or time (F(2, 136)=0.15, ns) on body shape perception. The diet\*time interaction (F(2, 136)=1.77, ns) was also not significant. Figure 3.16-1 indicates a tendency for ratings of body shape perception to reduce from week -1 to weeks 4 and then to plateau from week 4 to week 12.

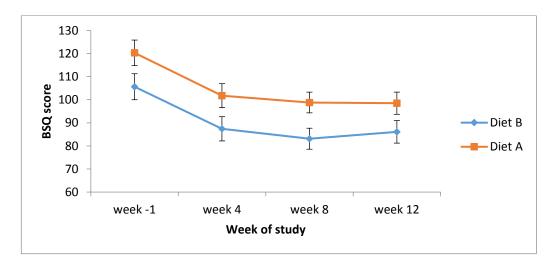


Figure 3.16-1 Mean (+/- SE) changes in body shape perception at baseline and during the two dietary interventions

#### 3.17 Eating Behaviour Characteristics

Participants completed the TFEQ and DEBQ questionnaires (described in section 3.4.5) at baseline (week -1) and week 12 and scores were used to evaluate any changes in eating behaviour characteristics measured by each questionnaire. Mixed ANOVAs were performed to examine the effects of the 12 week dietary interventions on each of the 6 eating behaviour characteristics (see Table 3.17-1). Main effects of time were found for all eating behaviour characteristics (smallest F(1, 69)=12.89, GG adjusted p<0.001). There were no significant main effects of diet (F(1, 69)=2.85, p=0.096) or diet\*time interactions (F(1, 69)=1.33,

GG adjusted p=0.25) for any of these characteristics. All DEBQ factor scores (dietary restraint, emotional and external eating) changed significantly over time in both diet groups. DEBQ scores of both emotional and external eating were significantly lower at the end of the intervention (week 12) compared to baseline (week -1) irrespective of diet group. In contrast, dietary restraint measured using both the DEBQ and the TFEQ, was significantly higher at week 12 compared to week -1 irrespective of diet group. TFEQ disinhibition and hunger scores were significantly lower at week 12 than week -1, irrespective of diet group (see Table 3.17-1).

 Table 3.17-1 Eating behaviour characteristics across the intervention period

	Baseline (week -1)			Intervention (week 12)			
	Diet A (n=36)	Diet B (n=35)	Total (n=71)	Diet A (n=36)	Diet B (n=35)	Total (n=71)	
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	
TFEQ							
Restraint	8.17 (0.77)	6.97 (0.63)	8.11 (0.8)	11.86 (0.83)	9.74 (0.75)	10.72 (0.94)*	
Disinhibition	9.44 (0.58)	9.6 (0.59)	9.57 (0.58)	7.94 (0.59)	8.03 (0.55)	7.57 (0.63)*	
Hunger	6.86 (0.67)	5.51 (0.54)	5.78 (0.67)	4.92 (0.57)	4.51 (0.51)	4.56 (0.66)*	
DEBQ							
Restraint	2.54 (0.12)	2.54 (0.11)	2.56 (0.15)	3.05 (0.14)	2.9 (0.09)	2.92 (0.13)*	
Emotional eating	2.89 (0.16)	2.92 (0.12)	2.93 (0.15)	2.56 (0.14)	2.5 (0.13)	2.35 (0.15)*	
External eating	2.92 (0.09)	2.86 (0.09)	2.84 (0.1)	2.61 (0.11)	2.63 (0.09)	2.6 (0.1)*	

\*indicates significance level at p<0.001 between total scores irrespective of diet at week-1 and week 12

# 3.18 Changes in subjective wellbeing symptoms in response to both dietary interventions (Diet A and Diet B)

The frequencies of each score level (0-4) for each wellbeing symptom were plotted according to diet for each week of the intervention and at baseline (week -1). These data are also shown in Appendix 3.24, presented as predicted probabilities. Appendix 3.23 shows the probability of being on Diet A and Diet B and scoring high or low on each wellbeing symptom, from baseline to week 12 of the intervention. A summary of the main findings for each symptom is given below. A negative beta coefficient (B) in the tables below indicates a lower score compared to the reference category (Diet A or baseline: week -1). For example,

a negative B indicates that participants allocated to Diet B scored lower than those allocated to Diet A. A positive beta coefficient indicates the opposite (i.e. higher scores as compared to the reference category).

#### 3.18.1 Feeling fat

The diet that participants were allocated to, predicted whether they scored low or high in terms of feeling fat (effect of diet, b=-0.75, p<0.001). Regardless of diet group, ratings of feeling fat at week 2 to week 12 were associated with lower scores than scores at baseline (indicated by negative beta coefficients). Ratings of feeling fat at week 4 and 5 for those following Diet B, compared to baseline ratings, were associated with higher scores than those following Diet A (indicated by significant diet B\*week 4 and diet B\*week 5 interactions in table 1)<sup>2</sup>. The odds ratio of higher ratings of feeling fat for those on Diet B relative to those on Diet A, at week 4 and 5 are shown in table  $3.18-1^3$ .

		95% CI for odds ratio		
Low vs High ratings of Feeling Fat	B (SE)	Lower	Odds Ratio	Upper
diet B	-0.75 (0.17)***	0.34	0.47	0.66
week 2	-0.3 (0.17)**	0.44	0.62	0.87
week 3	-0.67 (0.17)***	0.36	0.51	0.72
week 4	-0.8 (0.17)***	0.32	0.45	0.63
week 5	-0.81 (0.17)***	0.32	0.45	0.63
week 6	-0.85 (0.17)***	0.3	0.43	0.6
week 7	-0.79 (0.17)***	0.32	0.45	0.63
week 8	-0.93 (0.18)***	0.28	0.39	0.56
week 9	-0.6 (0.17)***	0.4	0.55	0.77
week 10	-0.62 (0.18)***	0.38	0.54	0.76
week 11	-0.6 (0.18)***	0.39	0.55	0.77
week 12	-0.45 (0.19)*	0.44	0.64	0.93
diet B x week 4	0.56 (0.24)*	1.08	1.75	2.82
diet B x week 5	0.58 (0.24)*	1.1	1.78	2.86

 Table 3.18-1 Odds ratios with 95% confidence intervals for ratings of feeling fat

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

<sup>2</sup> Positive B coefficient suggesting that those on Diet B score higher than those on A in weeks 4 and 5

<sup>3</sup> The odds of scoring high in ratings of feeling fat are 1.75 and 1.78 times greater for those on Diet B relative to Diet A, at week 4 and 5 respectively

those subsequently randomised to Diet B. Overall, throughout the intervention, those on Diet B felt less fat (lower scores) than those on Diet A. In weeks 4 and 5, those on Diet A shifted towards lower ratings of fatness as compared to

baseline, reflected in significant diet \*week interactions. The pattern for those on Diet B was fairly consistent overall, with women mostly reporting none to moderate feelings of fatness (scores of 0-2), whereas more women on Diet A rated feelings of fatness as moderate to severe (scores of 2-4).

#### 3.18.2 Feeling slim

Overall, the diet that participants were allocated to did not predict whether they scored low or high in ratings of feeling slim (b=0.17, p=0.33). Regardless of diet group, ratings of feeling slim at week 1 to week 12 were associated with higher scores than scores at baseline. The odds ratio of higher ratings of feeling slim at week 1 to week 12 as compared to baseline are shown in table 2. Ratings of feeling slim at week 1 to week 4 for those following Diet B, as compared to baseline ratings, were associated with lower scores than those following Diet A (indicated by negative coefficients in diet\*week interactions; table 2). However, ratings of feeling slim at weeks 5 to week 12 for those following Diet B, as compared to baseline ratings, were associated with higher ratings of feeling slim than those following Diet A (indicated by positive coefficient in table 2). The odds ratio of higher or lower ratings of feeling slim for those on Diet B relative to those on Diet A, at different weeks of the intervention are shown in table 3.18-2.

		95% CI for odds ratio		
Low vs High ratings of Feeling Slim	B (SE)	Lower	Odds Ratio	Upper
diet B	0.17 (0.17)	0.84	1.19	1.67
week 1	0.8 (0.18)***	1.58	2.23	3.17
week 2	0.98 (0.18)***	1.88	2.67	3.78
week 3	1.06 (0.18)***	2.05	2.89	4.09
week 4	1.03 (0.18)***	1.98	2.79	3.95
week 5	1.32 (0.17)***	2.67	3.73	5.23
week 6	1.27 (0.17)***	2.53	3.56	5.01
week 7	1.26 (0.18)***	2.49	3.52	4.99
week 8	1.22 (0.18)***	2.39	3.4	4.85
week 9	1.21 (0.18)***	2.37	3.36	4.77
week 10	1.28 (0.18)***	2.51	3.58	5.12
week 11	1.34 (0.18)***	2.67	3.81	5.44
week 12	0.98 (0.2)***	1.81	2.66	3.91
diet B x week 1	-0.64 (0.25)**	0.33	0.53	0.86
diet B x week 2	-0.81 (0.25)***	0.27	0.44	0.72
diet B x week 3	-0.76 (0.25)**	0.29	0.47	0.76
diet B x week 4	-0.77 (0.25)**	0.28	0.46	0.75
diet B x week 5	0.84 (0.25)***	1.42	2.33	3.81
diet B x week 6	1.51 (0.25)***	2.75	4.52	7.41
diet B x week 7	1.45 (0.25)***	2.58	4.25	6.98
diet B x week 8	1.47 (0.26)***	2.63	4.33	7.14
diet B x week 9	1.74 (0.25)***	3.46	5.7	9.38
diet B x week 10	1.39 (0.26)***	2.43	4.03	6.67
diet B x week 11	1.38 (0.26)***	2.38	3.98	6.63
diet B x week 12	1.78 (0.28)***	3.44	5.9	10.17

Table 3.18-2 Odds ratios with 95% confidence intervals for ratings of feeling slim

\*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of feeling slim:

The majority of women's ratings of feeling slim were low (scores of 0-1) at baseline (week -1). In the first month, there was a shift towards greater feelings of slimness for those on Diet A than those on Diet B who nevertheless also showed a shift in ratings from "none" to "minimal". This pattern was maintained until week 4. The pattern reversed after one month on the intervention. From week 5 to week 12, those on Diet B were more likely to report greater feelings of slimness ranging from moderate to extreme than those on Diet A. This suggests that women were more likely to feel slimmer on Diet B after continuing with this diet for longer than one month. Hence it may be worth emphasizing that making the effort to stick to a higher fibre diet for longer than 1 month has a greater impact on feelings of slimness in the medium term.

#### 3.18.3 Feeling energetic

The diet that participants were allocated to, did not predict whether they scored low or high in ratings of feeling energetic (b=0.03, p=0.86). Regardless of diet group, ratings of feeling energetic at week 1 to week 12 were associated with higher scores than scores at baseline. Ratings of feeling energetic at week 2, 3, 6, 7, 8, 11 and 12 for those following Diet B, as compared to baseline ratings, were associated with lower scores than those following Diet A. The odds ratio of lower ratings of feeling energetic for those on Diet B relative to those on Diet A, at week 2, 3, 6, 7, 8, 11 and 12 are shown in table 3.18-3.

Table 3.18-3 Odds ratios with 95% confidence intervals for ratings of
feeling energetic

		95% CI for odds ratio		
Low vs High ratings of Feeling Energetic	B (SE)	Lower	Odds Ratio	Upper
diet B	0.03 (0.17)	0.74	1.03	1.44
week 1	0.64 (0.17)***	1.35	1.9	2.67
week 2	1.12 (0.18)***	2.18	3.07	4.33
week 3	0.81 (0.17)***	1.6	2.25	3.16
week 4	0.62 (0.17)***	1.32	1.86	2.62
week 5	0.82 (0.17)***	1.63	2.27	3.18
week 6	0.95 (0.17)***	1.85	2.59	3.61
week 7	0.94 (0.17)***	1.83	2.56	3.59
week 8	0.84 (0.18)***	1.63	2.32	3.3
week 9	0.67 (0.17)***	1.39	1.95	2.74
week 10	0.87 (0.18)***	1.69	2.39	3.39
week 11	1.18 (0.18)***	2.3	3.26	4.6
week 12	0.94 (0.2)***	1.75	2.57	3.77
diet B x week 2	-0.92 (0.25)***	0.24	0.4	0.65
diet B x week 3	-0.55 (0.25)*	0.35	0.58	0.93
diet B x week 6	-0.66 (0.25)**	0.32	0.52	0.84
diet B x week 7	-0.7 (0.25)**	0.31	0.5	0.81
diet B x week 8	-0.54 (0.25)*	0.35	0.58	0.95
diet B x week 11	-0.74 (0.25)**	0.29	0.48	0.79
diet B x week 12	-0.71 (0.27)**	0.29	0.49	0.84

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of feeling energetic:

Overall ratings of feeling energetic were on average mostly "moderate" throughout the intervention with no large differences between the diets. However, ratings varied from week to week, shown by significant diet \*week interactions, with ratings of feeling energetic being greater on Diet A than those on Diet B in weeks 2, 3, 6, 7, 8, 11 and 12. However, the figures in Appendix 1 suggest that these differences were quite small (approximately one point) relative to baseline.

#### 3.18.4 Mental alertness

The diet that participants were allocated to did not predict whether they scored low or high in mental alertness (b=0.32, p=0.08). Regardless of diet group, ratings of mental alertness at week 2, 3, 6 and 11 were associated with higher scores than scores at baseline. In other words, being in either diet group increased the likelihood of higher ratings of mental alertness as week progressed from baseline to week 2, 3, 6 and 11. Ratings of mental alertness at week 2, 3, 6, 7, 11 and 12 for those following Diet B, as compared to baseline ratings, were associated with lower scores than those following Diet A. The odds ratio of lower ratings of mental alertness for those on Diet B relative to those on Diet A, at weeks 2, 3, 6, 7, 11 and 12 are shown in Table 3.18-4. Women who followed Diet B, compared to those following Diet A were more likely to score low than high in ratings of mental alertness at weeks 2, 3, 6, 7, 11 and 12.

		<b>95</b> %	95% CI for odds ratio			
Low vs High ratings of Mental Alertness	B (SE)	Lower	Odds Ratio	Upper		
diet B	0.32 (0.19)	0.96	1.38	1.99		
week 2	0.48 (0.19)*	1.12	1.61	2.33		
week 3	0.47 (0.19)*	1.11	1.6	2.31		
week 6	0.42 (0.19)*	1.1	1.53	2.19		
week 11	0.54 (0.19)**	1.19	1.72	2.5		
diet B x week 2	-0.68 (0.26)**	0.3	0.5	0.85		
diet B x week 3	-0.62 (0.27)*	0.32	0.54	0.91		
diet B x week 6	-0.62 (0.27)*	0.32	0.54	0.91		
diet B x week 7	-0.52 (0.27)*	0.35	0.59	1		
diet B x week11	-0.81 (0.27)**	0.3	0.44	0.76		
diet B x week 12	-0.58 (0.29)*	0.31	0.56	1		

 
 Table 3.18-4 Odds ratios with 95% confidence intervals for ratings of mental alertness

#### \*p<0.05; \*\*p<0.01

#### Summary of effect of diet on ratings of mental alertness:

There were no obvious differences between diets in ratings of mental alertness with the majority of participants on both diets rating mental alertness as moderate throughout the intervention. The significant diet\* week interactions in weeks 2, 3, 6, 7, 11 and 12 are driven by a shift from "moderate" to "very" for those on Diet A with no such shift for those on Diet B.

#### 3.18.5 Mental tiredness

The diet that participants were allocated to did not predict whether they scored low or high in mental tiredness (b=-0.1, p=0.58). Regardless of diet group, ratings of mental tiredness at week 3 to week 12 were associated with lower scores than scores at baseline. Ratings of mental tiredness at week 12 for those following Diet B, as compared to baseline ratings, were associated with higher scores than those following Diet A. The odds ratio of higher ratings of mentally tired for those on Diet B relative to those on Diet A, at week 12, was 2 (CI: 1.18, 3.39; see Table 3.18-5). Women who followed Diet B, compared to those following Diet A were more likely to score high than low in ratings of mental tiredness at week 12.

		95% CI for odds ratio			
Low vs High ratings of Mental Tired	B (SE)	Lower	Odds Ratio	Upper	
diet B	-0.1 (0.17)	0.65	0.91	1.27	
week 3	-0.56 (0.17)***	0.41	0.57	0.8	
week 4	-0.58 (0.17)***	0.4	0.56	0.78	
week 5	-0.49 (0.17)**	0.44	0.61	0.85	
week 6	-0.54 (0.17)**	0.42	0.58	0.8	
week 7	-0.65 (0.1.7)***	0.37	0.52	0.72	
week 8	-0.93 (0.17)***	0.28	0.39	0.55	
week 9	-0.56 (0.17)**	0.41	0.57	0.8	
week 10	-0.61 (0.17)***	0.38	0.54	0.76	
week 11	-0.86 (0.18)***	0.3	0.42	0.6	
week 12	-1.19 (0.19)***	0.21	0.31	0.44	
diet B x week 12	0.69 (0.27)*	1.18	2	3.39	

### Table 3.18-5 Odds ratios with 95% confidence intervals for ratings of mental tiredness

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of mental tiredness:

There were no overall differences between diets in ratings of mental tiredness throughout the intervention. However, the significant effect of week from week 3 to week 12 indicated that there was a significant reduction in ratings of mental tiredness relative to baseline from week 3 onwards, irrespective of diet. The diet\*week interaction at week 12 is probably affected by the large amount of missing data at week 12 but suggests greater ratings of mental tiredness on Diet B than those on Diet A relative to baseline.

#### 3.18.6 Difficulty concentrating

The diet that participants were allocated to did not predict whether they scored low or high in ratings of difficulty concentrating (b=0.13, p=0.44). For any rating score and regardless of diet group, ratings of difficulty concentrating at week 2 to week 12 were associated with lower scores than scores at baseline. Concentration improved over time, irrespective of diet group. The odds ratio of lower ratings of difficulty concentrating at week 2 to 12, as compared to baseline, are shown in Table 3.18-6.

		95%	CI for odds ra	tio
Low vs High ratings of Difficulty Concentrating	B (SE)	Lower	Odds Ratio	Upper
diet B	-0.2 (0.17)	0.82	1.14	1.59
week 2	-0.45 (0.17)**	0.46	0.64	0.89
week 3	-0.7 (0.17)***	0.36	0.5	0.7
week 4	-0.55 (0.17)**	0.41	0.58	0.8
week 5	-0.78 (0.17)***	0.33	0.46	0.64
week 6	-0.71 (0.17)***	0.35	0.49	0.69
week 7	-1.01 (0.17)***	0.26	0.36	0.51
week 8	-1 (0.18)***	0.26	0.37	0.52
week 9	-0.57 (0.18)**	0.4	0.56	0.79
week 10	-0.83 (0.18)***	0.31	0.44	0.61
week 11	-0.99 (0.18)***	0.26	0.37	0.53
week 12	-1.09 (0.19)***	0.23	0.33	0.49

Table 3.18-6 Odds ratios with 95% confidence intervals for ratings of difficulty concentrating

\*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of difficulty concentrating:

There were no overall differences between diets in ratings of difficulty concentrating throughout the intervention. Regardless of diet group, ratings of difficulty concentrating improved from week 2 to week 12 and were primarily in the "none" or "mild" category. No significant diet\*week interactions were found.

#### 3.18.7 Physical tiredness

The diet that participants were allocated to did not predict whether they scored low or high in physical tiredness (b=-0.1, p=0.58). For any rating score and regardless of diet group, ratings of physical tiredness at week 2 to week 12 were associated with lower scores than scores at baseline. Ratings of physical tiredness at week 12 for those following Diet B, as compared to baseline ratings, were associated with higher scores than those following Diet A. The odds of ratio of higher ratings of physically tired were 1.7 and 2.36 times greater for those on Diet B relative to Diet A, at week 5 and 12 respectively. Women who followed Diet B, compared to those following Diet A were more likely to score high than low in ratings of physical tiredness at weeks 5 and 12.

	95% CI for odds ratio			atio
Low vs High ratings of Physical Tired	B (SE)	Lower	Odds Ratio	Upper
diet B	-0.11 (0.17)	0.64	0.89	1.25
week 2	-0.42 (0.17)*	0.47	0.66	0.92
week 3	-0.41 (0.17)*	0.48	0.67	0.93
week 4	-0.53 (0.17)**	0.42	0.59	0.82
week 5	-0.64 (0.17)***	0.38	0.53	0.73
week 6	-0.65 (0.17)***	0.38	0.52	0.73
week 7	-0.81 (0.17)***	0.32	0.45	0.62
week 8	-0.88 (0.18)***	0.29	0.42	0.59
week 9	-0.55 (0.17)**	0.41	0.58	0.81
week 10	-0.82 (0.17)***	0.32	0.44	0.62
week 11	-0.9 (0.17)***	0.29	0.41	0.57
week 12	-0.98 (0.19)***	0.26	0.38	0.55
diet B x week 5	0.53 (0.24)*	1.05	1.7	2.74
diet B x week 12	0.86 (0.26)**	1.41	2.36	3.97

 Table 3.18-7 Odds ratios with 95% confidence intervals for ratings of physical tiredness

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of physical tiredness:

There were no overall differences between diets in ratings of feeling physical tiredness throughout the intervention. Ratings were predominately from "none" to "moderate" at baseline and this pattern remained throughout the intervention. At week 5, there was a significant diet\*week interaction, so that those on Diet A shifted towards lower ratings of physical tiredness relative to baseline, with little change for those on Diet B. A similar pattern was observed in week 12, probably influenced by a larger proportion of missing data.

#### 3.18.8 Headaches

The diet that participants were allocated to did not predict whether they scored low or high in ratings of headaches (b=-0.3, p=0.14). Regardless of diet group, ratings of headaches at week 3 and 6 were associated with lower scores than scores at baseline. Ratings of headaches at week 7 were associated with higher scores than scores at baseline. Ratings of headaches at week 3, 7, 8 and 11 for those following Diet B, as compared to baseline ratings, were associated with higher scores than those following Diet A (indicated by significant diet\* week interactions). The odds ratio of higher ratings of headaches for those on Diet B relative to those on Diet A, at week 3, 7, 8 and 11 are shown in Table 3.18-8.

	95% CI for odds ratio			atio
Low vs High ratings of Headaches	B (SE)	Lower	Odds Ratio	Upper
diet B	0.3 (0.2)	0.5	0.74	1.1
week 3	-0.48 (0.21)*	0.41	0.62	0.93
week 6	-0.57 (0.21)**	0.64	0.94	1.37
week 7	0.48 (0.21)*	0.37	0.56	0.85
week 11	-0.45 (0.21)	0.42	0.64	0.96
diet B x week 3	0.84 (0.29)**	1.32	2.32	4.08
diet B x week 7	1.03 (0.29)***	1.56	2.82	4.98
diet B x week 8	0.6 (0.3)*	1.02	1.82	3.27
diet B x week 11	0.59 (0.3)*	1	1.8	3.23

Table 3.18-8 Odds ratios with 95%	confidence intervals for ratings of
headaches	_

#### \*p<0.05; \*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of headaches:

There were no overall differences in ratings of headaches between diets. The majority of participants experienced no headaches at any phase of the intervention. The significant diet\*week interactions at weeks 3, 7, 8 and 11 are accounted for by the slight increase in mild headaches reported by those on Diet B relative to Diet A.

#### 3.18.9 Bowel Pain

The diet that participants were allocated to, predicted whether they scored low or high in ratings of bowel pain (b=-0.89, p<0.001). Regardless of diet group, ratings of bowel pain at week 4 to week 12 were associated with lower scores than scores at baseline. Ratings of bowel pain at week 1, 3, 4, 5, 6, 7, 8 and 12 for those following Diet B, as compared to baseline ratings, were associated with higher scores than those following Diet A (indicated by significant diet\*week interactions). The odds ratio of higher ratings of bowel pain for those on Diet B relative to those on Diet A, at week 1, 3, 4, 5, 6, 7, 8 and 12 are shown in Table 3.18-9.

		95% CI for odds ratio			
Low vs High					
ratings of Bowel	B (SE)	Lower	Odds Ratio	Upper	
Pain					
diet B	-0.89 (0.21)***	0.27	0.41	0.61	
week 4	-0.62 (0.2)**	0.36	0.54	0.79	
week 5	-0.45 (0.2)*	0.44	0.64	0.93	
week 6	-0.55(0.2)**	0.39	0.58	0.84	
week 7	-0.9(0.2)***	0.27	0.41	0.6	
week 8	-1.12 (0.22)***	0.21	0.33	0.5	
week 10	-0.55 (0.2)**	0.39	0.58	0.86	
week 11	-0.45(0.2)*	0.43	0.64	0.93	
week 12	-0.6 (0.22)**	0.35	0.55	0.84	
diet B x week 1	0.95 (0.28)***	1.48	2.57	4.49	
diet B x week 3	1.05 (0.29)***	1.63	2.84	5	
diet B x week 4	1.32 (0.29***	2.13	3.76	6.69	
diet B x week 5	1.13 (0.29)***	1.76	3.1	5.47	
diet B x week 6	0.61 (0.31)*	1.02	1.85	3.36	
diet B x week 7	1.44 (0.3)***	2.35	4.22	7.61	
diet B x week 8	1.34 (0.32)***	2.06	3.82	7.14	
diet B x week 12	0.96 (0.32)**	1.4	2.62	4.94	

Table 3.18-9 Odds ratios with 95% confidence intervals for ratings of bowel pain

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of bowel pain:

Overall, regardless of week, those on Diet B experienced lower ratings of bowel pain than those on Diet A. Ratings of bowel pain at baseline were overwhelmingly in the "none" category for both diet groups. The significant diet \*week interaction which occurred in weeks 1, 3, 4, 5, 6, 7, 8 and 12 reflects a small shift towards mild bowel pain for participants on Diet B as compared to baseline whilst those on Diet A remained stable with predominately no bowel pain. This slight increase in week 3 for those on Diet B reflects the likely effect of increasing fibre intake.

#### 3.18.10 Constipation

The diet that participants were allocated to did not predict whether they scored low or high in ratings of constipation (b=0.04, p=0.86). Regardless of diet group, ratings of constipation at week 8 and week 12 were associated with lower scores than scores at baseline. The odds ratio of lower ratings of constipation at week 8 and week 12 as compared to baseline are shown in table 3.18-10.

		95%	95% CI for odds ratio			
Low vs High ratings of Constipation	B (SE)	Lower	<i>Odds Ratio</i> Uppe			
diet B	0.04 (0.22)	0.68	3	1.6		
week 8	-0.85 (0.27)**	0.25	0.43	0.72		
week 12	-0.63 (0.28)*	0.3	3 0.53	0.91		

### Table 3.18-10 Odds ratios with 95% confidence intervals for ratings of constipation

\*p<0.05; \*\*p<0.01

#### Summary of effect of diet on ratings of constipation:

There were no overall differences in ratings of constipation between diets throughout the intervention. Regardless of diet group, ratings of constipation improved at week 8 and week 12 as compared with baseline ratings. There were no other significant effects or interactions.

#### 3.18.11 Bloating

The diet that participants were allocated to did not predict whether they scored low or high in ratings of bloating (b=-0.2, p=0.26). Regardless of diet group, ratings of bloating from week 2 to week 8, and from week 11 to week 12 were associated with lower scores than scores at baseline. Ratings of bloating at week 1 and 4 for those following Diet B, as compared to baseline ratings, were associated with higher scores than those following Diet A. However, ratings of bloating at week 9 for those following Diet B, as compared to baseline ratings, were associated with lower scores than those following Diet A (indicated by significant diet\*week interactions; see table 3.18-11).

		95% (	CI for odds ra	tio
Low vs High ratings of Bloating	B (SE)	Lower	Odds Ratio	Upper
diet B	-0.2 (0.17)	0.59	0.82	1.16
week 2	-0.41 (0.17)*	0.47	0.66	0.93
week 3	-0.57 (0.17)**	0.4	0.57	0.8
week 4	-0.66 (0.17)***	0.37	0.52	0.73
week 5	-0.6 (0.17)***	0.39	0.55	0.77
week 6	-0.58 (0.17)***	0.4	0.56	0.78
week 7	-0.56 (0.17)**	0.41	0.57	0.8
week 8	-0.56 (0.18)**	0.4	0.57	0.81
week 11	-0.74 (0.18)***	0.34	0.48	0.68
week 12	-0.67 (0.2)***	0.35	0.51	0.75
diet B x week 1	0.5 (0.25)*	1.02	1.65	2.68
diet B x week 4	0.54 (0.25)*	1.04	1.71	2.81
diet B x week 9	-0.54 (0.26)*	0.35	0.58	0.97

 Table 3.18-11 Odds ratios with 95% confidence intervals for ratings of bloating

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of bloating:

There were no overall differences between diets in ratings of bloating. In weeks 1 and 4, those on Diet B experienced higher ratings of bloating relative to baseline compared with those on Diet A (indicated by a positive coefficient). However, in week 9, those on Diet A showed a shift to moderate ratings of bloating relative to baseline which was not apparent in those on Diet B (indicated by a negative coefficient).

#### 3.18.12 Indigestion

The diet that participants were allocated to, predicted whether they scored low or high in ratings of indigestion (b=-0.44, p<0.05). Regardless of diet group, ratings of indigestion at weeks 3 to 8, week 11 and 12 were associated with lower scores than scores at baseline. The odds ratio of lower ratings of indigestion at weeks 3 to 8, week 11 and 12 were associated with lower scores to 8, week 11 and 12 as compared to baseline are shown in table 12. Ratings of indigestion at weeks 7 and 12 for those following Diet B, as compared to baseline ratings, were associated with higher scores than those following Diet A.

The odds ratio of higher ratings of indigestion for those on Diet B relative to those on Diet A, at weeks 7 and 12 are shown in table 3.18-12.

		95% CI for odds ratio				
Low vs High ratings of Indigestion	B(SE)	Lower	Odds Ratio	Upper		
diet B	-0.44 (0.21)*	0.42	0.65	0.98		
week 3	-0.55 (0.22)*	0.37	0.58	0.89		
week 4	-0.73 (0.23)**	0.31	0.48	0.74		
week 5	-0.51 (0.22)*	0.39	0.6	0.91		
week 6	-0.43 (0.21)*	0.43	0.65	0.94		
week 7	-1.11 (0.25)***	0.2	0.33	0.53		
week 8	-0.72 (0.23)**	0.31	0.49	0.77		
week 11	-0.75 (0.23)**	0.3	0.47	0.74		
week 12	-0.95 (0.27)***	0.22 0.39		0.65		
diet B x week 7	0.74 (0.35)*	1.06	2.1	4.2		
diet B x week 12	0.78 (0.37)*	1.06	2.19	4.59		

Table 3.18-12 Odds ratios with 95% confidence intervals for ratings of
indigestion

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of indigestion:

Overall, regardless of week, those on Diet B experienced lower ratings of indigestion than those on Diet A. Ratings of indigestion ranged from the "none" category to "moderate" for both diet groups throughout the intervention. In weeks 7 and 12 those on Diet A showed a shift towards "none" ratings of indigestion relative to baseline whilst those on Diet B remained stable throughout the intervention.

#### 3.18.13 Wind

The diet that participants were allocated to, did not predict whether they scored low or high in ratings of wind (b=-0.17, p=0.3). Regardless of diet group, ratings of wind at week 7 and week 8 were associated with lower scores than scores at baseline. Ratings of wind at week 2, 7 and 8 for those following Diet B, as compared to baseline ratings, were associated with higher scores than those

following Diet A. The odds ratio of higher ratings of wind for those on Diet B relative to those on Diet A, at weeks 2, 7 and 8 are shown in table 3.18-13.

	95% CI for odds rat					
Low vs High ratings of Wind	B (SE)	Lower	Odds Ratio	Upper		
diet B	-0.17 (0.17)	0.6	0.84	1.17		
week 7	-0.47 (0.17)**	0.45	0.63	0.87		
week 8	-0.82 (0.18)***	0.31	0.44	0.62		
diet B x week 2	0.5 (0.24)*	1.02	1.63	2.61		
diet B x week 7	0.79 (0.25)**	1.37	2.21	3.57		
diet B x week 8	1.05 (0.25)***	1.74	2.82	4.59		

Table 3.18-13 Odds ratios with 95% confidence intervals for ratings of wind

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of wind:

There were no overall differences between diets in ratings of wind. In weeks 2, 7 and 8 those on Diet A experienced lower ratings of wind (showing a shift to the none category) relative to baseline compared with those on Diet B, whilst those on diet B remained stable throughout the intervention with ratings of wind being predominately from "none" to "moderate" category.

#### 3.18.14 Breast tenderness

The diet that participants were allocated to did not predict whether they scored low or high in ratings of breast tenderness (b=-0.01, p=0.98). Regardless of diet group, ratings of breast tenderness at week 5, 6, 8, 10 and 11 were associated with lower scores than scores at baseline. Ratings of breast tenderness at week 5 and 8 for those following Diet B, as compared to baseline ratings, were associated with higher scores than those following Diet A. The odds ratio of higher ratings of breast tenderness for those on Diet B relative to those on Diet A, at week 5 and 8 are shown in table 3.18-14.

		95% CI for odds ratio				
Low vs High ratings of Breast Tenderness	B (SE)	Lower	Odds Ratio	Upper		
diet B	-0.01 (0.22)	0.65	0.99	1.52		
week 5	-0.86 (0.25)***	0.25	0.42	0.69		
week 6	-0.53 (0.24)*	0.37	0.59	0.94		
week 8	-1.28 (0.3)***	0.15	0.28	0.49		
week 10	-0.56 (0.24)*	0.35	0.57	0.91		
week 11	-0.67 (0.25)**	0.31	0.51	0.83		
diet B x week 5	0.84 (0.34)*	1.19	2.32	4.54		
diet B x week 8	1.17 (0.38)**	1.55	3.22	6.9		

Table 3.18-14 Odds ratios with 95% confidence intervals for ratings of breast tenderness

#### \*p<0.05; \*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of breast tenderness:

Overall ratings of breast tenderness were in the "none" category throughout the intervention with no overall differences between the diets. The significant diet\*week interactions at weeks 5 and 8, reflected a shift towards more ratings of breast tenderness in the "none" category for those on Diet A, whilst those on Diet B remained stable throughout the intervention.

#### 3.18.15 Happiness

The diet that participants were allocated to did not predict whether they scored low or high in ratings of happiness (b=-0.07, p=0.69). Regardless of diet group, ratings of happiness at weeks 2, 3, 6, 7, 8, 10, 11 and 12 were associated with higher scores than scores at baseline. The odds ratio of higher ratings of happiness at weeks 2, 3, 6, 7, 8, 10, 11 and 12 as compared to baseline are shown in table 15. Ratings of happiness at weeks 6, 10 and 12 for those following Diet B, as compared to baseline ratings, were associated with lower scores than those following Diet A. The odds ratio of lower ratings of happiness for those on Diet B relative to those on Diet A, at weeks 6, 10 and 12 are shown in table 3.18-15.

	95% CI for odds ratio						
Low vs High ratings of Feeling Happy	B (SE)	Lower	Odds Ratio	Upper			
diet B	-0.07 (0.18)	0.66	0.93	1.32			
week 2	0.43 (0.18)*	1.01	1.54	2.19			
week 3	0.38 (0.18)*	1.03	1.47	2.08			
week 6	0.52 (0.18)**	1.18	1.67	2.37			
week 7	0.57 (0.18)**	1.25	1.76	2.5			
week 8	0.49 (0.18)**	1.14	1.63	2.33			
week 10	0.57 (0.18)**	1.24	1.78	2.54			
week 11	0.52 (0.18)**	1.18	1.68	2.4			
week 12	0.58 (0.2)**	1.21	1.79	2.66			
diet B x week 6	-0.53 (0.27)*	0.36	0.59	0.98			
diet B x week 10	-0.69 (0.26)**	0.3	0.5	0.84			
diet B x week 12	-0.91 (0.28)**	0.23	0.4	0.69			

 Table 3.18-15 Odds ratios with 95% confidence intervals for ratings of happiness

\*p<0.05; \*\*p<0.01

#### Summary of effect of diet on ratings of happiness:

Overall, ratings of happiness were on the "moderate" category throughout the intervention with no overall differences between the diets. The significant diet \*week interactions at weeks 6, 10 and 12 reflected a shift towards more ratings of happiness in the "a lot/very" category for those on Diet A, compared to those on Diet B which showed consistent moderate ratings of happiness throughout the intervention.

#### 3.18.16 Stress

The diet that participants were allocated to did not predict whether they scored low or high in ratings of stress (b=0.04, p=0.82). Regardless of diet group, ratings of stress at week 4, 6, 7, 8 and week 12 were associated with lower scores than scores at baseline. The odds ratio of lower ratings of stress at week 4, 6, 7, 8 and week 12 as compared to baseline are shown in table 16. Ratings of stress at week 12 for those following Diet B, as compared to baseline ratings, were associated with higher scores than those following Diet A. The odds ratio of higher ratings of stress for those on Diet B relative to those on Diet A, at week 12, was 2.19 (CI:1.31, 3.67; see table 3.18-16).

	95% CI for odds ratio							
Low vs High ratings of Stress	B (SE)	Lower	Odds Ratio	Upper				
diet B	0.04 (0.17)	0.75	1.04	1.44				
week 4	-0.34 (0.17)*	0.51	0.71	0.99				
week 6	-0.36 (0.17)*	0.5	0.7	0.96				
week 7	-0.48 (0.17)**	0.45	0.62	0.86				
week 8	-0.62 (0.17)***	0.38	0.54	0.76				
week 12	-0.76 (0.19)***	0.32	0.47	0.67				
diet B x week 12	0.78 (0.26)**	1.31	2.19	3.67				

Table 3.18-16 Odds ratios with 95% confidence intervals for ratings of stress

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

#### Summary of effect of diet on ratings of stress:

Overall, ratings of stress were in the "moderate" category throughout the intervention with no overall differences between the diets. The diet\*week interaction at week 12 is probably affected by the large amount of missing data at week 12 but suggests greater ratings of stress on Diet B than those on Diet A relative to baseline.

#### 3.19 Summary of effects of dietary interventions on subjective wellbeing symptoms

- Overall findings of effect of diet on wellbeing symptoms from baseline (week -1) to week 12 of the intervention:<sup>4</sup>The diet that participants were allocated to predicted whether they scored low or high on ratings of feeling fat, ratings of bowel pain and ratings of indigestion (3 of the 16 symptoms investigated).
  - a) Overall, those on Diet B felt less fat than those on Diet A. Only at weeks 4 and 5 did those on Diet A feel less fat than those on Diet B
  - b) Overall, regardless of week, those on Diet B felt less bowel pain than those on Diet A. At weeks 1, 3, 4, 5, 6, 7, 8 and 12 those on Diet A felt less bowel pain than those on Diet B

- c) Overall, regardless of week, those on Diet B felt less indigestion than those on Diet A. Only at weeks 7 and 12 did those on Diet B feel more indigestion than those on Diet A
- 2. The diet that participants were allocated to did not predict whether they scored low or high on any other ratings of wellbeing symptoms (feeling slim, feeling energetic, mental alertness, mental tiredness, difficulty concentrating, physical tiredness, headaches, constipation, bloating, wind, breast tenderness, happiness and stress)
- **3.** For ratings of feeling slim, feeling energetic, mental alertness, mental tiredness, physical tiredness, headaches, bloating, wind, breast tenderness, happiness and stress significant diet \*week interactions were found (these findings are summarised in Table 3.19-17).
  - a) Those on Diet B felt less slim than those on Diet A at weeks 1, 2, 3 and 4. Those on Diet A felt less slim than those on Diet B at weeks 5, 6, 7, 8, 9, 10, 11 and 12, compared to baseline ratings
  - b) Those on Diet B felt less energetic at weeks 2, 3, 6, 7, 8, 11 and 12 than those on Diet A, as compared to baseline ratings
  - c) Those on Diet B felt less mentally alert at weeks 2, 3, 6, 7, 11 and 12 than those on Diet A, as compared to baseline ratings
  - d) Those on Diet B felt more mentally tired at week 12 than those on Diet A, as compared to baseline ratings
  - e) Those on Diet B felt more physically tired at weeks 5 and 12 than those on Diet A, as compared to baseline ratings
  - f) Those on Diet B reported more headache at weeks 3, 7, 8 and 11 than those on Diet A, as compared to baseline ratings
  - g) Those on Diet B felt more bloating at weeks 1 and 4, than those on Diet A. Those on Diet A felt more bloating at week 9 than those on Diet B, as compared to baseline ratings
  - h) Those on Diet B reported more wind at weeks 2, 7 and 8 than those on Diet A, compared to baseline ratings
  - i) Those on Diet B reported more breast tenderness at weeks 5 and 8 than those on Diet A, compared to baseline ratings
  - j) Those on Diet B felt less happy at weeks 6, 10 and 12 than those on Diet A, compared to baseline ratings

- k) Those on Diet B felt more stress at week 12 than those on Diet A, compared to baseline ratings
- **4.** No significant effects of diet or diet\*week interactions were found for symptoms of difficulty concentrating and constipation
  - a) Concentration improved over time as compared to baseline ratings in both diet groups
  - b) Overall, ratings of constipation were lower at weeks 8 and 12 compared to baseline for both diet groups

<sup>4</sup> Effect of week on wellbeing symptoms are not included as they are all mentioned in the main text of the thesis and they are less meaningful than the effect of diet and diet\*week interactions. Overall, regardless of diet, improvements in all symptoms were observed as the 12 week intervention progressed

Table 3.19-17 Summary of diet*week interactions for symptoms (red indicates positive outcomes for
those on Diet B)

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
Feeling fat				B>A	B>A							
Feeling slim	B <a< td=""><td>B<a< td=""><td>B<a< td=""><td>B<a< td=""><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td></a<></td></a<></td></a<></td></a<>	B <a< td=""><td>B<a< td=""><td>B<a< td=""><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td></a<></td></a<></td></a<>	B <a< td=""><td>B<a< td=""><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td></a<></td></a<>	B <a< td=""><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td><td>B&gt;A</td></a<>	B>A	B>A	B>A	B>A	B>A	B>A	B>A	B>A
Feeling energetic		B <a< td=""><td>B<a< td=""><td></td><td></td><td>B<a< td=""><td>B<a< td=""><td>B<a< td=""><td></td><td></td><td>B<a< td=""><td>B<a< td=""></a<></td></a<></td></a<></td></a<></td></a<></td></a<></td></a<>	B <a< td=""><td></td><td></td><td>B<a< td=""><td>B<a< td=""><td>B<a< td=""><td></td><td></td><td>B<a< td=""><td>B<a< td=""></a<></td></a<></td></a<></td></a<></td></a<></td></a<>			B <a< td=""><td>B<a< td=""><td>B<a< td=""><td></td><td></td><td>B<a< td=""><td>B<a< td=""></a<></td></a<></td></a<></td></a<></td></a<>	B <a< td=""><td>B<a< td=""><td></td><td></td><td>B<a< td=""><td>B<a< td=""></a<></td></a<></td></a<></td></a<>	B <a< td=""><td></td><td></td><td>B<a< td=""><td>B<a< td=""></a<></td></a<></td></a<>			B <a< td=""><td>B<a< td=""></a<></td></a<>	B <a< td=""></a<>
Mental alertness		B <a< td=""><td>B<a< td=""><td></td><td></td><td>B<a< td=""><td>B<a< td=""><td></td><td></td><td></td><td>B<a< td=""><td>B<a< td=""></a<></td></a<></td></a<></td></a<></td></a<></td></a<>	B <a< td=""><td></td><td></td><td>B<a< td=""><td>B<a< td=""><td></td><td></td><td></td><td>B<a< td=""><td>B<a< td=""></a<></td></a<></td></a<></td></a<></td></a<>			B <a< td=""><td>B<a< td=""><td></td><td></td><td></td><td>B<a< td=""><td>B<a< td=""></a<></td></a<></td></a<></td></a<>	B <a< td=""><td></td><td></td><td></td><td>B<a< td=""><td>B<a< td=""></a<></td></a<></td></a<>				B <a< td=""><td>B<a< td=""></a<></td></a<>	B <a< td=""></a<>
Mental tiredness												B>A
Physical tiredness					B>A							B>A
Headaches			B>A				B>A	B>A			B>A	
Bowel pain	B>A		B>A	B>A	B>A	B>A	B>A	B>A				B>A
Bloating	B>A			B>A					B <a< td=""><td></td><td></td><td></td></a<>			
Indigestion							B>A					B>A
Wind		B>A					B>A	B>A				
Breast tenderness					B>A			B>A				
Happiness						B <a< td=""><td></td><td></td><td></td><td>B<a< td=""><td></td><td>B<a< td=""></a<></td></a<></td></a<>				B <a< td=""><td></td><td>B<a< td=""></a<></td></a<>		B <a< td=""></a<>
Stress												B>A

Key: A refers to Diet A and B to Diet B

#### 3.20 Predictors of weight loss

### 3.20.1 Relationship between randomization (Visit 2) variables and body weight at the end of the intervention (week 12)

Pearson's product moment correlations examined the relationship between baseline variables and body weight at the end of the intervention. Body weight at week 12 was associated with body weight at randomisation (r=0.44, n=71, p<0.001) and baseline fasting plasma leptin (r=0.5, df=70, p<0.001). Regression models with or without interactions were performed and the best model with the smallest AIC (112.15),  $\Delta$ AIC=5.27, was the one including baseline leptin, age and body weight at randomisation. The model with the interactions did not differ significantly with the simplest model and therefore the full model is presented. The results of the regression indicated that baseline leptin, body weight at randomisation explained 97% of the variance (F(3, 66)=653.2, p<0.001, $R^2$ =0.97). It was found that body weight at randomisation ( $\beta$ =0.98, t=38.78. p<0.001), age ( $\beta$ =-0.09, t=2.24. p<0.05) and leptin ( $\beta$ =-0.04, t=-1.2, p<0.05) predicted body weight at week 12. Higher baseline leptin scores were associated with higher weight at week 12. Lower body weight at randomisation predicted lower body weight at week 12. Older participants had higher body weight at week 12. Pearson's product moment correlations examined the relationship between baseline psychological variables (BSQ, TFEQ and DEBQ scores) and body weight at the end of the intervention. There were no significant correlations between any baseline psychological variables and body weight at week 12. When entered in a regression model, none were significant predictors of weight loss.

#### 3.20.2 Changes in physiological and psychological variables (V2-V5) and body weight at the end of the intervention (week 12)

Body weight at week 12 was associated with changes in plasma leptin from baseline to week 12 (r=-0.30, n=66, p<0.05). The best model AIC (AIC=345.23,  $\Delta$ AIC= 2.04) was the one including changes in leptin, BSQ score and TFEQ hunger with no interactions and explained 9% of the variance, (F(3,67)=3.27, p<0.05, Adjusted R<sup>2</sup>=0.09). Only leptin was a significant predictor ( $\beta$ =-0.14, t=-2.13, p<0.05). Reduction in fasting leptin during the intervention predicted lower body weight at week 12 ( $\beta$ =-0.17, t=-1.89, p=0.06) and this is the same for both diets (see Figure 3.20-1).

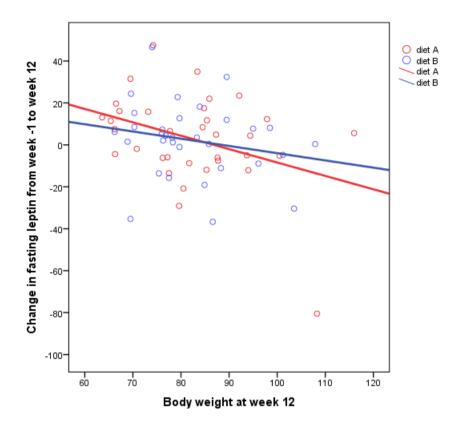


Figure 3.20-1 Regression lines showing relationship between changes in fasting leptin from week -1 (V2) to week 12 (V5) and body weight at the end of the intervention (week 12) for both diets

#### 3.20.3 Relationship between baseline (randomisation, Visit 1) psychological and physiological variables and weight change during the intervention (assessed from V2-V5)

Weight change during the intervention (difference in body weight from V2 to body weight at V5; positive value denotes more weight loss and a negative value indicates weight gain) was associated with baseline triglyceride concentrations (r=-0.25, n=71, p<0.05), leptin (r=0.33, n=71, p<0.01), body weight at randomisation (r=0.54, n=71, p<0.001) and age at screening (r=-0.25, n=71, p<0.05). The best model (AIC=110.84,  $\Delta$ AIC=3.56) included baseline leptin, triglycerides, age and body weight at randomization. The results of the regression indicated that age and baseline leptin explained 17% of the variance (F(4.65)=3.39, p<0.05, Adjusted R<sup>2</sup>=0.17). It was found that age significantly predicted weight loss ( $\beta$ =-0.10, t=-3.33, p<0.05) as did leptin ( $\beta$ =-0.04, t=-2.13, p<0.05 see Figure 3.20-2. Lower baseline leptin levels predicted more weight loss at 12 weeks as shown in Figure 3.20-3. Younger participants lost consistently

more weight as shown in other Figure. There were no significant correlations between weight change during the intervention and baseline psychological variables (largest r=0.19, n=71, p=0.11). A regression was run including baseline TFEQ hunger, BSQ score and interactions. The best model (AIC=114.69,  $\Delta$ AIC=5.12) explained 17% of the variance (F(5,65)=2.73, p<0.05, Adjuster R=0.11). The diet\*BSQ score was a significant predictor of weight loss ( $\beta$ =0.06, t=3.15, p<0.01). Lower baseline BSQ scores were associated with more weight loss for those on Diet B.

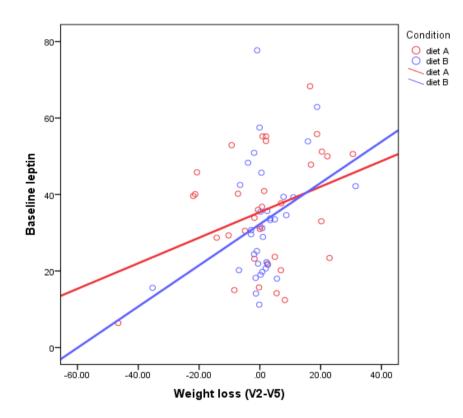


Figure 3.20-2 Regression lines showing the relationship between baseline leptin and weight loss during the intervention (V2-V5; positive value indicates weight loss) for both diets

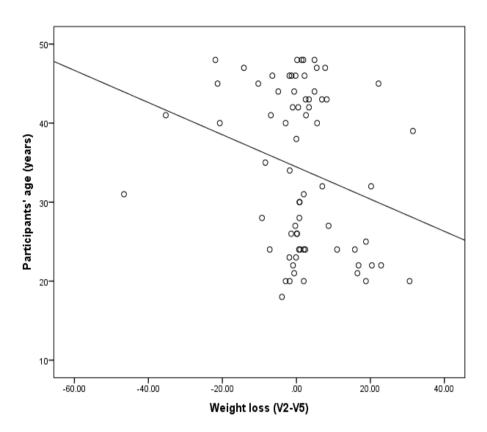


Figure 3.20-3 Regression line showing the relationship between participants' age and weight loss during the intervention (V2-V5; positive value indicates weight loss) irrespective of diet group

### 3.20.4 Changes in physiological and psychological variables (V2-V5) and weight change during the intervention

Weight change was associated with changes in emotional (r=0.27, n=71, p<0.05), external eating (DEBQ) (r=0.26, n=71, p<0.05), TFEQ disinhibition (r=0.27, n=71, p<0.05), triglycerides (r=-0.32, n=68, p<0.01) and leptin (r=0.60, n=66, p<0.001). A multiple regression including changes in triglycerides and leptin during the intervention was not significant. A multiple regression including changes in TFEQ disinhibition, DEBQ emotional and external eating and changes in TFEQ hunger was performed. Based on AIC (110.17,  $\Delta$ AIC=1.21) the best fitting model was the one including DEBQ emotional and external eating, TFEQ disinhibition and their interactions with diet, The model was significant and explained 17% of the variance (F(6,64)=3.37, p<0.01, R<sup>2</sup>=0.24, Adjusted R<sup>2</sup>=0.17). The diet\*TFEQ disinhibition interaction was a significant predictor of weight loss ( $\beta$ =0.40, t=2.08, p<0.05). As TFEQ disinhibition decreased, weight loss increased. Greater

reductions in disinhibition predicted greater weight loss for those on Diet A, but not for those on Diet B as can be seen in Figure 3.20-4.

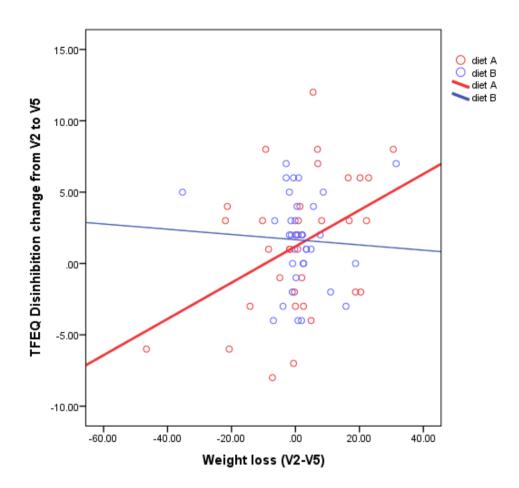


Figure 3.20-4 Regression line showing the relationship between changes in TFEQ disinhibition during the intervention (+value indicates reduction) and weight loss during the intervention (V2-V5; positive value indicates weight loss) for both diet groups

#### 3.20.5 Summary of predictors of weight loss

- Higher leptin scores at randomization were associated with higher body weight at week 12
- Lower body weight at randomisation predicted lower body weight at week
   12
- Older participants had higher body weight at week 12
- There were no significant correlations between any baseline psychological variables and body weight at week 12; none of them were significant predictors of weight loss.

- Reduction in leptin during the intervention predicted lower body weight at week 12
- Lower baseline leptin levels predicted greater weight loss at 12 weeks
- Younger participants lost consistently more weight than older ones
- Lower baseline BSQ scores were associated with more weight loss for those on Diet B
- Greater reductions in disinhibition predicted greater weight loss during the intervention for those on Diet A

#### 3.21 PART 2 Weight maintenance phase – 1 month followup

### 3.21.1 Baseline (screening) characteristics of participants who completed the 1 month follow-up

Forty-nine participants (26 on Diet A and 23 on Diet B) attended and completed the 1 month follow-up visit. Table 3.21-1 summarises the baseline characteristics of these participants at screening. At screening there were no significant differences between participants subsequently assigned to Diet A and Diet B with respect to age, body weight, height, BMI or habitual fibre intake (largest t=1.30, df=32, p=0.20).

	Whole sample	Diet A	Diet B
	(n=49)	(n=26)	(n=23)
	Mean (SE)	Mean (SE)	Mean (SE)
	(Min, Max)	(Min, Max)	(Min, Max)
Demographics			
Age (y)	35.43 (1.45)	35.27 (2.05)	35.61 (2.09)
	(18, 48)	(20, 48)	(18, 47)
Body weight			
(kg)	82.5 (1.46)	83.16 (1.95) (67.4,	81.77 (2.23) (61.3,
	(61.3, 112.9)	104.9)	112.9)
Height (m)	1.65 (0.01)	1.65 (0.01)	1.64 (0.01)
	(1.52, 1.78)	(1.53 <i>,</i> 1.78)	(1.52 <i>,</i> 1.76)
BMI (kg/m)	30.46 (0.42)	30.5 (0.54)	30.42 (0.67)
	(26, 36.9)	(26, 36.3)	(26.4, 36.9)
EAT-26	7.18 (0.76)	6.77 (0.9)	7.6 (1.27)
	(1, 20)	(1, 19)	(1, 20)
DINE	27.39 (1.4)	26.62(1.78)	28.26 (2.22)
	(5, 48)	(9 <i>,</i> 45)	(5 <i>,</i> 48)
LWW-DINE	10.28 (0.44)	9.78 (0.61)	10.85 (0.64)
	(2.2, 16.7)	(2.2, 15.6)	(5.2, 16.7)

### Table 3.21-1 Baseline participant characteristics who completed the 1 month follow-up (N=49).

#### 3.21.2 Anthropometric characteristics at randomisation (week -1), week 12 and at 1 month follow up

Anthropometric characteristics (assessed by bioimpedance) at randomisation (week -1 of the intervention), week 12 of the dietary intervention and at 1 month follow-up are presented in table 3.21-2. There were no significant baseline differences between participants in terms of anthropometric characteristics (weight, BMI and body composition variables assessed by bioimpedance; largest t=0.36, df =47, p=0.72).

	Screening			Week 12			1 month f		
	Diet A (N=26)	Diet B (N=23)	Total	Diet A (N=26) Diet B (N=23)		Total	Diet A (N=26) Diet B (N=23)		Total
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)
Body weight (kg	82.8 (1.96)	81.7 (2.32)	82.28 (1.49)	81.23 (1.95)	80.7 (2.26)	80.99 (1.47)	81.47 (2.02)	81.2 (2.36)	81.34 (1.52)
BMI (kg/m²)	30.42 (0.51)	30.6 (0.73)	30.52 (0.43)	29.83 (0.48)	30.3 (0.75)	30.05 (0.43)	29.92 (0.49)	30.5 (0.79)	30.18 (0.45)
Fat mass	33.03 (1.18)	32.4 (1.44)	32.75 (0.92)	32.22 (1.2)	31.7 (1.5)	31.98 (0.94)	32.67 (1.26)	33.4 (2.02)	33.02 (1.15)
Fat %	39.67 (0.66)	39.3 (0.77)	39.52 (0.5)	39.41 (0.71)	38.9 (0.94)	39.17 (0.57)	39.82 (0.71)	39.1 (0.94)	39. 49 (0.58)
Lean mass (kg)	49.77 (0.96)	49.3 (1.02)	49.54 (0.69)	49.01 (0.94)	49 (1)	49.01 (0.68)	48.82 (0.95)	49.1 (1.03)	48.96 (0.69)

Table 3.21-2 Anthropometric, body composition characteristics at randomisation (week -1 of the intervention), week 12 and at 1 month follow-up (N=49)

### 3.21.3 Body weight change (kg) from randomisation (week - 1) to 1 month follow-up

Body weight change from randomisation (week -1) to 1 month follow-up is reported based on the data collected using bioimpedance (BodPod data were not obtained during the 1 month follow-up). A 2x2 ANCOVA with body weight at baseline as a covariate was conducted in order to examine changes in body weight from week -1 to follow-up. There was a significant covariate\*time interaction (F(1, 49)= 2.59, p<0.05) on body weight (kg). There was no significant main effect of diet (F(1, 49)= 1.01, ns) or effect of time (F (1, 46) =3.33, p=-0.07) on body weight or significant diet\*time interaction (F (1, 49) =0.92, ns). There was a significant time\*covariate interaction (F(1, 46)=2.59, p<0.05). Body weight at week -1 was a significant covariate (F(1, 46)= 884.09, p<0.001). Post hoc tests showed that body weight at baseline was significantly higher than week 12 (p<0.01) and 1 month follow-up (p=0.05). Figure 3.21-1 shows that across both dietary interventions, participants lost a small amount of weight which tended to be maintained at follow-up.

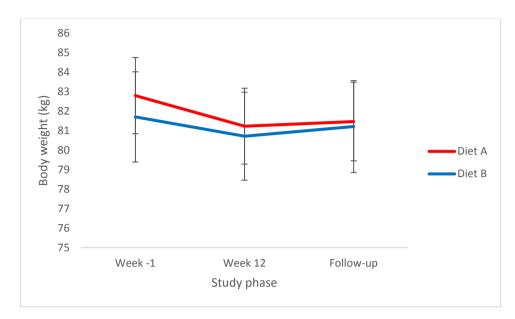
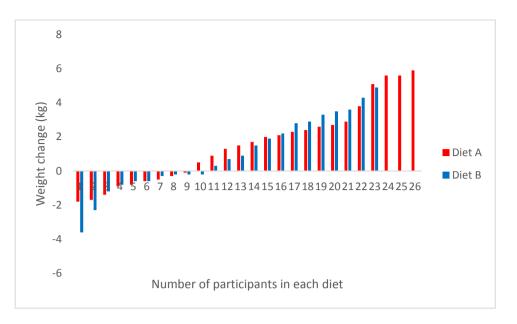


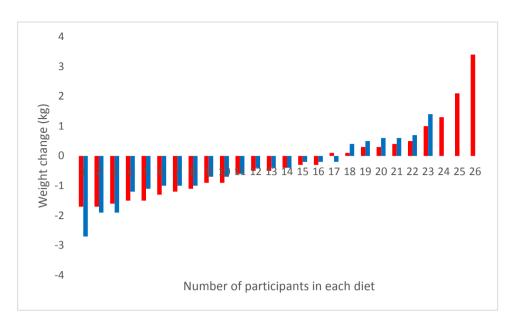
Figure 3.21-1 Mean (+/-SE) body weight change (kg) assessed using bioimpedance from randomisation (week -1) to 1 month follow-up (N=49)

However, weight loss and weight loss maintenance across diet groups and between participants varied considerably. Figure 3.21-2 illustrates individual variability in the amount of body weight lost in each diet group during the 12 week intervention for those who returned for 1 month follow-up. The average weight loss during the 12 week intervention for Diet A was 1.57 (SE=0.45) kg and for those in Diet B was 0.99, (SE=0.46) kg. There was considerable individual variability in the amount of body weight lost, with participants following Diet B losing up to 4.9 kg and gaining up to 3.6 kg over the 12 week intervention. A similar pattern of weight loss/gain was observed for participants following Diet A, with some of them losing up to 5.9 kg and others gaining up to 1.8 kg over the 12 week intervention.



## Figure 3.21-2 Weight change (kg) for each participant who attended the 1 month follow-up during the 12 week intervention according to diet group (+ values indicate weight loss)

Figure 3.21-3 shows individual variability in the amount of body weight regained in each diet group during the maintenance period (from week 12 to 1 month follow-up). The average weight regained during the maintenance phase was minimal for both diets (0.24kg, SE=0.24 for Diet A and 0.49kg, SE=0.2 for Diet B). There were no significant differences between the two diets in terms of weight change during the maintenance phase. Ten participants from Diet A and 6 from Diet B maintained their weight loss during the first follow up period.



### Figure 3.21-3 Weight change (kg) for each participant who attended the 1 month follow-up from week 12 to 1 month follow-up according to diet group

#### 3.21.4 Changes in fibre intake from screening to 1 month follow-up

Dietary fibre intake during the weight loss phase and at follow-up was assessed using the DINE (score), and LWW-DINE (fibre g/d). Table 3.21-3 shows fibre intake assessed using the DINE (score) and LWW-DINE (fibre g/d) at screening, week 12 and 1 month follow-up. There were no significant baseline differences between the groups in terms of fibre intake assessed by the DINE and LWW-DINE (largest t=-1.21 df=47, p=0.23).

Table 3.21-3	Habitual	fibre	intake	at	screening,	week	12 a	and a	at 1	month
follow-up (N=	=49)									

	Screening		Total	Week 12		Total	1 month f	Total	
	Diet A (N=26)	Diet B (N=23)		Diet A (N=26)	Diet B (N=23)		Diet A (N=26)	Diet B (N=23)	
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)
LWW-DINE (g/d)	9.78 (0.61)	10.85 (0.64)	10.28 (0.44)	14.3 (1.52)	21.61 (2.37)	17.73 (1.46)	16.2 (2.13)	22.47 (2.39)	19.2 (1.64)
DINE (score)	26.62 (1.78)	28.26 (2.22)	27.39 (1.4)	32.12 (2.05)	46.35 (3.14)	38.94 (2.1)	33.04(2.63)	41.54 (2.98)	37.11 (2.05)

A 2x2 repeated measures ANCOVA with DINE scores at screening as a covariate was performed to evaluate changes in DINE scores over time. There was a significant main effect of diet (F (1, 44) =9.94, p<0.01) and a significant diet\*time interaction (F (1, 44)=5.71, p<0.05). DINE scores at screening were a significant covariate (F(1,44)= 14.12, p<0.01) such that DINE scores at screening predicted subsequent DINE scores during. There was no significant main effect of time or

screening DINE\*time interaction (smallest F(1, 44)= 0.34, p=0.56). A post hoc ttest at week 12 revealed that DINE scores were significantly higher for those following Diet B than those following Diet A (t=-3.85, df=46, p<0.001). Further, a post hoc t-test at follow-up revealed that DINE scores were higher for those following Diet B than those following Diet A (t=-2.15, df=46, p<0.05; Figure 3.21-4).



#### Figure 3.21-4 Changes in DINE scores from screening to 1 month followup (N=49)

Changes in fibre intake (g/d) assessed using the LWW-DINE for both diets are presented in Figure 3.21-5. A 2x2 ANCOVA with fibre intake at screening as a covariate revealed that LWW DINE at screening was not a significant covariate and therefore a 2x3 ANOVA was conducted. There was a significant main effect of diet (F (1, 46) =10.92, p<0.01) and a significant main effect of time (F(2, 92)= 16.85, p<0.01). There was no significant diet\*time interaction (F(2, 92)= 2.37, p=0.11). Fibre intake was significantly higher for those following Diet B (M=13.15, SE=1.08) than those following Diet A (M=18.31, SE=1.13) (see Figure 3.20.4-2). Post hoc t-tests showed that across all participants fibre intake (g/d) was significantly higher at week 12 and follow-up than baseline (p<0.001). Although fibre intake (g/d) at follow-up was higher than week 12 this was not significant.



### Figure 3.21-5 Mean (+/-SE) changes in fibre intake (g/d) assessed using the LWW-DINE from screening to 1 month follow-up (N=49)

# 3.21.5 Changes in psychological variables (BSQ, TFEQ and DEBQ measures)

There were no significant baseline differences between participants in terms of restraint (DEBQ and TFEQ), emotional and external eating, and disinhibition (TFEQ) (largest t=1.39, df =47, p=0.17). However, participants allocated to Diet A had higher baseline (week -1) body shape perception scores (as per the whole sample) indicating worse body satisfaction and higher baseline TFEQ hunger scores, indicating greater hunger sensitivity than those allocated to Diet B (t=2.49, df=47, p<0.05 and t=2.76, df=47, p<0.01 respectively).

#### 3.21.6 Subjective measures of Body Shape

Participants completed the BSQ (described in section 3.4.6) at week -1 (baseline), week 12 (end of the intervention) and at 1 month follow up. A 2x2 repeated measures ANCOVA with BSQ scores at baseline as a covariate was employed to examine any differences in BSQ scores. There was no significant main effect of time, or diet or significant diet\*time and covariate\*time interactions (largest F (1, 46) = 34.97, p=0.55). BSQ score at baseline was a significant covariate (F(1,46)= 33.73, p<0.001). Figure 3.20-6 shows the tendency for scores of body shape perception to reduce from baseline to week 12 indicating an

improvement in body satisfaction and then to slightly increase from week 12 to 1 month follow-up, but remain lower than initial baseline scores.

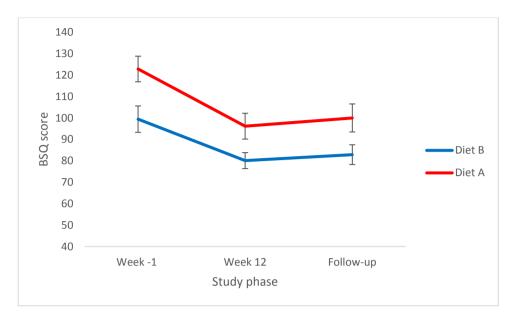


Figure 3.21-6 Mean (+/- SE) changes in body shape perception from baseline (week -1) to 1 month follow-up (N=49). Higher scores indicate lower body satisfaction

#### 3.21.7 Eating Behaviour Characteristics

Participants completed the TFEQ and DEBQ questionnaires (described in section 3.4.5) at baseline (week -1), week 12 and 1 month follow-up and scores were used to evaluate any changes in eating behaviour characteristics measured by each questionnaire.

Mixed 2x2 ANCOVAs were performed to evaluate any changes in each of the six eating behaviour characteristics. TFEQ scores of restraint, disinhibition and hunger at baseline (week -1) of the intervention were used as covariates in each respective analysis and they were all found to be significant (smallest F(1,46)=21.78, p<0.001). No significant main effects of time or significant diet\* time and covariate\*time interactions were found (largest F(1,46)=3.09, p=0.09). There was no significant main effect of diet on disinhibition, restraint or hunger (largest F(1,46)=3.36, p=0.07). Post hoc tests showed that restraint at week 12 and follow-up was higher for those following Diet A than those following Diet B (t=2.15, df=47, p<0.05 and t=2.31, df=47, p<0.05 respectively, see Figure 3.21-7).

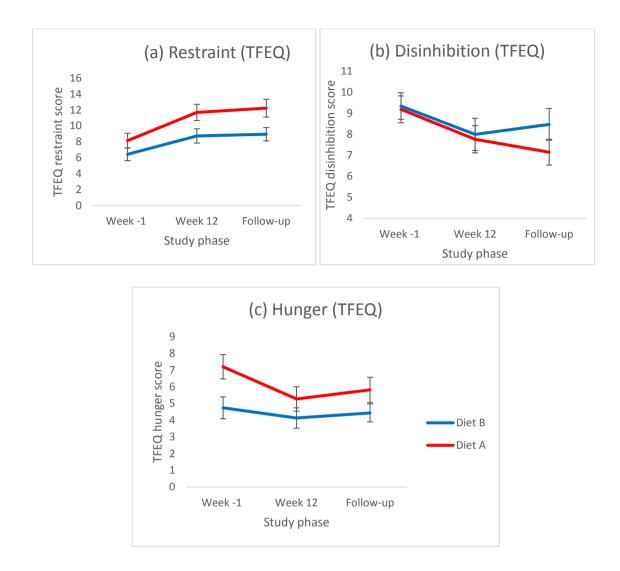
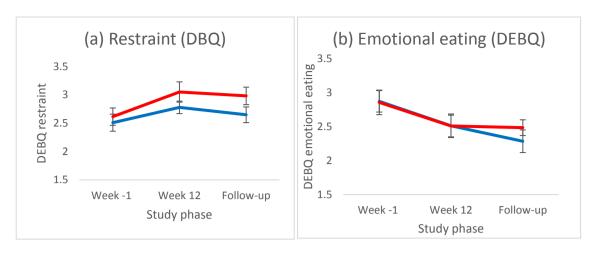


Figure 3.21-7 Mean (+/- SE) changes in TFEQ restraint (a), disinhibition (b) and hunger (c) from baseline (week -1) to 1 month follow-up (N=49)

Baseline (week -1) DEBQ eating behaviour scores of restraint, emotional and external eating were also used as covariates in their respective analyses and all were significant predictors of subsequent scores (smallest F(1,46)= 30.76, p<0.001). No significant main effects of time, diet or diet\*time or interactions with covariates and time or diet interactions were found (largest F(1, 46)=2.34, p=0.13; Figure 3.21-8).





# Figure 3.21-8 Mean (+/- SE) changes in DEBQ restraint (a), emotional (b) and external eating (c) from baseline (week -1) to 1 month follow-up (N=49)

#### 3.21.8 Summary of findings

- There were no significant differences between participants randomized to Diet A or Diet B at screening with respect to age, body weight, height or BMI. There were also no significant diet group differences in terms of fibre intake assessed by the DINE and LWW-DINE at screening.
- Body shape perception scores and TFEQ hunger scores were significantly higher for those on Diet A than those on Diet B at randomization (week -1; p<0.05)</li>
- There were no significant diet group differences at baseline in terms of body weight (kg) assessed using bioimpedance
- Overall, irrespective of diet group, participants lost a small amount of weight during the 12 week intervention which was maintained at 1 month follow-up

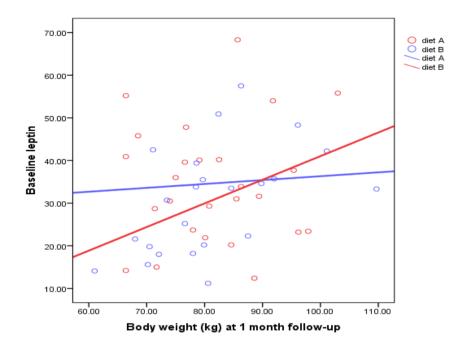
- Weight loss and weight loss maintenance varied considerably both within and between diet groups
- Fibre intake assessed using the DINE and LWW-DINE significantly increased over the 12 week intervention for those on Diet B
- Fibre intake assessed using the LWW-DINE significantly increased from week 12 upto the 1 month follow-up for both diets
- Body shape perception scores significantly improved in both diet groups over the intervention and then slightly increased from week 12 to 1 month follow-up, but remained lower than initial scores at baseline
- Baseline TFEQ and DEBQ scores predicted subsequent eating behavior scores at week 12 and 1 month follow-up
- TFEQ restraint at week 12 and follow-up was significantly higher for those following Diet A than those following Diet B

# 3.22 Predictors of weight loss maintenance at 1 month follow-up

# 3.22.1 Relationship between randomization (week -1) variables and body weight at 1 month follow-up

Body weight at follow-up was associated with baseline body weight (r=0.97, df=49, p<0.001) and age (r=-0.35, df=49, p<0.05). Variables which were significantly related with body weight at follow-up were tested as potential predictors in multiple regression analyses. The best fitting model (AIC=90.50,  $\Delta$ AIC=3.05) included baseline age, body weight at randomisation (week-1), baseline leptin and diet\*leptin interactions. The model explained 95% of the variance in body weight at 1 month follow up (F(6,42)= 156.4, p<0.001, Adjusted R<sup>2</sup>=0.95). Baseline body weight (week -1), age, leptin and diet\*leptin were significant predictors of body weight at 1 month follow-up. Lower body weight at randomisation (week-1) was associated with lower body weight at 1 month follow-up ( $\beta$ = 0.98, t=27.09, p<0.001). Higher age and baseline leptin were associated with higher body weight at 1 month follow-up ( $\beta$ = -0.12, t=-3.08, p<0.001 and  $\beta$ =-0.1, t=-2.57, p<0.05 respectively). Older participants had higher body weight at 1 month follow-up. Higher baseline leptin was associated with higher body weight at 1 month follow-up ( $\beta$ = 1.12, t=-3.08, p<0.001 and  $\beta$ =-0.11, t=-2.57, p<0.05 respectively). Older participants had higher body weight at 1 month follow-up. Higher baseline leptin was associated with higher body weight at 1 month follow-up. Higher baseline leptin were body weight at 1 month follow-up. Higher baseline leptin was associated with higher body weight at 1 month follow-up. Higher baseline leptin was associated with higher body weight at 1 month follow-up only for those on Diet B as indicated by the positive

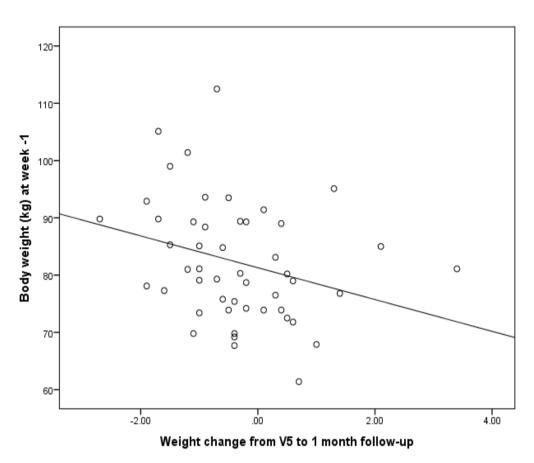
regression line for Diet B (shown in blue in Figure 3.22-1) ( $\beta$ = 0.13, t=2.41, p<0.05). There were no significant correlations between baseline psychological variables and body weight at 1 month follow-up (largest r=0.18, n=49, p=0.24).

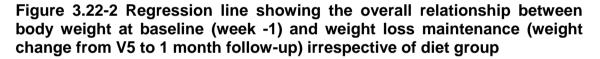


### Figure 3.22-1 Regression lines showing the relationship between baseline fasting leptin and body weight at 1 month follow-up for doth diets

# 3.22.2 Relationship between randomization (week -1) variables and weight loss maintenance (V5-1 month follow-up)

Weight change from week 12 to 1 month follow-up was only associated with body weight at randomisation (week -1) (r=-0.29, n=49, p<0.05), such that higher body weight at week -1 was associated with less weight loss (Figure 3.22-2). There were no significant relationships between psychological variables assessed at randomisation and weight loss maintenance (largest r=0.13, n=49, p=0.39).





# 3.22.3 Relationship between variables at V5 (week 12) and body weight at 1 month follow-up

Body weight at follow-up was significantly associated with body weight at week 12 (r=-0.99, df=49, p<0.001), insulin (r=0.32, df=46, p<0.05 see Figure XX below), leptin (r=0.37, df=45, p<0.05), DEBQ emotional eating (r=0.45, df=49, p<0.001), DEBQ external eating (r=0.42, df=49, p<0.01), TFEQ disinhibition (r=0.43, df=49, p<0.01) and TFEQ hunger (r=0.37, df=49, p<0.01) at week 12. A multiple regression was conducted to predict body weight at 1 month follow-up from physiological variables (insulin and leptin). The best fitting model included leptin, insulin and interaction terms (AIC=218.31,  $\Delta$ AIC=2.76). The model explained 21% of the variance (F(5, 41)= 3.5, p<0.05, Adjusted R<sup>2</sup>=0.21). Insulin at week 12 and diet\*insulin were significant predictors of body weight at 1 month follow-up ( $\beta$ = 0.68, t=2.25, p<0.05 and  $\beta$ =-1.34, t=-2.89, p<0.01 respectively). Higher insulin at the end of the intervention predicted higher body weight at 1

month follow-up for those on Diet A, but not for those on Diet B (see Figure 3.22-3). A multiple regression was conducted to predict body weight at 1 month followup from DEBQ emotional and external eating and TFEQ disinhibition and hunger assessed at the end of the intervention. The best fitting model (AIC=222.48,  $\Delta$ AIC=5.53) included DEBQ emotional and external eating and explained 22% of the variance (F(2,46)=7.85, p<0.001, Adjusted R<sup>2</sup>=0.22). DEBQ emotional eating at week 12 predicted body weight at 1 month follow-up ( $\beta$ = 4.18, t=1.94, p<0.05), indicating that women who had higher emotional eating scores at week 12 had higher body weight at 1 month follow-up.

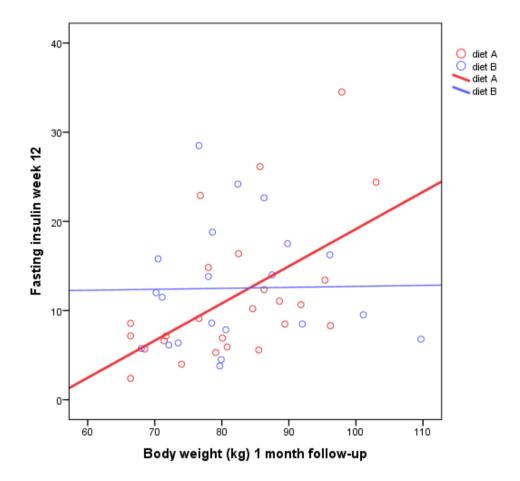
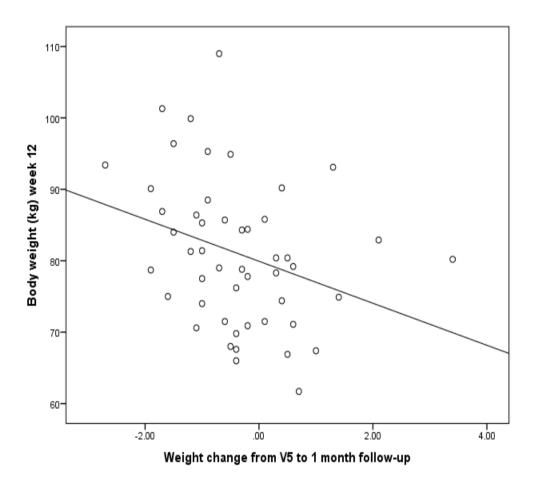


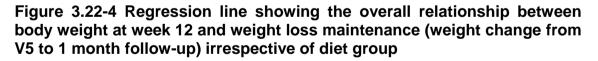
Figure 3.22-3 Regression lines showing the relationship between fasting insulin levels at week 12 and body weight at 1 month follow-up for doth diets

# 3.22.4 Relationship between variables at week 5 and weight loss maintenance (V5-1 month follow-up)

Weight change from V5 to 1 month follow-up was significantly associated with body weight at week 12 (r=-0.32, df=49, p<0.05). There were no significant associations between weight loss maintenance and any biomarkers assessed at

week 12 (largest t=0.17, df=46, p=0.25). The best fitting model (AIC=7.67,  $\Delta$ AIC=1.31) included only body weight at week 12 and explained 8% of the variance (F(1,47)=4.98, p<0.05, Adjusted R<sup>2</sup>=0.08). Higher body weight at week 12 was indicative of less weight loss maintenance ( $\beta$ = -0.03, t=-2.23, p<0.05; Figure 3.22-4).





#### 3.22.5 Changes in physiological and psychological variables from V5 (week 12) to 1 month follow-up and body weight at 1 month followup

Pearson's Product Moment correlation coefficients were calculated to examine the relationships between changes in physiological variables (fibre intake) and psychological variables from week 12 to 1 month follow-up and body weight at follow-up. Body weight at follow-up was significantly associated with changes in BSQ score from week 12 to follow-up (r=-0.38, df=49, p<0.01) and changes in emotional eating (r=0.28, df=46, p=0.05). The best model (AIC=224.68,  $\Delta$ AIC=2.5) included changes in DEBQ emotional eating and BSQ score from V5 to 1 month follow up. The model explained 19% of the variance (F(2,46)=6.50, p<0.01, Adjusted R<sup>2</sup>=0.19). Changes in emotional eating ( $\beta$ =6.29, t=2.12, p<0.05) and changes in BSQ score ( $\beta$ = -0.3, t=-2.94, p<0.001) predicted body weight at 1 month follow-up. A greater reduction in BSQ score (i.e. improved body satisfaction) from V5 to 1 month follow-up was associated with lower body weight at 1 month follow-up (see Figure 3.22-5). A greater reduction in DEBQ emotional eating was associated with higher body weight at 1 month follow-up (see Figure 3.22-6).

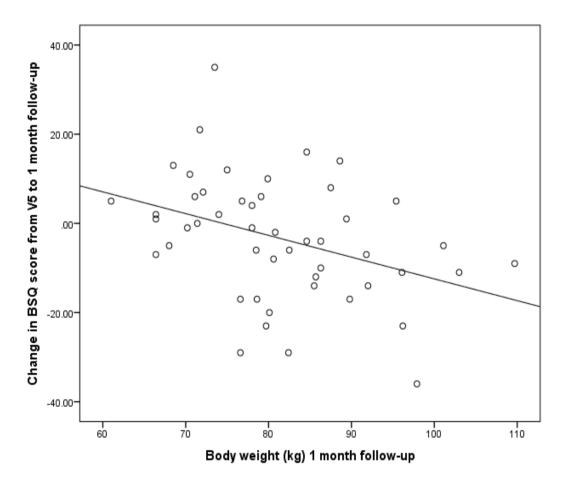


Figure 3.22-5 Regression line showing the overall relationship between changes in BSQ from V5 (week 12) to 1 month follow-up and body weight at 1 month follow-up irrespective of diet group

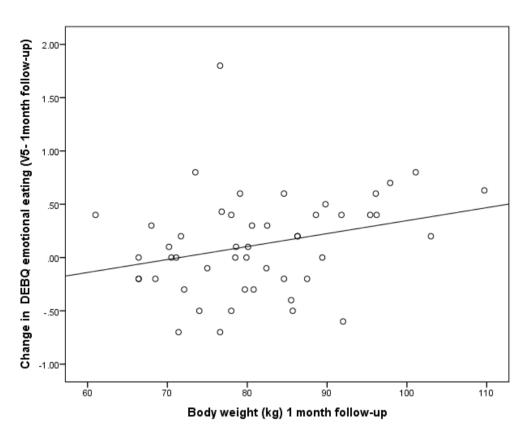
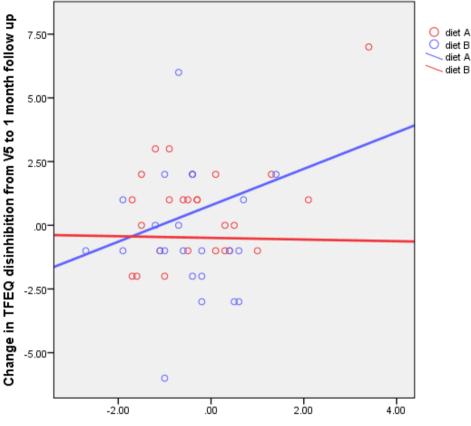


Figure 3.22-6 Regression line showing the overall relationship between changes in DEBQ emotional eating from V5 (week 12) to 1 month follow-up and body weight at 1 month follow-up irrespective of diet group

#### 3.22.6 Changes physiological and psychological variables from V5 (week 12) to 1month follow-up and weight loss maintenance (V5-1 month follow-up)

Pearson's Product Moment correlation coefficients were performed to test the associations between changes in variables from week 12 to 1 month follow-up and weight change from week 12 to 1 month follow-up. Weight change was significantly associated with changes in BSQ score from week 12 to follow-up (r=0.3, df=49, p<0.05). The best fitting model (AIC=5.68,  $\Delta$ AIC=1.5) included changes in BSQ score, TFEQ disinhibition and diet\*BSQ score. The model explained 16% of the variance (F(4,44)=3.32, p<0.05, Adjusted R<sup>2</sup>=0.16). Changes in BSQ score from week 12 to 1 month follow up predicted weight change ( $\beta$ =0.02, t=2.26, p<0.05). Greater reduction in BSQ scores were associated with greater weight loss maintenance. Changes in TFEQ disinhibition from week 12 to 1 month follow-up predicted weight change ( $\beta$ =0.28, t=2.76, p<0.01), such that greater reduction in TFEQ disinhibition was associated with

greater weight loss maintenance. There was a significant diet\*TFEQ disinhibition indicating that greater reduction in TFEQ disinhibition was associated with greater weight loss maintenance for those on Diet A (Figure 3.22-7).



weight change from V5 to 1 month follow uploss

Figure 3.22-7 Regression lines showing changes in TFEQ disinhibition from V5 (week 12) to 1 month follow-up and weight loss maintenance (weight change from V5 to 1 month follow-up) for each diet group

#### 3.22.7 Summary of predictors of weight loss maintenance (1 month followup)

- Lower body weight at randomisation (week-1) was associated with lower body weight at 1 month follow-up
- Higher age and baseline leptin were associated with higher body weight at 1 month follow-up
- Higher baseline leptin was associated with higher body weight at 1 month follow-up for those on Diet B

- There were no significant correlations between baseline psychological variables and body weight at 1 month follow-up
- Higher body weight at week -1 was correlated with less weight loss maintenance
- Fasting Insulin at week 12 and diet\*insulin were significant predictors of body weight at 1 month follow-up
- Higher insulin at the end of the intervention predicted higher body weight at 1 month follow-up and this was more evident for those on diet A
- Higher DEBQ emotional eating scores at week 12 predicted higher body weight at 1 month follow-up
- Higher body weight at week 12 was associated with more weight regain/less weight maintenance
- Greater reduction in BSQ score from V5 to 1 month follow-up was associated with lower body weight at 1 month follow-up
- Greater reduction in DEBQ emotional eating was associated with higher body weight at 1 month follow-up
- Greater reduction in BSQ score from week 12 to 1 month follow-up was associated with greater weight loss maintenance
- Changes in TFEQ disinhibition from week 12 to 1 month follow-up predicted weight change, such that greater reduction in TFEQ disinhibition was associated with greater weight loss maintenance
- There was a significant diet\*TFEQ disinhibition indicating that greater reduction in TFEQ disinhibition was associated with greater weight loss maintenance for those on Diet A

#### 3.2312 month Follow-up

#### 3.23.1 Participant characteristics at screening and at 12 months

Thirty-four participants (19 on Diet A and 15 on Diet B) attended and completed the follow up visit (1 year after completion of the LWW study). Table 3.23-1 summarises the baseline characteristics of participants (N=34) at screening. At screening there were no significant differences between the participants subsequently assigned to Diet A and Diet B who returned for follow up, with respect to age, body weight, height, BMI or habitual fibre intake (largest t=-1.21, df=47, p=0.23).

Table 3.23-1 Characteristics of participants who returned for 12 month follow- up at screening (N=34).

	Whole follow up	Diet A	Diet B		
	sample (n=34)	(n=19)	(n=15)		
	Mean (SE)	Mean (SE)	Mean (SE)		
	(Min, Max)	(Min, Max)	(Min, Max)		
Demographics					
Age (y)	37.09 (1.59)	37.31 (2.12)	36.8 (2.48)		
Dedu	(21, 48)	(21, 48)	(23, 47)		
Body weight (kg)	80.4 (1.68)	80.24 (1.98)	80.59 (2.93) (61.3,		
	(61.3, 112.9)	(64.3, 93.4)	112.9)		
Height (m)	1.64 (0.01)	1.63 (0.01)	1.64 (0.02)		
	(1.52, 1.78)	(1.53, 1.78)	(1.52, 1.76)		
BMI					
(kg/m²)	29.95 (0.49)	30.09 (0.66)	29.78 (0.77)		
	(26, 36.3)	(26, 36.3)	(26.4, 36.9)		
EAT-26	5.7 (0.76)	6.58 (1.11)	4.6 (0.97)		
	(1, 19)	(1, 19)	(1, 15)		
DINE	28.65 (1.69)	27.89(2.16)	29.6 (2.74)		
	(5, 48)	(9, 43)	(5, 48)		
LWW-DINE	10.67 (0.43)	10.37 (0.63)	11.05 (0.58)		
	(4.9,15.1)	(4.9, 15)	(6.8, 15.1)		

# 3.23.2 Anthropometric characteristics at baseline (week -1), week 12 and at 12 month follow up

Anthropometric characteristics (assessed by ADP) at baseline (week -1 of the intervention), week 12 of the dietary intervention and at 12 month follow-up are presented in table 3.23-2. There were no significant baseline differences between participants in terms of anthropometric characteristics (weight, BMI and body composition variables assessed by ADP; largest t=-1.03, df =32, p=0.31).

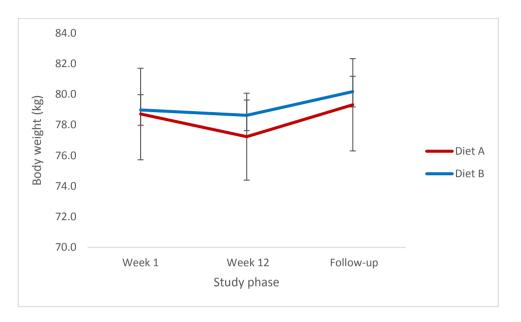
Table 3.23-2 Anthropometric, body composition characteristics at baseline (week -1 of the intervention), week 12 and at 12 month follow-up (N=34)

	Wee	ek -1	Wee	ek 12	12 months follow-up				
	Diet A (n=19)	Diet B (n=15)	Total (n=34)	Diet A (n=19)	Diet B (n=15)	Total (n=34)	Diet A (n=19)	Diet B (n=15)	Total (n=34)
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)
Body weight (kg)	78.71 (1.98)	78.97 (2.99)	78.83 (1.69)	77.23 (1.96)	78.63 (2.84)	77.85 (1.64)	79.31 (2.74)	80.18 (3.01)	79.69 (1.99)
BMI (kg/m²)	29.61 (0.64)	29.43 (0.85)	29.53 (0.51)	29.04 (0.59)	29.33 (0.87)	29.17 (0.49)	29.6 (0.74)	29.82 (0.94)	29.7(0.58)
Fat mass	33.44 (1.56)	33.01 (1.99)	33.26 (1.22)	31.79 (1.57)	32.59 (1.92)	32.15 (1.20)	32.6 (2.02)	32.73 (2.03)	32.66 (1.42)
Fat %	42.27(1.35)	41.35 (1.32)	41.88 (0.95)	40.92 (1.45)	41.12 (1.37)	41 (0.99)	40.59 (1.56)	40.43 (1.30)	40.52 (1.03)
Lean mass (kg)	45.25 (1.27)	47.69 (2.13)	46.33 (1.17)	45.42 (1.26)	46.03 (1.45)	45.69 (0.94)	46.72 (1.42)	47.43 (1.40)	47.04 (0.99)

# 3.23.3 Body weight change (kg) from baseline (week - 1) to 12 month follow up

Body weight was measured using three different techniques (described in section 3.5.1). Body weight change from baseline (week -1) to 12 month follow-up is reported based on the data collected using the BodPod (ADP) equipment as it is more sensitive and accurate than bioimpedance (Lee and Gallagher, 2008). A 2x2 ANCOVA with body weight at baseline as a covariate was conducted in order to examine changes in body weight from week -1 to follow-up. There was no significant main effect of time (F (1,31) =1.89, ns) or diet (F (1,31) =0.08, ns) on

body weight (kg). There was also no significant diet\*time interaction (F (1,31) =0.03, ns) or time\*covariate interaction (F(1,31)=2.73, ns). Body weight at week -1 was a significant covariate (F(1,31)= 39.41, p<0.001). Figure 3.22-1 suggests that across both dietary interventions on average, participants lost a small amount of weight which was regained at 12 months follow-up.



### Figure 3.23-1 Mean (+/-SE) body weight change (kg) assessed using the BopPod from baseline (week -1) to 12 month follow up (N=34)

However, weight loss and weight loss maintenance across diet groups and between participants varied considerably. This is shown in Figure 3.23-2 which illustrates individual variability in the amount of body weight lost in each diet group. The solid lines represent weight regain from week 12 to follow-up and the dotted lines represent weight loss and/or maintenance from week 12 to follow-up. Overall, from week 12 of the intervention to 12 month follow-up, body weight was regained in 15 participants and the final weight was higher than baseline weight (7 on Diet A and 8 on Diet B). Nine participants continued in losing weight from week 12 to follow-up (4 on Diet A and 5 on Diet B). At 12 month follow-up, two participants on Diet A had maintained weight loss. Three participants regained their lost weight and final weight at follow-up was same as baseline body weight (2 on Diet A and 1 on Diet B). Five participants showed weight regain from week 12 to follow-up, but body weight at follow-up was less than baseline body weight (4 on Diet A and 1 on Diet B).

- R010 A 115 Diet A Diet B - R014 A \_\_\_\_ - - R015 A 110 R020 A **– –** R021 A **— —** R030 A 105 **–** – R034 A - R035 A 100 **– –** R039 A **– –** R052 A **– –** R054 A 95 **– – –** R056 A **– –** R065 A 90 - R066 A **- - -** R071 A Body Weight (kg) **—** — R076 A 85 **– –** R077 A **– –** R078 A 80 - - R001 B **– –** ROO3 B **— — —** R006 B 75 **– – –** R007 B - R009 B 70 - R028 B **–** R043 B 65 - R050 B - R051 B **– – –** R059 B 60 **-** R063 B **— — —** R064 B 55 **–** R067 B **—** R073 B **— — —** R079 B 50 Week -1 Week 12 Follow-up Study phase

# Figure 3.23-2 Weight loss (kg) for each participant from baseline (week -1) to 12 month follow up (solid lines represent weight regain and dotted lines weight loss and/or maintenance)

#### 3.23.4 Changes in fibre intake from screening to 12 month follow up

Dietary fibre intake during the weight loss phase and at follow up was assessed using the DINE (score), LWW-DINE (fibre g/d) and fibre g/d calculated from 3 day

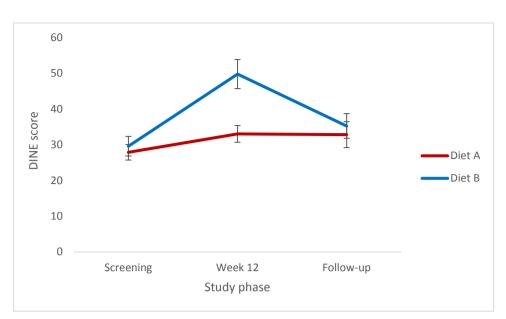
234

food diaries. Table 3.23-3 shows fibre intake assessed using the DINE (score) and LWW-DINE (fibre g/d) at screening, week 12 and follow up. There were no significant baseline differences between the groups in terms of fibre intake assessed by the DINE and LWW-DINE (largest t=-0.78, df=32, p=0.44).

	Week -1			Wee	ek 12		12 months follow-up			
	Diet A (n=19) Diet B (n=15) T		Total (n=34)	Diet A (n=19)	Diet B (n=15)	Total (n=34)	Diet A (n=19)	Diet B (n=15)	Total (n=34)	
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	
	(Min, Max)	(Min, Max)	(Min, Max)	(Min, Max)	(Min, Max)	(Min, Max)	(Min, Max)	(Min, Max)	(Min, Max)	
DINE (score)	27.89 (2.16)	29.6 (2.74)	28.65 (1.69)	33.05 (2.35)	49.8 (4.07)	40.44 (2.62)	32.84 (3.63)	35.27 (3.46)	33.91 (2.51)	
	(9, 43)	(5, 48)	(5, 48)	(16, 57)	(18, 76)	(16, 76)	(5, 66)	(11, 59)	(5, 66)	
LWW-DINE (g/d)	10.37 (0.63)	11.05 (0.58)	10.67 (0.43)	14.98 (1.97)	25.11 (3.27)	19.45 (1.99)	12.89 (0.9)	14.39 (1.38)	13.55 (0.79)	
	(4.9, 15)	(6.8, 15.1)	(4.9, 15.1)	(6.1, 41.4)	(10.8, 62)	(6.1, 62)	(7.2, 22)	(7.9, 24.9)	(7.2, 24.9)	

Table 3.23-3 Habitual fibre intake of participants who returned for follow up at screening, week 12 and at 12 month follow up (N=34)

A 2x2 repeated measures ANCOVA with DINE scores at screening as a covariate was performed to evaluate changes over time in DINE scores. There was a significant main effect of diet (F (1, 31) =5.3, p<0.05) and a significant diet\*time interaction (F (1, 31)=9.16, p<0.01) on DINE scores. DINE scores at screening were a significant covariate (F(1,31)= 10.61, p<0.01). A post hoc t-test at week 12 revealed that DINE scores were significantly higher for those following diet B than those following diet A (t=-3.75, df=34, p<0.01). A post hoc t-test at follow up revealed that DINE scores were not different between groups (t=-0.47, df=34, ns; Figure 3.23-3).



# Figure 3.23-3 Changes in DINE scores from screening to 12 month follow up (N=34)

Changes in fibre intake (g/d) assessed using the LWW-DINE for both diets are presented in Figure 4.2. A 2x2 ANCOVA with fibre intake at screening as a covariate revealed that there was a significant effect main effect of diet (F (1, 31) =5.16, p<0.05) and a significant diet\*time interaction (F (1, 31) =7.16, p<0.05). The covariate was also significant (F(1, 31)= 5.61, p<0.05). There was no significant main effect of time (F(1,31)= 0,65, ns.). A post hoc t-test at week 12 revealed that fibre intake was significantly higher for those following diet B than those following diet A (t=-2.77, df=32, p<0.01). A post hoc t-test at follow up revealed that there were no differences between groups in terms of fibre intake (g/d) (t=-0.94, df=32, ns; Figure 3.23-4).

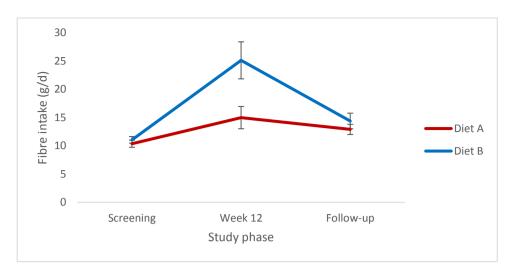


Figure 3.23-4 Mean (+/-SE) changes in fibre intake (g/d) assessed using the LWW-DINE from screening to 12 month follow up (N=34)

# 3.23.5 Changes in psychological variables (BSQ, TFEQ and DEBQ measures)

Psychological characteristics (body shape perception and eating behaviour characteristics assessed using the TFEQ and DEBQ) are shown in Table 3.23-4. There were no significant baseline differences between participants in terms of restraint (DEBQ and TFEQ), emotional and external eating, and disinhibition (TFEQ) (largest t=1.74, df =32, p=0.10). However, participants allocated to Diet A had higher baseline (week -1) body shape perception scores and higher baseline TFEQ hunger scores than those allocated to Diet B (t=2.34, df=32, p<0.05 and t=2.46, df=32, p<0.05 respectively).

	Week -1			Week 12			12 months follow-up		
	Diet A (n=19)	Diet B (n=15)	Total (n=34)	Diet A (n=19)	Diet B (n=15)	Total (n=34)	Diet A (n=19)	Diet B (n=15)	Total (n=34)
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)				
BSQ	113.84 (6.34)	91 (7.48)	103.76 (5.16)	87.05 (5.69)	72.67 (3.47)	80.71 (3.7)	92.47 (6.64)	80.01 (7.73)	87 (5.08)
TFEQ outcomes									
Restraint	8.37 (1.1)	5.67 (1.05)	7.18 (0.79)	12.16 (1.25)	7.87 (1.14)	10.26 (0.93)	9.84 (1.18)	7.47 (1.13)	8.79 (0.84)
Disinhibition	8.95 (0.8)	8.87 (0.7)	8.91 (0.54)	7.45 (0.72)	6.6 (0.8)	7.09 (0.53)	7.57 (0.73)	7.6 (0.76)	7.59 (0.52)
Hunger	6.79 (0.85)	4 (0.68)	5.56 (0.6)	4.21 (0.71)	3.33 (0.67)	3.83 (0.49)	4.89 (0.83)	4.2 (0.73)	4.56 (0.56)
DEBQ outcomes									
Restraint	2.71 (0.18)	2.34 (0.2)	2.55 (0.14)	3.05 (0.22)	2.68 (0.15)	2.89 (0.14)	2.69 (0.17)	2.5 (0.22)	2.61 (0.14)
Emotional eating	2.8 (0.21)	2.72 (0.15)	2.77 (0.13)	2.41 (0.14)	2.28 (0.19)	2.35 (0.11)	2.5 (0.16)	2.41 (0.24)	2.46 (0.14)
External eating	2.93 (0.11)	2.86 (0.14)	2.9 (0.08)	2.46 (0.11)	2.51 (0.13)	2.49 (0.08)	2.5 (0.12)	2.67 (0.17)	2.57 (0.1)

# Table 3.23-4 Body shape perception and eating behaviour characteristics at baseline (week -1), week 12 and at 12 months follow up (N=34)

#### 3.23.6 Subjective measures of Body Shape

Participants completed the BSQ (described in section 3.5.6) at week -1 (baseline), week 12 (end of the intervention) and at 12 month follow up. A 2x2 repeated measures ANCOVA with BSQ scores at baseline as a covariate was employed to examine any differences in BSQ scores. There was a significant main effect of time (F (1, 31) = 4.02, p<0.05) and a significant covariate\*time interaction (F (1, 31) = 6.76, p<0.05). There was no significant diet\*time interaction (F(1, 31) = 1.62, ns). BSQ score at baseline was a significant covariate (F(1, 31) =18.76, p<0.001). A post hoc ANOVA showed that BSQ score was significant higher at baseline than week 12 (p<0.001) and follow-up (p<0.01). There were no significant differences between BSQ score at week 12 and 12 month followup. A post hoc t-test at week 12 revealed that those on Diet A had a higher BSQ score than those on Diet B (t=2.16, df=32, adjusted p<0.05) (as per baseline). However, a post hoc t-test at follow-up showed no significant differences between diet groups (t=1.22, df=32, ns.). Figure 3.23-5 shows the tendency for scores of body shape perception to reduce from baseline to week 12 and then to slightly increase from week 12 to 12 month follow-up, but remain lower than initial baseline scores.

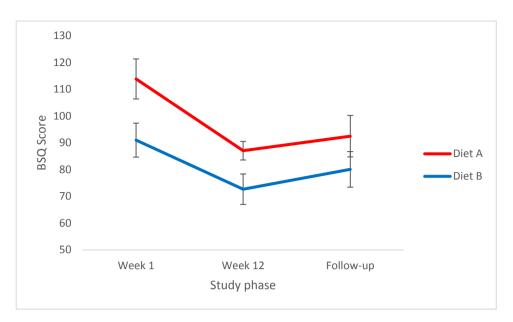


Figure 3.23-5 Mean (+/- SE) changes in body shape perception from baseline (week -1) to 12 months follow-up (N=34)

#### 3.23.7 Eating Behaviour Characteristics

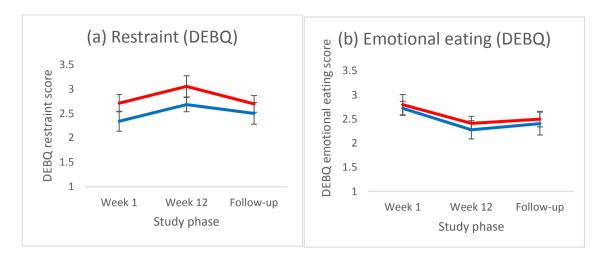
Participants completed the TFEQ and DEBQ questionnaires (described in section 3.5.5) at baseline (week -1), week 12 and follow up and scores were used to evaluate any changes in eating behaviour characteristics measured by each questionnaire.

Mixed 2x2 ANCOVAs were performed to evaluate any changes in each of the six eating behaviour characteristics. TFEQ scores of restraint, disinhibition and hunger at baseline (week -1) of the intervention were used as covariates in each respective analysis and they were all found to be significant. No significant main effects of time, diet or significant diet\* time and covariate\*time interactions were found (largest F(1,31)=2.26, p=0.14; Figure 3.23-6).



# Figure 3.23-6 Mean (+/- SE) changes in TFEQ restraint (a), disinhibition (b) and hunger (c) from baseline (week -1) to 12 month follow-up (N=34)

Baseline (week -1) DEBQ eating behaviour scores of restraint, emotional and external eating were also used as covariates in their respective analysis and they were all significant (smallest F(1,31)=11.74, p<0.001). No significant main effects of time, diet or diet\*time and covariate\*time interactions were found (largest F(1, 31)=1.62, p=0.21; Figure 3.23-7).



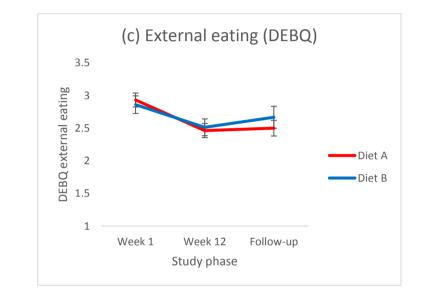


Figure 3.23-7 Mean (+/- SE) changes in DEBQ restraint (a), emotional (b) and external eating (c) from baseline (week -1) to 12 month follow-up (N=34)

#### 3.23.8 Summary of findings

- There were no significant diet group differences in participant characteristics, of those who returned for follow up, at screening with respect to age, body weight, height or BMI. There were also no significant diet group differences in terms of fibre intake assessed by the DINE and LWW-DINE at screening
- Body shape perception scores and TFEQ hunger scores were significant higher for those on Diet A than those on Diet B at baseline (week -1; p<0.05)</li>

- There were no significant diet group differences at baseline in terms of body weight (kg) assessed using ADP
- On average, participants in both diet groups lost a small amount of weight during the 12 week intervention which was regained at 12 month follow-up
- There was large individual variability in weight loss and weight loss maintenance across both diets
- Fibre intake assessed using the DINE and LWW-DINE significantly increased over the 12 week intervention for those on Diet B, but changes were not maintained at 12 month follow-up
- Body shape perception scores significantly reduced in both diet groups over the intervention and changes were maintained at 12 month follow-up
- Baseline TFEQ and DEBQ scores predicted subsequent scores at week
   12 and at 12 month follow-up

# 3.24 Predictors of weight loss maintenance at 12 month follow-up

# 3.24.1 Relationship between randomization (week -1) variables and body weight at 12 month follow-up

Pearson's product correlations were conducted in order to examine the relationships between baseline (week -1) physiological and psychological factors and body weight at 12 month follow-up. Only body weight at baseline was significantly positively associated with body weight at 12 month follow-up (r=0.9, n=34, p <0.001). There were no significant correlations between baseline psychological variables and body weight at 12 month follow-up (largest r=0.27, df=34, p=0.13).

# 3.24.2 Relationship between randomization (week -1) variables and weight loss maintenance (V5-12 month follow-up)

There were no significant correlations between any physiological or psychological variables and weight change from V5 (week 12) to 12 month follow-up (largest r=-0.28, df=34, p=0.11).

# 3.24.3 Relationship between variables at V5 (week 12) and body weight at 12 month follow-up

Body weight at 12 month follow-up was significantly associated with body weight at week 12 (r=0.95, df=34, p<0.001) and TFEQ disinhibition (r=0.34, df=34,

p=0.05). The best fitting model (AIC=94.13,  $\Delta$ AIC=2.98)) included only body weight at the end of the intervention and explained 89% of the variance (F(1,32)=265.5, p<0.001, Adjusted R=0.89). Higher body weight at week 12 predicted higher body weight at 12 month follow-up ( $\beta$ = 1.13, t=14.89, p<0.001).

# 3.24.4 Relationship between variables at week 12 and weight loss maintenance (V5-12 month follow-up)

Weight change from V5 (week 12) to 12 month follow-up was only associated with body weight at week 12 (r=-0.35, df=34, p<0.05). There were no significant correlations between any psychological variables and weight loss maintenance (largest r=-025, n=34, p=0.16). A regression was conducted to predict weight loss maintenance from body weight at week 12. The model was significant and explained 12% of the variance (F(1,32)=4.55, p<0.05, Adjusted R=0.10). Body weight at week 12 was a significant predictor of weight loss maintenance ( $\beta$ =-0.15, t=-2.13, p<0.05). Higher body weight at week 12 was associated with less weight loss maintenance.

#### 3.24.5 Changes in physiological and psychological variables from V5 (week 12) to 12 month follow-up and body weight at 12 month follow-up

There were no significant correlations between changes in physiological and psychological variables from week 12 to 12 month follow-up and body weight at 12 month follow-up (largest r=-0.19, p=0.28, n=34).

#### 3.24.6 Changes in physiological and psychological variables from V5 (week 12) to 12 month follow-up and weight loss maintenance (weight change from V5 to 12 month follow-up)

There were no significant correlations between changes in physiological variables and weight change from week 12 to 12 month follow-up. The positive correlation between changes in BSQ score from week 12 to follow-up and weight loss maintenance failed to reach significance (r=0.31, n=34, p=0.08). This suggested that greater reduction in BSQ scores from week 12 to 12 month follow-up tended to be associated with greater weight loss maintenance.

#### (a) Changes in physiological and psychological variables from baseline (week -1) to week 12 and body weight at 12 month follow-up

There were no significant correlations between changes in any variables from baseline to week 12 and body weight at 12 month follow-up (largest r=0.22, df=34, p=0.21).

#### 3.24.7 Changes in physiological and psychological variables from baseline (week -1) to week 12 and weight loss maintenance (weight change from V5 to 12 month follow-up)

There were no significant correlations between changes in any variables from baseline (week -1) to week 12 and weight change from V5 to 12 month follow-up (largest r=-0.24, df=34, p=0.17).

# 3.25Psychosocial measures assessed only at 12 month follow up

Psychosocial measures assessed only at 12 month follow-up included depression, anxiety, stress, intuitive eating, stressful life events, diet satisfaction and beliefs about causes of obesity.

#### 3.25.1 Relationship between psychosocial measures assessed at 12 month follow-up and body weight at 12 month follow-up

Depression and intuitive eating assessed at 12 month follow-up were significantly associated with body weight at 12 month follow-up (r=0.4,df=34, p<0.05 and r=-0.4,df=34, p<0.05). The best model (AIC=75.34,  $\Delta$ AIC=1.85) included depression and body weight at week 12 and explained 94% of the variance (F(2,31)=250, p<0.001, Adjusted R<sup>2</sup>=0.94). Body weight at week 12 and depression at 12 month follow-up were significant predictors of body weight at 12 month follow-up ( $\beta$ = 1.1, t=20.37, p<0.001 and  $\beta$ =0.34, t=5.11, p<0.001 respectively), indicating that women who were heavier at week 12 and had higher depression scores at 12 months follow-up, had higher body weight at 12 month follow-up.

#### 3.25.2 Relationship between psychosocial measures assessed at 12 month follow-up and weight loss maintenance (weight change from V5 to 12 month follow-up)

Lower depression, anxiety, stress, stressful life events, intuitive eating and ascribing medical reasons as beliefs about causes of obesity were significantly associated with weight change from week 12 to 12 months follow-up (smallest r=-0.34, n=34, p=0.05). The best model (AIC=72.01,  $\Delta$ AIC=0.75) included

depression and beliefs of causes of obesity (medical reasons) in the model and explained 57% of the variance (F(2,31)=20.48, p<0.001, Adjusted R=0.54). Depression and attributing medical causes for obesity at 12 month follow up predicted weight loss maintenance ( $\beta$ = -0.34, t=-5.42, p<0.001 and  $\beta$ =2.06, t=2.6, p<0.05 respectively). Higher depression at 12 month follow-up was associated with weight regain at 12 month follow-up. Having more beliefs that obesity is due to medical causes was associated with better weight loss maintenance.

3.26 Successful vs unsuccessful weight loss maintenance

The sample was split into successful and unsuccessful groups based on whether participants regained their lost weight during the maintenance period (from the end of the intervention until follow-up) (n=22) and whether they maintained their weight/kept losing (n=12). Those in the unsuccessful group regained an average of 3.83 (SE=0.77) kg and those in the successful group lost an additional 1.79 (SE=0.46) kg during the maintenance period. There were no significant differences between successful and unsuccessful participants with respect to age, body weight at screening and habitual fibre intake (smallest t=1.67, df=32, p=0.10). There were also no significant differences between successful and unsuccessful participants with respect to baseline (week -1) physiological and psychosocial variables (smallest t=-1.48, df=32, p=0.15). Several independent ttests were conducted to test whether there were any differences in psychological variables (depression, anxiety, stress, intuitive eating, diet satisfaction, stressful life events and beliefs about causes of obesity) between successful and unsuccessful participants. There were no significant differences between successful and unsuccessful participants in terms of depression, anxiety, stress, intuitive eating, diet-satisfaction and beliefs of obesity due to psychological, behavioural or social causes. There was a significant difference between successful and unsuccessful participants in stressful life events scores (t=2.03, df=32, p=0.05). Those in the unsuccessful group significantly experienced more stressful life events (M=193.64, SE=23.59) during the maintenance period than those in the successful group (M=132.67, SE=64.03). There was a significant difference between successful and unsuccessful participants in beliefs of obesity due to medical reasons (t=-2.51, df=32, p<0.05). Those in the successful group had significantly more beliefs (M=2.5, SE=0.58) that causes of obesity were due to medical reasons than those in the unsuccessful group (M=1.98, SE=0.57).

A logistic regression was performed to ascertain the effects of depression, stressful life events and beliefs of causes of obesity (medical reasons) on the likelihood that participants were successful in maintaining their weight lost from the end of the intervention till 12 month follow-up (or not). The logistic regression model was statistically significant,  $\chi^2$  (3) = 9.7, p<0.05. The model explained 34.0% (Nagelkerke R<sup>2</sup>) of the variance in being successful in weight loss maintenance and correctly classified 71.0% of cases. More beliefs of causes of obesity due to medical reasons were associated with an increased likelihood of being in the successful group (Exp (B)=5.84, 95%CI:1.07-31.72). In other words, the odds of participants being successful and having beliefs of causes of obesity due to medical reasons were 5.84 times higher than those who did not have these beliefs.

# 3.26.1 Summary of predictors of weight loss maintenance (12 month follow-up)

- Only body weight at baseline (week-1) was significantly positively associated with body weight at 12 month follow-up. There were no significant correlations between baseline psychological variables and body weight at 12 month follow-up
- There were no significant correlations between any baseline physiological or psychological variables and weight change from V5 (week 12) to 12 month follow-up
- Body weight at week 12 predicted body weight at 12 follow-up, accounting for 89% of the variance in body weight at follow-up; higher body weight at week 12 predicted higher body weight at 12 month follow-up
- Body weight at week 12 was a significant predictor of weight loss maintenance, such that a higher body weight at week 12 was associated with less weight loss maintenance
- Greater reduction in BSQ scores from week 12 to 12 month follow-up tended to be associated with greater weight loss maintenance although the correlation between changes in BSQ score from week 12 to 12 month follow-up and weight loss maintenance failed to reach significance
- There were no significant correlations between changes in any physiological and psychological variables from baseline to week 12 and body weight at 12 month follow-up

- There were no significant correlations between changes in any variables from baseline (week -1) to week 12 and weight change from V5 to 12 month follow-up
- Body weight at week 12 and depression (DASS-21) assessed at 12 month follow-up predicted body weight at 12 month follow-up; women who were heavier at baseline and had higher depression scores at 12 month followup, had higher body weight at 12 month follow-up
- Depression and beliefs of causes of obesity due to medical reasons at 12 month follow up predicted weight loss maintenance. Higher depression at 12 month follow-up was associated with weight regain at 12 month followup. Having more beliefs that obesity is due to medical causes was associated with more weight loss maintenance.
- There were no significant differences between successful and unsuccessful participants in terms of DASS anxiety, DASS stress, IES intuitive eating, D-SAT diet-satisfaction scores and beliefs that causes of obesity are due to psychological, behavioural or social causes
- There was a significant difference between successful and unsuccessful participants in stressful life events scores (SRRS). Those in the unsuccessful group experienced significantly more stressful events during the maintenance period than those in the successful group
- There was a significant difference between successful and unsuccessful participants in beliefs about obesity due to medical reasons. Those in the successful group had significantly more beliefs that causes of obesity were due to medical reasons than those in the unsuccessful group
- The odds of participants being successful and having beliefs of causes of obesity due to medical reasons were 5.84 times higher than those who did not have these beliefs

#### 3.27 Discussion

# 3.27.1 Summary of the main findings from the two 12-week dietary interventions

This study was a randomised controlled trial which was designed to compare the effects of two 12-week dietary interventions on body weight, body composition, physiological markers of health and psychological wellbeing in female overweight low fibre consumers. Participants were randomly assigned to either a healthy eating diet (Diet A) or to a healthy eating diet with additional advice to increase fibre intake up to the recommended level of 25g/day (Diet B). The primary outcome variable was body weight change during the 12-week dietary intervention. It was hypothesized that adding fibre to a healthy diet (Diet B) would lead to greater weight loss than following a healthy eating diet alone (Diet A). It was further hypothesized that significant weight loss would be associated with improvements in other physiological markers of health and also psychological wellbeing, body shape perception and eating behaviour characteristics. These effects were also hypothesized to be greater for participants following the high fibre/healthy eating diet (Diet B).

The results of the study show that it is possible to achieve the dietary recommendations for fibre intake (within 3-4 weeks) by following a relatively simple fibre points-based system. Furthermore, this increase in fibre intake in combination with a general healthy eating diet led to a significant reduction in body weight at 12 weeks. However, following a healthy eating diet without extra advice to increase fibre intake also promoted similar weight loss. This modest but significant weight loss, irrespective of diet group, was associated with significant improvements in body composition parameters (decreased fat mass and fat percent, increased lean mass) assessed by ADP and a significant reduction in fasting leptin levels. Additionally, weight loss in both diet groups was associated with improved body shape perception and significant improvements in eating behaviour assessed by the TFEQ and/or DEBQ (namely, increased dietary restraint and decreased disinhibition, emotional and external eating).

The effects of the dietary interventions on subjective feelings of wellbeing (physiological and psychological symptoms) were also examined. Results showed that overall, regardless of week of the intervention, those on Diet B felt

less fat, and reported less bowel pain and less indigestion than those on Diet A. Those on Diet B felt slimmer than those on Diet A after 4-5 weeks of the intervention. Both diets, regardless of week, resulted in improvements in all wellbeing symptoms as the 12 week intervention progressed.

# 3.27.2 Summary of results for weight loss maintenance phase (1 and 12 month follow-up)

Weight lost during the intervention was regained in 35% of participants who attended the 1 month follow up visit (17/49) and in around 50% of the sample (16/34) who attended the 12 month follow-up. Results from 1 month follow-up showed that the amount of body weight regained in each diet group during the maintenance period (from week 12 to 1 month follow-up) varied across individuals. The average weight regained during the maintenance phase was minimal for both diets. Around 33% (16/49) of participants who attended the one month follow-up maintained their weight loss. Changes in habitual fibre intake observed during the intervention were maintained at 1 month follow-up for Diet B. Body shape perception scores significantly reduced in both diet groups over the intervention and then slightly increased from week 12 to 1 month follow-up (although not significantly), but remained lower than initial baseline scores. Dietary restraint (TFEQ) at week 12 and 1 month follow-up was significantly higher for those following Diet A than those following Diet B.

Participants who attended the 12 month follow-up visit (n=34), lost a small amount of weight during the intervention, which was regained at follow-up on a group level but not for all participants (i.e. some continued to lose weight, some maintained weight loss and some regained part but not all of the lost weight). Weight loss maintenance across diet groups and between participants varied considerably. Furthermore, those who had followed the healthy eating/fibre diet (Diet B) significantly increased their fibre intake over the 12 week intervention, but changes were not maintained at 12 month follow-up. Body shape perception scores significantly reduced in both diet groups during the intervention and although they slightly increased during the maintenance period, they were significantly lower at follow-up than baseline. Baseline TFEQ and DEBQ scores (all subscales) predicted subsequent scores at week 12 and at follow-up. When participants were divided into those who were successful at weight loss maintenance, there were no significant differences between successful and unsuccessful participants in terms of anxiety, stress, intuitive eating and dietsatisfaction scores. In addition those in the unsuccessful group experienced significantly more stressful events during the maintenance period than those in the successful group. Based on Holmes and Rahe's (1997) guidelines, stressful life events scores for those in the successful group indicated a low amount of stress and low susceptibility to stress related disorders. On the contrary, scores of those in the unsuccessful group implied moderate levels of stress and a 50% chance of major health breakdown in the next 2 years.

#### 3.28 Effects of dietary interventions on wellbeing

The present study showed that both dietary interventions promoted significant improvements in subjective wellbeing, but those who followed Diet B based on increasing cereal fibre (i.e. wheat bran fibre) experienced larger reductions in feeling fat, bowel pain and indigestion. It was also found that complying with Diet B for more than one month had a greater impact on feeling slim. This was the first study to our knowledge, to examine the effects of fibre consumption on various daily physiological and psychological symptoms of wellbeing, using a robust statistical method (OLS) which accounts for daily changes over the 12 weeks.

A number of reviews suggest that consumption of breakfast cereal is associated with wellbeing in terms of better physical and mental health and cognitive function in adults (Williams et al., 2014; Dye and Blundell, 2002; Dye et al., 2000) and children (Hoyland et al., 2008; Bellisle et al., 2004). Smith et al. (2010) conducted a study to examine the association between breakfast cereal intake and subjective wellbeing using online surveys. They found that lower stress, anxiety, depression and mental health problems were greater in those who consumed breakfast cereal on most days or every day.

Digestive disorders, such as bowel dysfunction and constipation are health problems which impact on wellbeing and can be related to fibre intake (Schmier et al., 2015; Smith, 2005). Aller et al. (2004) investigated the effects of dietary fibre on symptoms of irritable bowel syndrome (IBS). Participants were randomly assigned to either a low fibre (10.4 g/d: 1.97g soluble and 8.13g insoluble fibre) or high fibre diet (30.5 g/d: 4.11g soluble and 25.08g insoluble fibre). Body weight, nutritional intake and symptoms were assessed at baseline and 3 months later.

Participants completed a symptom questionnaire to rate symptoms of abdominal pain, bowel frequency, nausea, vomiting, flatulence and bloating. Although neither group reached the desired daily fibre intake, the high fibre group reached a total fibre intake of 26g/d which was the same with the present study. Both groups reported an improvement in symptoms of pain, bowel function and overall wellbeing at 3 months (Aller et al., 2004). It is possible that consumption of high fibre cereals does have an impact on wellbeing by reducing digestive problems. It is also likely that as weight is lost, feelings of wellbeing are amplified and increased feelings of wellbeing may subsequently lead to greater adherence with the intervention (Slavin et al., 2005: Slavin et al., 2013). However, further prospective controlled studies are needed to confirm these findings. Future research could also examine whether the effects observed here can be demonstrated with different types of fibres.

#### 3.29 Summary of predictors of weight loss and weight loss maintenance: physiological and psychological predictors

#### 3.29.1 Weight loss phase

Various psychosocial factors have been shown to predict weight loss. These were discussed in detail in the systematic review presented in Chapter 2. The present study showed that age, baseline (week-1) body weight and baseline plasma leptin concentrations predicted weight loss. Lower body shape perception at baseline predicted greater weight loss for those on Diet B and greater reductions in disinhibition predicted greater weight loss during the intervention for those on Diet A. Also, younger participants lost consistently more weight than older participants.

#### 3.29.2 Weight loss maintenance phase

Age, baseline body weight and baseline leptin predicted body weight at 1 month follow-up. Higher baseline leptin was associated with higher body weight at 1 month follow-up for those on Diet B. This is consistent with the lipostatic hypothesis of leptin (Kennedy et al., 1953). Leptin is a fat-derived hormone that signals satiety, and is decreased in women with low body mass index and high in obes (Lawson et al., 2012). Lower baseline triglycerides tended to predict lower body weight at 1 month follow-up (Rosenbaum & Leibel, 2014). Higher fasting

insulin at the end of the intervention predicted higher body weight at 1 month follow-up and this was more evident for those on Diet A. Higher emotional eating at week 12 of the intervention was associated with higher body weight at 1 month follow-up. Higher body weight at week 12 predicted more weight regain. Changes in DEBQ emotional eating and body shape perception (from the end of the intervention till 1 month follow-up) predicted body weight at 1 month follow-up. Greater reduction in BSQ score during the month from the end of the intervention until 1 month follow up was associated with higher body weight at 1 month followup. Greater reductions in body shape perception predicted lower body weight at 1 month follow-up. Also greater reductions in body shape perception and TFEQ disinhibition from week 12 to 1 month follow-up were associated with greater weight loss maintenance.

Baseline body weight was significantly associated with body weight at 12 month follow-up. Lower body weight at week 12 predicted body weight at 12 month follow-up and weight loss maintenance, such that a higher body weight at week 12 was associated with less weight loss maintenance (12 month follow-up). No other physiological or psychological factors predicted 12 month weight loss. Depression assessed at 12 month follow-up predicted 12 month body weight and weight loss maintenance, such that higher depression at 12 month follow-up predicted higher body weight at week 12 and greater weight regain. Also having more beliefs that causes of obesity are due to medical reasons (e.g. genes, hormones) were associated with more weight loss maintenance. The systematic review presented in Chapter 2 found that beliefs about causes of obesity were significant predictors of weight loss (Wamsteker et al., 2005). No studies were found that tested its predictive value in the long-term. Those who were more successful in weight loss maintenance at 12 months experienced significantly less stressful life events during the last 12 months and had significantly more beliefs that causes of obesity were due to medical reasons. More beliefs about causes of obesity due to medical reasons were associated with an increased likelihood of being in the successful group.

# 3.30 Effects of age on weight loss and/or weight loss maintenance

Age was a significant predictor of weight loss indicating that younger participants lost more weight than older ones. This finding is consistent with previous findings by Valera- Mora et al. (2005) who also found that age of obese patients undergoing malabsorptive bariatric surgery was an independent negative predictor of weight loss. LaRose et al. (2013) aimed to compare young (18-35 yrs) and older (36-50 yrs) adults in the National Weight Control Registry on motivation for weight loss, strategies for weight loss, diet, physical activity and the TFEQ. They found that young adults were able to achieve significant weight loss comparable with older adults but maintained their weight loss for a shorter time than older adults. In addition, the motivations and strategies used by the two groups differed. Young adults appeared more interested in appearance, social factors, and physical activity and less interested in their health status and using commercial weight management programmes. These differences in age should be taken into consideration in future efforts to develop weight loss interventions targeting obese and/or overweight individuals.

# 3.31 Effects of initial body weight on weight loss and/or weight loss maintenance

Initial weight was a strong predictor of weight loss and weight loss maintenance. Baseline body weight was significantly associated with body weight at the end of the intervention and 12 month body weight such as higher baseline body weight predicted higher body weight at the end of the intervention and higher baseline body weight predicted less weight loss maintenance. Teixeira et al. (2005) in their review of psychosocial predictors of weight loss and/or weight loss maintenance found mixed evidence regarding the predictive power of initial weight. Sixteen studies in the review mentioned initial weight as a predictor of weight loss and/or weight loss maintenance with some studies showing a positive association, some studies showing negative associations and some no associations at all. There was a tendency for studies to show either no association or for subjects who were initially heavier to be less successful (Teixeira et al., 2005). Teixeira et al. (2005) argued that higher baseline BMI may be associated with more absolute weight loss, but only in samples including obese individuals with a mean BMI > 35 kg/m<sup>2</sup>.

It is possible that a threshold of initial weight may be necessary in order that initial weight is a significant predictor of results.

# 3.32 Effects of biomarkers on weight loss and/or weight loss maintenance

Leptin resistance is involved in the genesis of obesity (Reinehr, Kleber, de Sousa and Andler, 2009). The finding that baseline fasting leptin concentrations were significantly negatively correlated with the degree of weight loss in a dietary intervention supports the hypothesis of leptin resistance in obesity. In addition to psychosocial factors, (discussed in detail in Chapter 2) that affect weight loss success, other physiological factors such as ghrelin or insulin sensitivity have been examined as potential predictors of weight loss maintenance with mixed results (Strohacker, McCaffery, MacLean and Wing, 2013). Other hormonal predictors such as cholecystokinin (CCK), peptide YY, insulin, pancreatic polypeptide (PP), and glucagon-like peptide 1 (GLP-1) have also been linked with weight loss (Sumithran et al., 2011). Ghrelin, peptide YY, GLP-1, CCK, PP and amylin are released from the gastrointestinal tract and pancreas in response to nutrient intake (Sumithran et al., 2011). All, but ghrelin which stimulates hunger, inhibit food intake. Sumithran et al. (2011) found that weight loss was associated with reductions in PYY, amylin, and CCK and increases in ghrelin, and PP after a 10 very low calorie dietary intervention including exercise advice. Polsky et al. (2013) examined biological predictors of weight loss success in obese individuals enrolled in a 16 week cognitive-behavioural control weight management programme that provided individualized goals for diet and physical activity. Biological predictors included concentrations of 12 different hormones and cytokines (i.e. leptin, insulin, ghrelin, gastric inhibitory polypeptide (GIP), cpeptide, pancreatic polypeptide (PP), and peptide YY (PYY)). None of the biomarkers tested were significant predictors of weight loss success. Differences in these studies might be explained by the fact that Sumithran et al (2011) used a very-low calorie diet compared to the one by Polsky et al. (2013). Very lowcalorie diets may upregulate secretion of hunger signals and downregulate satiety signals as the energy deficit is more extreme than that of a low-calorie diet (Polsky et al., 2013).

Leptin is a hormone involved with the regulation of appetite, energy intake and basal metabolic rate, which may also affect weight loss. Ramel et al. (2010) found that baseline plasma serum leptin concentrations predicted weight loss in overweight men after an eight week of a dietary intervention, but not in overweight women. Di Stefano et al. (2000) studied prepubertal and pubertal obese children and found that high baseline leptin levels were related to greater weight reductions after a long-term, education-based weight reduction program. On the contrary, Sartorio et al. (2003) showed that a high baseline leptin concentration negatively affected weight loss in severely obese patients after a 3-week weight management programme. Shih et al. (2006) examined the effects of an 8-week integrated, hospital-based body weight reduction (BWR) regimen on plasma leptin concentration in obese men and women. This study also indicated that individuals with low initial plasma leptin concentrations achieved substantial weight loss, which is consistent with the present findings. There is a complicated relationship between obesity, leptin concentration, and activity of antioxidative enzymes (such as glutathione peroxidase (GSH-Px),1 superoxide dismutase (SOD), catalase) and this should be examined in future studies (Shih et al., 2006).

Fasting insulin was also found to predict body weight, such that higher fasting insulin at the end of the intervention predicted higher body weight at one month follow-up. Kong et al. (2013) examined biological predictors of weight loss and weight loss maintenance following a 12 week dietary intervention in obese individuals. They found that higher plasma insulin was associated with less weight loss and rapid regain during the 6 week stabilization period. However, measures of insulin to predict weight loss outcomes has proved controversial in different populations (Kong et al., 2013). Studies in similarly overweight or obese populations, baseline fasting plasma insulin was not shown to predict weight loss induced by energy restriction in healthy obese women (McLaughlin et al., 1999) or weight maintenance (Marquez-Quinones et al., 2010).

# 3.33 Effects of eating behaviour characteristics on weight loss and/or weight loss maintenance

Eating behaviour characteristics have also been examined as potential predictors of weight loss and maintenance. Previous studies have reported that an increase in dietary restraint and decrease in disinhibition is related to body weight loss and to better weight maintenance over time (Drapeau et al., 2003). The present findings are consistent with previous studies. Changes in eating behaviour over time were observed in this study. It was found that TFEQ disinhibition and hunger decreased in both groups over time, while dietary restraint increased. DEBQ restraint also increased over time in both groups while emotional and external eating decreased. A study by Womble et al. (2001) found that participants who had high levels of emotional eating at baseline and who reduced emotional eating during treatment were more successful at reaching the desired body weight than those who continued to have high levels of emotional eating. Also, a review by Bryant et al. (2007) indicated that disinhibition was associated with a higher body mass index and less healthy food choices, which can also lead to poor physiological and psychological health. These findings are consistent with the present findings, which showed that reduced disinhibition predicted weight loss.

Several previous short-term studies have shown that variables such as cognitive restraint, emotional and disinhibited eating closely relate to weight changes (Teixeira et al., 2010). The authors randomly assigned overweight women to either a control (general health education based on preventive nutrition, stress management and self-care) or 1 year intervention group (30 behavioural treatment sessions) and assessed body weight and eating behaviour at 12 months and weight maintenance at 24 months. They found significant decreases in disinhibition scores in both groups and these reductions were consistently predictive of improved weight loss at 12 and 24 months (Teixeira et al., 2010). Changes in TFEQ restraint and disinhibition during the intervention were maintained at one month follow-up, irrespective of diet group. TFEQ restraint at week 12 and one month follow-up was higher for those following diet A than those following diet B. In the present study, TFEQ hunger reduced in both diet groups during the intervention phase, but tended to increase at 1 month follow-up. Studies have shown that maintenance of weight loss is associated with high restraint scores and low disinhibition and hunger scores (McCrory et al., 2002), which might also explain the present findings. Beneficial changes in emotional eating, external eating and DEBQ restraint were also maintained at 1 month follow-up.

The results of the present study were consistent with the findings from the systematic review (Chapter 2) and previous reviews of eating behaviour as potential predictors of weight loss and/or weight loss maintenance (Elfthag and Rossner, 2005). Greater reduction in TFEQ disinhibition predicted greater weight loss and weight loss maintenance. It was also found that higher DEBQ emotional eating predicted greater body weight at 1 month follow-up. Higher disinhibition predicted weight loss in six studies included in the systematic review in Chapter 2 (Batra et al., 2013; Fogelholm et al., 1999). Overall, evidence suggests that low disinhibition is related to weight loss and weight loss maintenance, which is consistent with the present findings. Lower emotional eating (eating to regulate mood and in response to emotional stress or avoidance of unpleasant thoughts) predicted weight loss in five studies included in the review in Chapter 2 (Gripeteg et al., 2010, Teixeira et al., 2010, Leon et al., 1984, Stotland et al., 2005, Canetti et al., 2009). However, Teixeira et al. (2005) found little or no evidence between weight changes and eating behaviour characteristics. Although eating behaviour appears to be a potential predictor of weight loss and weight loss maintenance, the evidence is mixed. More studies investigating the predictive power of eating behaviours in the long term are also needed.

Although short-term intervention studies show a positive influence of increased restraint on weight loss, large-scale cross-sectional and prospective studies present less consistent findings with some reporting no association between restraint and BMI and others reporting the opposite, including reports of no association (McGuire et al., 2001) and positive associations between restraint and BMI (Bellisle et al., 2004). More common are prospective studies showing that baseline restraint scores predict BMI increases even after several years. This suggests that the relationship may change over time, positive in the short term but not necessarily in the long term (Teixeira et al., 2010). The role of cognitive restraint for successful eating regulation and weight control has been the subject of much debate. Dietary restraint is not a homogenous construct and Westenhoefer (1991) suggested that dieters should be categorised on the basis of levels of rigid and flexible control (Westenhoefer et al., 1994). Rigid and flexible control assess different sets of restraint behaviours, some of which may promote overeating and others which may not (Westenhoefer, 1991; Westenhoefer et al., 2091; Westenhoefer

al.,1999; Ogden, 1993). Studies have indicated that rigid dieting behaviours, but not flexible ones are associated with eating disorder symptoms, concerns with body shape and a higher BMI in non-obese women (Stewart et al., 2002). Studies have shown that dietary restraint is negatively correlated with disinhibition suggesting that the combination of high dietary restraint and low disinhibition might be a better predictor of weight loss and/or weight loss maintenance than each of these factors alone (Vogels et al., 2005). Studies have suggested that sub-factors within the scales of disinhibition (internal and external disinhibition) and dietary restraint (flexible and rigid control) scales might also be better predictors of weight loss and/or weight maintenance than the total scales scores (Elfthag & Rossner, 2005). Studies have also shown that flexible control is a better predictor of successful long term weight loss than rigid control (Teixeria et al., 2010). Future studies should also aim to examine these sub-factors of dietary restraint.

# 3.34 Effects of body shape perception on weight loss and/or weight loss maintenance

Results showed that changes in body shape perception (assessed using the BSQ) during the intervention predicted weight loss. Also changes in body shape perception predicted body weight at the 12 month follow-up. Body shape perception was identified as a significant predictor of weight loss and/or weight loss maintenance in 7 out of 15 studies, which were included in the systematic review and had assessed body image as a predictor. Mixed evidence was found in Teixiera's systematic review (2005) regarding the predictive power of body image. This could be due to the great heterogeneity of measures used to assess this construct and its multifactorial nature. Weight loss intervention studies indicate that overweight individuals may experience improved body image satisfaction following a range of intervention therapies (Dalle Grave et al., 2007). However, other studies have reported that changes in weight and body image coincide and influence each other during the course of lifestyle interventions (Palmeira et al., 2009). Improvement in body image may act as a motivator for healthy behaviours and lead to better adherence with weight loss interventions (Lattimore et al., 2010).

Studies have shown that women with high body dissatisfaction scores are less likely to lose weight (Teixeira et al. 2004; 2010) but this was not the case in the present study as both diet groups lost a similar amount of weight and improved their body shape perceptions. However, this improvement in body shape perception was greater for those on Diet A, who also started from a worse point than those on Diet B. Studies have reported a negative association between body image and mood, psychological impairment and lack of self-confidence following previous failed attempts to lose weight and change body shape (Cooper and Fairburn, 2001). However, other psychosocial factors such as cultural attitudes and social influences about the ideal body shape and weight are also responsible for individual differences (Mumford and Choudry, 2000).

## 3.35 Effects of depression on weight loss and/or weight loss maintenance

Depression is common in obese individuals and is known to affect adherence to treatment recommendations. However, many studies including the present study exclude participants with clinical depression or other psychopathologies, suggesting that this variable might not be an appropriate measure to predict weight loss, due to heterogeneity of samples and lack of variance in participants scores (Teixeira et al., 2005, Stubbs et al., 2011). Depression was assessed at 12 month follow-up and it significantly predicted 12 month body weight and weight loss maintenance. Depression was assessed as a predictor of weight loss and weight loss maintenance in 22 studies reported in the systematic review (Chapter 2) and only six studies found evidence that depression predicted weight loss. None of the studies included found that depression predicted weight loss maintenance. Depression was mainly assessed with the BDI and other measures and none of the studies included in the review used the DASS questionnaire used in the present study. Teixeira et al. (2005) argued that the BDI does not adequately identify subjects with low likelihood of success for weight management and Somerset et al. (2011) suggested the DASS score to be a more informative and useful measure. Blaine et al. (2008) in a meta-analysis found that weight loss treatments resulted in reductions in depression scores and this was independent of changes in weight that occurred as a result of treatment. They argued that depression is causally prior to weight change, but nevertheless improves with psychotherapeutic attention in the context of weight loss treatment. It is likely that depression causes weight gain, perhaps through more binge eating and/or less activity.

Depression and stress are strongly correlated and they tend to limit health behaviours that promote weight loss (Trief et al., 2014). Researchers might screen participants for depression and stress to identify those less likely to succeed and consider referral to behavioural treatment and develop innovative tailored interventions to address these issues, i.e. to reduce depression and teach coping strategies for dealing with stressful life events.

### 3.36 Stressful life events as potential predictors of weight loss and/or weight loss maintenance

Stress has been shown to be a contributing factor in weight change and risk for obesity (Proper et al., 2013). Stress may contribute to changes in dietary behaviours that lead to weight change, with various effects related to gender (Wardle et al., 2000), baseline BMI (Kivimaki et al., 2006), or cortisol reactivity in response to stress (Newman, O'Connor and Conner, 2007). These factors may cause some people to gain more weight under stressful circumstances, while others may gain less weight or even lose weight when stressed (Block et al., 2009). The stimulus based-approach is one theoretical approach which links stress to life events and treats stress as synonymous with life events by the definition "life events are stress that require adaptation efforts" (Holmes and Rahe, 1967, p 217). The central proposition of this model is that too many life changes in a relatively short period of time increase one's vulnerability to illness (Schwarzer & Schulz, 2003).

The evidence that stressful life events and their severity contribute to changes in body weight is scarce. Some studies showed associations between life events and body weight in adults (Ogden, Stavrinaki and Stubbs, 2009), whereas others found no relationship between stressful life events and BMI among African American women (StrickInad, Giger, Nelson and Davis, 2007). Differences in results across studies might be explained by assessment of different life events, or a single life event and different study populations. Considering the results found in the present study, it may be that stressful life events resulted in unhealthier eating or lower levels of physical activity, which resulted in weight gain for those in the unsuccessful group.

Additional research is needed to examine the relationship that may exist between stressful life events and weight change. Life events may positively and/or negatively influence an individual's commitment to a weight management programme (Cox et al., 2011). Hence, researchers must design programmes that incorporate ways to deal with stressful life events, thus providing individuals with the skills required to be successful in implementing and maintaining the desired behaviour change.

### 3.37 Effect of beliefs about causes of obesity on weight management

Successful weight loss maintenance was associated with holding more beliefs that obesity is due to medical reasons (i.e. genetics, glands/hormones and slow metabolism). Personal beliefs about the causes of obesity might be barriers to the prevention and treatment of obesity (Jiménez-Cruz et al.,2012). It has been suggested that the readiness to make behavioural changes is preceded by knowledge about the causes and consequences of a disease (Hurley et al., 2010), which indicates the importance of exploring and examining the beliefs about the causes of obesity held by populations with high prevalence of obesity. This highlights the need for public health campaigns to target people's beliefs just as much as they target their behaviours (McFerran and Mukhopadhyay, 2013).

Individuals' dietary and exercise choices are influenced by the beliefs they hold (Burnette, 2010), and the stigma of obesity is based on the belief that individuals are largely responsible for their weight (McFerran and Mukhopadhyay, 2013). It may be that those who were more successful in maintaining their weight felt less responsible for their weight problem and by attributing it to medical reasons (factors over which the individual has limited control), experienced less weight stigma and engaged in more healthy strategies to maintain their weight. Believing it to be medically significant may also have provided a further motivation to lose weight. Weight stigmatization was associated with greater caloric intake, higher programme attrition, lower energy expenditure, less exercise, and less weight loss in overweight and obese adults who completed a behavioural weight loss

programme (Carels et al., 2009). Studies have consistently demonstrated that experiencing weight stigma increases the likelihood of engaging in unhealthy eating behaviours and lower levels of physical activity, both of which exacerbate obesity and weight gain (Puhl, Chelsea and Heuer, 2010). Weight-based stigmatization has also been associated with more frequent binge eating and eating disorder symptoms (Friedman, Ashmore and Applegate, 2008). Research has found that psychological distress may mediate the association between stigma and binge eating, where experiences of stigma increase susceptibility to poor psychological functioning, which in turn increases risk of binge eating behaviours (Ashmore et al., 2008). Future studies are needed to explore the effects of beliefs about causes of obesity on weight loss and/or weight loss maintenance and to identify how the knowledge about causes and consequences of obesity is related to behavioural and attitudinal changes that might promote better weight management.

### 3.38 Effects of the dietary interventions on body weight and possible reasons for similar weight loss

The similar weight loss seen in both diet groups could be explained by the fact that both groups altered their diets to a healthier eating pattern, which was enough to affect weight loss in the medium term. There are a number of possible explanations for the finding that both groups lost a similar amount of body weight. These relate to the nature of the dietary changes which were prescribed, the provision of breakfast cereals and promotion of breakfast consumption and healthy cereal-based snacks (to promote substitution of unhealthy snacks with healthier alternatives), compliance, dietary and psychological support during the intervention and the impact of the diet on psychological wellbeing and eating behaviour characteristics which may have reinforced compliance through positive feedback mechanisms.

### 3.39 Promotion of breakfast consumption and the effects of breakfast consumption on body weight

Previous studies have demonstrated the beneficial effects of consuming breakfast on body weight and other health related problems (de la Hunty and

Ashwell, 2007). People who skip breakfast tend to be heavier than those who consume breakfast on a regular basis (de la Hunty and Ashwell, 2007). Research has shown that people who eat breakfast cereals have a significantly lower BMI than those who do not eat breakfast or who consume a non-cereal breakfast after adjusting for other physical and cultural factors (Cho et al., 2003). Although the majority of participants perceived themselves as regular breakfast consumers, and indicated this on the recruitment questionnaire, feedback from the dietary advice sessions provided at the start of the study suggested that for many participants this behaviour was not consistent or regular and many of the participants did not regularly consume breakfast foods such as toast, yoghurt and fruit. The positive impact on body weight seen in both groups could be explained in part by the fact that both groups altered their diets and incorporated regular daily consumption of a cereal breakfast into their lifestyle, which was enough to affect weight loss over the course of the study.

# 3.40 Incidental effects of taking part in a dietary intervention

Participants in both diet groups received dietetic and social support from the Leeds Women's Wellbeing (LWW) study team and especially from the dietitian who was in regular contact with them. Williams et al. (1996) reported that the perceived type of support from an intervention team predicted motivation for weight loss in patients following a very low fat weight loss diet. Motivation is a function of both individual differences and support received from a social context (Williams et al., 1996). People who decided to participate in the present study were most likely to be highly motivated to lose weight, dissatisfied with their present physical appearance (as indicated by their high BSQ scores) and consequently, were in state of psychological readiness to act.

People are often motivated to view themselves in a favourable way and may use impression management strategies to portray a desired image of themselves to significant others (Vartanian, Herman and Polivy, 2007). Studies have shown that impression management tactics increase when motivation is heightened (Vartanian et al., 2007), which might also explain the present findings.

Participants were recruited to a healthy eating intervention which could promote weight loss. This might have increased participants' desire to impress and behave in a particular way (e.g. eating less of certain foods) so as to project a desired impression to others, particularly the researchers. An alternative recruitment strategy which did not refer to healthy eating or possible weight loss would have been deceptive, and likely to affect recruitment, compliance and retention of participants.

The psychological support provided by the research team may have further reinforced participants' motivation. It is likely that the regular contact with the study team and the individual counselling sessions with the dietitian helped participants to adhere to the diets. This is further supported from the feedback received at the end of the study (via the debriefing questionnaire) when participants were asked to report aspects of the study they particularly enjoyed. Some of these quotes included: "I think I enjoyed the overall experience, chatting with staff (getting goodies, finding out about research)" "coming and chatting with people", "talking with the dietitian".

Most of the participants who took part in the study, irrespective of diet group, reported in the end of study debriefing questionnaire that they were planning to carry on with the healthy eating diet and (participants on Diet B only) continue consuming high fibre cereals after the study was completed. This was consistent with the fact that fibre intake was maintained at one month, but not at 12 months follow-up which might also account for the greater weight regain at 12 month follow-up. Approximately half of the women who took part in the follow-up study felt that they needed more support to help them lose weight and maintain their weight loss. Some women stated that they thought using the internet would aid women in their struggle to lose weight. Previous research has indicated that webbased programmes may be effective for reducing fat intake and consequently assisting in weight loss and weight loss maintenance (Brug et al, 2003; Tate et al, 2001; Williamson et al, 2005).

It is likely that if psychological support and contact with the dietitian was available during the weight loss maintenance phase, participants might have felt better in dealing with stressful life events and depression and consequently feeling more capable in maintaining their dietary changes. However, contrary to the findings that prolonged periods of intervention are needed in order to further improve weight loss maintenance (Fjedoe et al., 2011), evidence is mixed with some people regaining weight despite following a supervised maintenance period, including prolonged support by the research team (Williamson et al., 2010; Jakubowitz et al., 2012).

Participants were also asked to complete the food diary records every 4 weeks and WDBs every day. The WDBs required them to rate different physical and psychological feelings on a daily basis and to write down anything they wished to share with the research team. This may have acted as a cathartic experience. Other studies have reported the positive effects of emotional disclosure such as writing and talking about emotions and the association of such activities with better heath (Francis and Pennebaker, 1992; Pennebaker and Francis, 1996). Participants were asked to record their feelings and complete wellbeing diaries throughout the intervention which may have also played a role in their improved psychological profiles.

A systematic review of effective interventions to promote physical activity and healthy eating (Michie et al., 2009) found that interventions which combined selfmonitoring with one of the five behaviour techniques described in control theory (Carver and Scheier, 1998) were most effective. According to control theory, setting goals, monitoring behaviour, receiving feedback and reviewing relevant goals in the light of feedback are important to self-management and behavioural control (Abraham and Michie, 2008). Food diaries engage people in selfmonitoring and participants in the present study were exposed to some of these behavioural techniques. Some participants' quotes taken from end of study debriefing questionnaires, when they were asked to describe their experience of completing the WDBs further support this: "I felt that it made me reflect upon my health and be more aware of myself"; "Okay for first few month, bit of a pain near the end but I do think it makes me more controlled- so plan to continue". This is another explanation of why those who followed the healthy eating diet were also successful in achieving a similar weight change to those who followed the high fibre/healthy eating diet. Future interventions should aim to prescribe diets with

and without behavioural techniques to test whether the diet alone or a combined diet-behaviour approach is most effective. This could provide additional information to design the most effective public health interventions.

# 3.41 Why weight loss maintenance is so difficult to achieve?

Long-term weight loss maintenance is a difficult task. Most individuals who start with good intentions and commit to change their behaviour fail to sustain these changes (Bouton, 2015). There is considerable variation in how individuals lose and maintain weight, which may come at the expense of excessive exercise, dietary restraint, and/or mental health concerns/preoccupation with weight. The human body naturally resists weight loss and promotes weight gain over time, which could be attributed to strong psychobiological factors involved with homeostatic regulation of body weight and appetite, and in turn could be exacerbated by repeated weight cycling (Ferraro, Patterson, & Chaput, 2015). Additionally, weight cycling may promote weight gain over time and increase the risk of adipose-related comorbidities.

Graham et al. (2014) evaluated the effects of behaviour change on weight-loss trajectories over a 10 year follow-up in NWCR participants and found that the majority maintained lost weight at 5 and 10 years. Greater weight regain was associated with decreased physical activity, less dietary restraint, lower frequency of self-weighing, increased energy intake from fat and disinhibited eating (Graham et al., 2014). Other factors associated with weight regain include negative life events and family dysfunction, higher levels of depression and negative emotions, physiological cravings, impulsiveness and binge eating, infrequent physical activity, eating unconsciously in response to emotions and low use of available social support (Stubbs and Lavin, 2013). Although long-term weight control is possible, it requires meticulous attention and sustained behaviour changes. Monitoring dietary intake, understanding caloric literacy and energy balance, regular contact with a dietitian, higher protein intake, and tracking progress in lifestyle-based weight management programmes appear to have the most beneficial effects on weight control (Wadden, 2014; Aller et al., 2014; Hartmann-Boyce et al., 2014).

Behaviour change techniques can be used to enhance participants' motivation and adherence to regular physical activity and healthy diet, rather than only focusing on weight changes. Dombrowski et al. (2012) found that programmes using the behaviour change techniques of providing instructions, self-monitoring, relapse prevention and prompting participant to rehearse/repeat behaviour were associated with greater weight loss. However, Hartmann-Boyce et al. (2014)'s review did not find any evidence of any significant associations between behaviour change techniques and weight change. Differences in these reviews may be explained by differences in inclusion criteria of studies and by the fact that Dombrowski et al. (2012) used an earlier behaviour taxonomy than the one used by Hartmann-Boyce et al., (2014). Overall, weight maintenance can be an unstable and unsteady process with frequent lapses and relapse, which are context dependent (Bouton, 2015) and entails constant commitment and access to appropriate clinical care.

#### 3.42 Limitations of the present study

Although the external validity of a free living study is high, there are some methodological problems that limit internal validity. For example, errors in data collection and missing data are higher with free living studies than with tightly controlled laboratory studies (Blundell et al., 2010). Specific limitations of the present study are discussed below.

**3.43 Problems assessing habitual food and nutrient intake** Measurements of habitual food intake relying on food diary records are problematic, as people tend to underreport energy intake and misreport macronutrient intake. This tendency is also observed more in overweight and obese people (Livingstone and Black, 2003). People tend to underestimate their energy intake or probably change their diet habits while they are completing food diaries (Goris and Westerterp, 1999). People become more conscious of what they are eating when they have to record it. It could also be that people taking part in a dietary intervention start changing their diets (i.e. under eat or alter food choices) before they actually start the intervention because they are aware they are about to take part in a study (i.e. a reactive effect) (de Castro, 2000). Therefore, underreporting may include denial of consumption and underreporting of both the number of occasions and the quantity per occasion (de Castro, 2000; Livingstone and Black, 2003). Evidence also suggests differences in the reporting of different food types and portions (Livingstone and Black, 2003). Cultural, behavioural and psychological factors may also moderate dietary reporting behaviour (Livingstone and Black 2003). Attitudes towards food and weight are different amongst different cultures and this may also account for reporting differences in food intake (Livingstone and Black 2003).

One of the limitations of the present study was the use of the DINE (Roe et al., 1994) to screen out participants with a habitual fibre intake less than 15 grams per day. Although the DINE is a validated questionnaire, it was first published in 1994 and hence it may not adequately reflect foods consumed currently and frequently in the UK. Moreover, it classifies respondents into three rather crude categories - low, medium and high and its discriminant validity for UK samples has not been confirmed. Although 7-day food diaries would have been more appropriate to identify people with a low fibre intake, there are limitations with the use of these for this purpose as discussed above and they require considerable time and expertise to be analysed fully. The need to screen many people in order to identify those with a low fibre intake (see figure 3.2-2), necessitated the development of a more accurate but quick and easy fibre screening tool. The LWW-DINE was, therefore designed to better estimate fibre intake. The LWW-DINE correlated strongly with the 7 day food diary and the DINE suggesting that it is a promising tool for future nutritional intervention studies. However, further studies are needed to confirm its reliability and validity.

# 3.44 Problems encountered when assessing predictors of weight loss and weight loss maintenance

Identifying reliable predictors of weight loss and weight loss maintenance is still an important subject, since this information could provide a guide for weight management so that interventions could be targeted to those most likely to succeed and tailored to those participating in a weight loss programme. Beliard et al. (1992) using individual interview and questionnaires, matched participants to one of three treatment modalities (individual counselling, group therapy, or a combined approach) and found that 65% achieved moderate to high success after 30–70 weeks. However, only a few studies have been designed and conducted under this context and not all have found that matching participants to treatments is a successful strategy (Burke et al., 2008, Renjilian et al., 2001). However, given the fact that psychosocial and behavioural predictors are dimensional, the idea of matching individuals to treatments in a categorical way might not be appropriate.

Another problem encountered when investigating predictors of weight loss and/or weight loss maintenance is statistical power. Although, an appropriate a priori power analysis was conducted to calculate number of participants needed to detect a significant weight loss during the 12 week intervention, the weight loss observed was moderate, less than anticipated and similar in both diets. Analysis of predictors of weight loss maintenance may have suffered from a lack of a power due to the small sample sizes during the 1 month and 12 month follow-up.

Attrition rate is another obstacle to detecting predictors of weight loss and alternative strategies need to be employed in order to account for high attrition rates such as early monitoring and gain feedback from participants to detect potential drop outs. Attrition can be influenced by initial weight loss, but attendance can also affect weight loss (Stubbs et al., 2011). It is likely that those who lose weight early in a weight loss intervention are more motivated to continue with behavioural changes than those who are less successful.

#### 3.45 Generalisability of the results

Participants in the present study were ostensibly healthy, overweight and obese British women and so the results cannot be generalised to individuals with health problems. Future studies should also examine the effects of gender and target more vulnerable individuals such as those with diabetes, hypercholesterolemia and from different cultures.

Additionally, the intervention provided monetary incentive based on completion of the programme which may indirectly influence efficacy by shifting motivation from intrinsic to extrinsic (Davis, 2012). This could bias the results and it also limits the generalizability of any findings to other settings.

#### 3.46 Methodological strengths of the present study

One of the strengths of the present study is the randomised controlled design and the medium term (12-week) nature of the intervention. The long term (12 month follow up) was also another strength of the study. This is the first randomised controlled trial comparing the effects of a healthy eating diet with those of a combined high fibre and healthy eating diet under free living conditions. A related strength is the comparison of the high fibre/ healthy eating diet with a healthy eating diet representing another treatment rather than simply a no intervention or waiting list control. Both dietary interventions utilised ad-libitum healthy eating (rather than very low calorie restrictive diets or fad diets) and thus are ecologically valid and likely to be more achievable and sustainable in the longer term than more extreme or unusual dietary manipulations. The sustainability of both diets was evident from the data collected at the one month follow-up visit where increased fibre intake was maintained and weight maintenance was evident in around 50% of participants. However, these changes in fibre intake were not maintained at 12 month follow-up and weight maintenance at 12 follow-up was only achieved by 35% of the sample (12/34). This could be explained by the fact that the psychological support available during the study by the dietitian and the research team was discontinued and its termination affected 12 month follow-up outcomes, but not the 1 month follow-up data since this was the interval of contact during the intervention (monthly meetings). Research has shown that longer treatment times are important as they allow for continued support and provide patients with a greater opportunity to practice the behaviours necessary for long term weight management success (Jiandani et al., 2016).

Another strength of the present study was the use of rigorous statistical approaches to ensure a detailed analytical exploration of the data. For example ordinal logistic regression was used to test whether being on Diet A or Diet B predicted greater or lower wellbeing symptoms. Instead of using average scores, individual daily scores were used in the analysis, the error term is constant and normally distributed. However, the errors are neither normally distributed nor

constant across the entire data (Peng, Manz and Keck, 2001). Logistic regression solves the problem of error terms not being constant and normally distributed by applying the logit transformation. Logistic regression is a more complicated method than linear regression models, as it is not easy or straightforward to interpret the coefficients and test for the goodness of fit of the model. In linear regression, the coefficient of determination  $(R^2)$  is used to evaluate the goodness of fit of models, but it is not the gold standard, since it is insensitive to additive and proportional differences between model simulations and observations (Harmel and Smith, 2007). Regression modelling using R and using the AIC criterion and the weighted AIC was used in the present study to identify the best fitting model amongst competing models (Wagenmakers and Farrell, 2004). AIC is a popular method of comparing multiple models, taking both descriptive accuracy and parsimony into account and has rarely been used in the social sciences (Wagenmakers and Farrell, 2004). The AIC has been used as a measure of model adequacy in structural equation modelling (Jöreskog & Sörbom, 1996), time series analysis (McQuarrie& Tsai, 1998), factor analysis (Akaike, 1987), regression (Burnham & Anderson, 2002) and latent class analysis (Eid & Langeheine, 1999). Future studies are needed to incorporate advanced and appropriate statistical analysis to better understand the interrelatedness of psychosocial factors.

### 3.47 Implications of the study and recommendations for future studies

The findings of this study support the protective role of dietary fibre in maintaining a healthy body weight and body composition. The beneficial effects of both intervention diets can be partly explained by the fact that they were both based on the same BHF healthy eating guidelines designed to prevent obesity and overweight. However, further long term intervention studies are needed in order to validate and extend the present findings. The study presented in this chapter showed that adding high fibre cereals to a healthy eating diet can help people reach the recommended daily fibre intake (25g/d) which has been linked with beneficial effects on various physiological and psychological factors (Anderson et al., 2009; Slavin, 2005; Smith, 2005; Howarth et al., 2001). Following a healthy diet can also help people increase their fibre intake, which can lead to improvements in physical and psychological wellbeing. Increasing breakfast cereal consumption and consumption of healthy snacks whilst following a healthy diet may therefore help to control weight while improving fasting insulin and other physiological and psychological factors. Ability to adhere to a diet over time may be influenced by the way the diet affects hunger and metabolism (Ludwig et al., 2010). Additional research is required to investigate the mechanisms by which dietary fibre affects hunger and satiety and whether such effects can translate into body weight changes and how these can be maintained in the long term.

In a real life context, as in a weight loss programme, individual physiological and psychological factors, often genetically influenced, interact with social and environmental factors, giving a multitude of individual responses to both the magnitude and rate of weight changes. There is no evidence in the research literature of a single variable strongly predicting weight loss and/or weight loss maintenance. It is rather many different variables that account for a small amount of the variance in weight loss and/or weight loss maintenance (Teixeira et al., 2005; Stubbs et al., 2011).

#### 3.48 Overall Conclusions of weight loss success

This study has shown that fibre intake can be increased to meet the current dietary recommendations (to achieve intake of 25g/day) using a relatively simple points-based system. However, the results suggest that this level of fibre consumption can be difficult to be maintained without dietetic and nutritional support in the long term. The medium term (12 week) healthy eating diets with (Diet B) or without advice to increase daily fibre intake (Diet A) promoted modest but significant body weight changes. Longer term dietary interventions with larger sample sizes and longer periods of follow-up are now needed to fully explore the effects of high fibre foods and healthy diet interventions on physiological and psychological wellbeing in overweight women and to extend these findings to other groups.

# 3.49Towards an understanding of putting the person back into weight loss and weight loss maintenance

Taken together, the results show that this modest amount of weight loss was associated with both physiological and psychological benefits such as

improvements in body composition parameters (physiological factors), body shape perception (affective factor) and eating behaviour characteristics (behavioural factors). This study also expanded previous research by identifying pretreatment factors and psychological factors targeted by the intervention as independent predictors of weight loss and/or weight loss maintenance. Age, baseline body weight and fasting leptin concentrations were significant predictors of weight loss and weight loss maintenance. In addition, both affective and behavioural factors were associated with weight loss and weight loss maintenance. Behavioural factors including lower disinhibition and emotional eating and affective factors including lower body shape perception i.e. higher body image satisfaction predicted weight loss consistent with previous literature. Depression and stressful life events (affective factors) were also associated with poorer weight loss maintenance (12 month follow-up). Our findings offer important insights into which modifiable and non-modifiable pretreatment characteristics and which affective and behavioural factors were associated with successful weight loss and/or weight loss maintenance. Health care providers should be aware of these personal characteristics that may hinder or enhance success with weight loss and consider strategies that will improve individual skills to maximize sustainable weight outcomes. The findings may also help researchers in community settings to streamline and prioritize the number and type of measures used as they translate these results to real world practice settings. Future research is needed to examine whether taking action on the basis of these results is effective in improving weight loss and weight loss maintenance outcomes. The following chapter (Chapter 4) aimed to examine affective, cognitive, behavioural and motivational factors which could predict weight loss in a real world setting with individuals who have previously attempted to lose weight using a wide range of weight loss methods.

### Chapter 4 - An internet survey of the psychological and behavioural characteristics, and weight loss strategies of successful weight losers

#### 4.1 Overview

The previous chapter (Chapter 3) presented the effects of a 12 week dietary intervention on weight loss and weight loss maintenance. It also allowed for exploration of different physiological, affective and behavioural factors associated with weight loss maintenance. In addition, both affective and behavioral factors were associated with weight loss and weight loss maintenance. Behavioural factors including lower disinhibition and emotional eating and affective factors including lower body shape perception i.e. higher body image satisfaction predicted weight loss consistent with previous literature. Depression and stressful life events (affective factors) were also associated with poorer weight loss maintenance (12 month follow-up). The present chapter will examine affective, cognitive, behavioural and motivational factors addressed in a real world setting with individuals who have previously attempted to lose weight using a wide range of weight loss methods.

#### 4.2 Introduction

The previous study (presented in Chapter 3) presented the effects of a dietary intervention on promoting weight loss and weight loss maintenance. This study offered the platform to examine physiological and psychological predictors of weight loss and weight loss maintenance. An important finding was a great intra and inter variability in weight loss and weight loss maintenance, suggesting that different psychological, physiological and/or behavioural characteristics differentiate between those who are more or less successful in weight loss and/or weight loss maintenance. Online survey methodology offers a useful medium in reaching large samples and obtaining data in a time and cost-effective way. With the tremendous increase in internet use and computer-based communication, researchers find the internet as a fruitful area of recruiting individuals who would be difficult to reach through other channels (Wright, 2005). Therefore the present study aimed to expand on findings from previous chapter (Chapter 3) and

examine psychological and behavioural characteristics of individuals who have tried to lose weight using different weight management methods.

Current diet interventions are not very effective over the long term with most people who follow weight loss programme regaining all of their lost weight within five years (Lang & Froelicher, 2006). Franz et al. (2007), in a meta-analysis of clinical trials of different weight loss interventions, found that although interventions had a positive impact in the short term (6 months), subsequent weight regain ranged from 30 to 70% of the original loss. In the National Weight Control Registry (NCWR) study, Wing and Phelan (2005) suggested that engaging in high levels of physical activity, eating a diet that is low in calories and fat, consuming breakfast, engaging in regular weight self-monitoring, keeping a consistent eating pattern and paying attention to small weight regain, before this develops into a large relapse, are key factors to achieve long term weight maintenance. People who maintained weight loss for 2 or more years were less likely to relapse, which indicates that weight maintenance might become easier over time (Gage, 2012). Gage (2012) highlighted the importance of addressing small increases in weight at an early stage before this develops to large relapse, since regains greater than 2.3kg led to complete relapse in 89% of cases.

Until recently, only simple forms of quantitative (statistical) analyses have been conducted to identify the behaviours and strategies most commonly reported for successful weight loss maintenance and to compare defined groups of participants (e.g., comparing those who lost weight on their own with those utilizing different programmes). Ogden et al. (2012) used multivariate latent class cluster analysis to identify unique clusters of individuals within the NWCR study who had distinct experiences, strategies, and attitudes with respect to weight loss and weight loss maintenance. Variables entered into the cluster analysis included weight and health history, weight control behaviours and strategies, effort and satisfaction with maintaining weight, psychological and demographic characteristics (Ogden et al., 2012). Four clusters were identified ("typical", "struggling", "immediate and long-term success" and "less physically active"), providing evidence for the idea that "one size does not fit all" (p. 2046) with respect to weight loss strategies (Ogden et al., 2012). They concluded that not all individuals are the same and different strategies are used by individuals engaging in weight loss attempts. More recently, Madigan et al. (2015) used cluster analysis to identify weight management behaviours in 8125 women who participated in the second survey of the Australian Longitudinal Study of Women's Health (ALSWH) with weight change assessed in three subsequent surveys over a period of 9 years (Madigan et al., 2015). Most women self-reported actively trying to control their weight at survey 2. However, on average the women gained weight over the next 9 years. Analysis resulted in four unique clusters: the "dieters", the "healthy living" group, the "do nothing" group and the "perpetual dieters". They concluded that the most successful strategy was to follow public health guidelines on healthy eating and physical activity.

It is possible that individuals with different psychological profiles use different strategies to achieve successful weight loss and/or weight loss maintenance. The aim of the present study was to identify psychological and behavioural characteristics in free-living individuals, who have previously attempted to lose weight using exercise, diet or other behavioural methods. Cluster analysis was chosen as a method to identify unique characteristics of successful weight losers as this method can be used to segment and identify patterns within the study population (Grafenauer, Tapsell, Beck, & Batterham, 2013). An additional aim was to assess the self-monitoring and weight loss strategies reported by participants in each cluster.

### 4.3 Methods

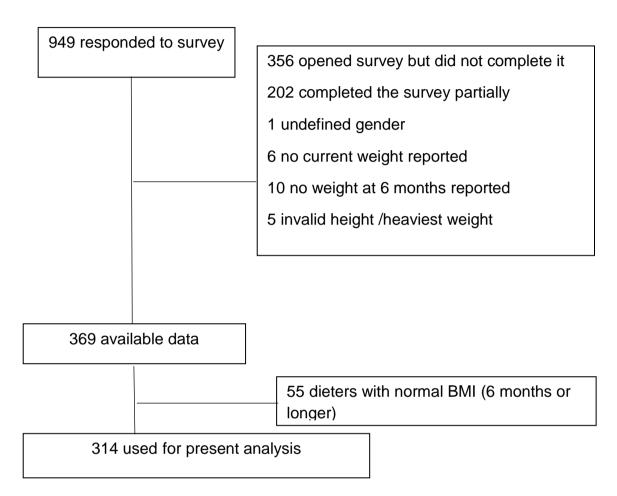
#### 4.3.1 Inclusion/exclusion criteria

Participants were included if they reported that they had tried to lose weight in the past 6 months. Participants were automatically excluded if they reported that they had not tried to lose weight in the past 6 months; if they were younger than 18 or older than 65 years old, or reported current or recent pregnancy or breastfeeding.

#### 4.3.2 Participants

A convenience sampling method, yielded 949 hits on the survey website. Of the 949 individuals who initially logged onto the survey's introductory page, 314 participants commenced the survey, answered sufficient questions for calculation of their Body Mass Index (BMI) and answered all psychosocial questionnaires.

The data of those participants whose BMI could not be calculated was considered invalid and excluded from further analysis. Also those dieters within normal BMI (for 6 months ago or longer) were also excluded. A total of 314 valid cases were included in the present study. A flow diagram of participants is shown in Figure 4.2-1. There were 232 females (73.9%) and 82 males (26.1%).



### Figure 4.3-1 Flow diagram of participants

#### 4.3.3 Measures

Participants completed an online questionnaire, which was advertised using social media (e.g. Twitter, Facebook) and posters distributed around the Leeds area. The questionnaire included sections related to demographic and weight-history characteristics, weight-loss methods and strategies and various psychological outcomes. The sections below describe the measures used to assess each of these areas:

1) Demographic and weight characteristics.

All respondents were asked to provide some standard demographic information (age, gender, education level and marital status) and details about body weight history (weight status at both 3 and 6 months previously, heaviest weight, current weight, height). Calculations were made to estimate maximum lifetime body mass index (BMI, kg/m<sup>2</sup>), current BMI, change in BMI (maximum lifetime BMI – current BMI), and change in body weight (maximum lifetime body weight – current body weight) for each subject.

2) Weight-loss outcome and weight-loss strategies.

Respondents were asked the outcome of their most recent weight-loss attempt (i.e. lost, gained or no change) and the strategies used for weight-loss. The suggested behaviours comprised strategies associated with successful weight-loss (i.e. dietary, self-regulatory, physical activity and other self-monitoring strategies).

3) Diet Satisfaction Questionnaire (D-SAT)

The D-SAT is a 45 items scale (D-SAT; Ello-Martin, Miller, & Rolls., 2004; Appendix 3.15) assessing overall satisfaction with current diet. The D-SAT consists of 7 factors measuring healthy lifestyle, convenience, cost, family dynamics, preoccupation with food and negative aspects. Participants were asked respond on a 5 point Likert-type scale from1 (disagree strongly) to 5 (agree strongly). Higher scores indicate higher diet satisfaction. Cronbach's alpha has been reported from 0.74 to 0.88.

4) Dutch Eating Behaviour Questionnaire (DEBQ)

The DEBQ (van Strien, Frijters, Bergers, & Defares, 1986) (Appendix 3.11) is a 33-item, self-assessment scale for assessing three eating behaviour domains: restraint (10 items), emotional eating (13 items) and external eating (10 items). Cronbach's alpha was reported as .85 (12) indicating high reliability.

5) Three Factor Eating Questionnaire (TFEQ)

The TFEQ (Stunkard & Messick, 1985) (Appendix 3.12) is a validated instrument incorporating measures of restraint (21 items), disinhibition (16 items), and hunger (14 items). High reliability has been reported with Cronbach's alpha ranging between .75 to .87 (Jáuregui-Lobera, García-Cruz, Carbonero-Carreño, Magallares, & Ruiz-Prieto, 2014).

6) Body Shape Questionnaire (BSQ)

The BSQ (Cooper et al., 1987) (Appendix 3.13) is a 34-item self-report questionnaire that measures concern about body weight and body shape dissatisfaction over the past four weeks. Cronbach's alpha has been reported as .95 (15) indicating high reliability.

7) Depression Anxiety and Stress Scales (DASS-21)

Respondents were asked to complete the DASS-21 (Lovibond, 1995) (Appendix 3.17) which assesses symptoms of depression, anxiety and stress using 3 scales, each with 7 items. The reliabilities of the DASS scales, as measured by Cronbach's alpha, were .90 for anxiety, .95 for depression, .93 for stress and .97 for the total scale.

8) Weight Efficacy Lifestyle Questionnaire (WEL)

The WEL (Clark et al., 1991) (Appendix 4.1) is a 20 item questionnaire used to measure the ability to control eating under specific occasions. Higher scores indicate greater confidence to resist eating. Cronbach's alpha has been found to be between 0.7-0.9 (Dutton, Martin, Rhode, & Brantley, 2004).

#### 4.4 Statistical Analysis

All questionnaire outcome variables were included in the cluster analysis via a two-step clustering procedure to allow the data to drive the clustering rather than setting a predefined number of clusters. IBM Statistics (IBM Corp. 2010) was used to analyse the data. The Log Likelihood distance was chosen and no forced solution was applied. The procedure guides the decision of how many clusters to retain from the data by calculating Akaike's Information Criterion (AIC) or Schwarz's Bayesian Criterion (BIC) measures-of-fit (Dell'Aguila & Ronchetti, 2006). Smaller values of AIC or BIC indicate better fit. AIC is well-known for overestimating the "correct" number of clusters, while BIC has a slight tendency to underestimate this number (Mooi & Sarstedt, 2011). Thus, the clustering outcomes of both criteria were checked and since both resulted in the same outcome, only the AIC solution is presented. Psychological measures e.g. restraint, emotional and external eating, anxiety depression, stress, body shape satisfaction and eating self-efficacy were included in the cluster analysis. An independent t-test was performed to determine whether the clusters differed significantly with respect to self-reported weight loss. Non parametric tests were computed in order to test whether the clusters differentiated on the basis of different self-monitoring and weight loss strategies. Chi squared tests were performed to test associations between nominal variables. If nominal variables included more than two levels, Fisher's exact test was used and Bonferroni correction was applied to adjust for multiple comparisons.

#### 4.5 Ethical Considerations

Ethical approval was obtained from the Institute of Psychological Sciences Ethics Committee (Ref: 12-0223 12-0143, Appendix 4.2). Participants remained anonymous and were told they had the right to withdraw at any time without providing reason, by closing the web page. Because the questionnaire focused on dieting behaviour, participants under the age of 18 were not included, as previous research has shown increasing the awareness of dieting can influence the desire for thinness in girls as young as six years of age (Lowes & Tiggemann, 2003). Therefore completion of the questionnaire may impact upon influencing subsequent eating habits and pressure to diet.

#### 4.6 Results

A total of 314 respondents were included in the present study. Demographic characteristics of the whole sample are displayed in Table 4.6-1. Weight status and weight history of the whole sample is shown in Table 4.6-2.

	Whole sample (N=314)
Age (%)	
18-24	120 (38.2)
25-34	118 (37.6)
35-50	51 (16.2)
51-65	25 (8)
Gender (%)	
Male	82 (26.1)
Female	232 (73.9)
Social Class (%)	· ·
high managerial	40 (12.7)
intermediate	87 (27.7)
junior	90 (28.7)
skilled manual	25 (8)
unskilled manual	14 (4.5)
student	49 (15.6)
Education (%)	, , , , , , , , , , , , , , , , , , ,
NVQ	3 (1)
GCSE	16 (5.1)
Alevel	24 (7.6)
Undergraduate	139 (44.3)
Postgraduate	89 (28.3)
None	31 (9.9)
Marital Status (%)	
married	89 (28.3)
single	122 (38.9)
widowed	1 (0.3)
divorced	10 (3.2)
living with partner	51 (16.2)
in a relationship but not living with partner	31 (9.9)
Major illness in the past 6 months (%)	21 (6.7)
Smoking in the past 6 months (%)	77 (24.5)

 Table 4.6-1 Demographic and weight history of the whole sample (N=314)

	(N=314)
Current weight (Kg)	84.52 (21.89)
Current BMI (kg/m <sup>2</sup> )	29.14 (6.43)
Weight 3 months ago (kg)	89.1 (22.91)
BMI 3 months ago (kg/m <sup>2</sup> )	30.72 (6.77)
Weight 6 months ago (kg)	91.15 (23.54)
BMI 6 months ago (kg/m <sup>2</sup> )	31.42 (6.88)
Heaviest weight (kg)	99.47 (25.08)
Heaviest BMI (kg/m <sup>2</sup> )	34.31 (7.47)
Absolute weight loss (6 months) (kg)	6.64 (8.36)
Percentage weight loss 6 months	6.88 (7.87)
Absolute weight loss since heaviest (kg)	14.95 (13.54)
Percentage weight loss since heaviest	14.43 (10.24)

Table 4.6-2 Weight status and weight history of the whole sample (N=314)

Whole sample

Variables used for the cluster analysis included all the psychological factors mentioned in Section 4.3.3. These variables drove the cluster solution, which revealed two unique clusters. The two cluster solution had the lowest BIC and provided an overall adequate fit (the silhouette measure of cohesion and separation was between 0.2 and 0.5) (Mooi and Sarstedt, 2011). The ratio of sizes was 1.17, which was considered adequate (<3) (Mooi and Sarstedt, 2011). Demographic characteristics of the participants by cluster assignment are displayed in Table 4.6-3. Weight history, current weight and BMI of participants by cluster assignment are shown in Table 4.6-4. The two clusters differed in terms of age, gender, weight history, reliance on weight-loss and weight-maintenance strategies, attitudes towards weight loss, behavioural and psychological measures.

The two clusters were labelled as "less successful" (Cluster 1) and "more successful" (Cluster 2). The justification for this labelling is the fact that although both groups were successful at weight loss (on average), one group (Cluster 2)

was more successful than the other (Cluster 1) in terms of mean absolute weight loss (8.17kg vs. 5.32kg, p<0.01, see Table 4.6-4) and mean percentage weight loss (8.8% vs. 5.22%, p<0.001, see Table 4.6-4). The fact that the clusters were not significantly different in terms of their mean heaviest weight and mean weight at 3 and 6 months (see Table 4.6-4) indicates that those participants in the more successful group were not merely more successful because they were heavier to start off with and therefore had more weight to lose. Although those in the less successful group were heavier and more obese than the more successful group (at the time of survey completion), there is no evidence to suggest that they were heavier to start off with.

Participants were also asked to report whether they lost, gained or experienced no change in body weight during their most recent weight loss attempt (see Table 4.6-4). Despite the fact that most respondents in both clusters reported having lost weight, those in Cluster 1 were more likely to have gained weight or experienced no weight change during their most recent weight loss attempt than those in Cluster 2. They were significantly more likely to have gained weight over the last 6 months (76.5 %) or experienced no change (72.5%) as compared to those in Cluster 1. A 2x3 Fisher's exact test, followed by 2x2 Fisher's exact tests to examine where the differences lie, showed that the association between weight outcome following the most recent weight loss attempt and cluster group was significant ( $\chi^2$ = 11.13, df=2, p<0.01). There was a significant difference between cluster groups in terms of weight outcome following the most recent weight loss attempt. In other words, the percentage of those losing and gaining weight between the two clusters was significantly different (p<0.05). A significantly higher percentage of participants who experienced no change in weight or gained weight (approximately 2/3 of the whole sample) were categorised into Cluster 1 (less successful) as opposed to Cluster 2 (more successful).

	Cluster 1 (N=169) Less successful	Cluster 2 (N=145) More successful	p value
Age (%)	Gubbbbblui	Gueecolai	
18-24	62.5	37.5	
25-34	48.3	51.7	
35-50	58.8	41.2	
51-65	28	72	0.01
Gender (%)			
Male	45.1	54.9	
Female	56.9	43.1	0.07
Social Class (%)			
high managerial	55	45	
intermediate	48.3	51.7	
junior	55.6	44.4	
skilled manual	52	48	
unskilled manual	57.1	42.9	
student	59.2	40.8	0.87
Education (%)			
NVQ	33.3	66.7	
GCSE	56.2	43.8	
A level	33.3	66.7	
Undergraduate	59	41	
Postgraduate	50.6	49.4	
None	54.8	45.2	0.26
Marital Status (%)			
married	46.1	53.9	
single	59.8	40.2	
widowed	0	100	
divorced	60	40	
living with partner in a relationship but not	51	49	
living with partner Major illness in the past 6 months	61.3	38.7	0.3
(%)	61.9	38.1	0.45
Smoking in the past 6 months (%)	58.4	41.6	0.34
Kev: NVG: National Vocational Qualification.	GCSE: Gene	ral Certificate	of

### Table 4.6-3 Characteristics of participants by cluster assignment (less or more successful at weight loss)

Key: NVG: National Vocational Qualification, GCSE: General Certificate of

Secondary Education; <sup>1</sup> p values are based on chi-squared tests

	Cluster 1 (N=169)	Cluster 2 (N=145)	p value <sup>1</sup>
	Less successful	More successful	
Current weight (Kg)	87.27 (23.66)	81.31 (19.21)	<0.05
Current BMI (kg/m2)	30.29 (7.15)	27.81 (5.17)	<0.01
Current BMI category (%)			
Normal weight <25	48.8	51.2	
Overweight 25-29.9	44.5	55.5	
Obese ≥ 30	67.3	32.7	<0.012
Weight 3 months ago (kg)	91.17 (24.68)	86.71 (20.51)	0.08
BMI 3 months ago (kg/m2)	31.64 (7.54)	29.66 (5.59)	<0.05
Weight 6 months ago (kg)	92.58 (25.49)	89.48 (21.01)	0.25
BMI 6 months ago (kg/m2)	32.1 (7.64)	30.63 (5.8)	0.05
Heaviest weight (kg)	101.52 (27.38)	97.08 (21.94)	0.11
Heaviest BMI (kg/m2)	35.22 (8.38)	33.26 (6.11)	<0.05
Absolute weight loss (6 months) (kg)	5.32 (8.78)	8.17 (7.58)	<0.01
Percentage weight loss 6 months	5.22 (8.01)	8.8 (7.25)	<0.001
Absolute weight loss since heaviest (kg)	14.25 (14.69)	15.77 (12.05)	0.32
Percentage weight loss since heaviest	13.33 (10.27)	15.71 (10.08)	<0.05

### Table 4.6-4 Weight history, current weight and BMI of participants by cluster assignment

Abbreviation: BMI: Body mass index; <sup>1</sup> p values are based on independent ttests except where

Abbreviation: BMI: Body mass index; <sup>1</sup> p values are based on independent t-tests except where indicated otherwise; <sup>2</sup> p values are based on chi-squared tests

#### Cluster 1: "less successful" participants (N =169; 53.8 % of participants)

The members of the first cluster can be described as "less successful" in terms of self-reported weight loss and characterised as scoring high in emotional and external eating, high in hunger and disinhibition, being highly depressed, anxious and stressed, having low eating self-efficacy low restraint and being less satisfied with their body image (Table 4.5-5). On average this cluster had an average current mean BMI of  $30.29 \pm 7.15 \text{ kg/m}^2$  reduced from their heaviest reported BMI

of  $35.22 \pm 8.38$  kg/m<sup>2</sup>. Their average BMI reported for 6 months earlier was  $32.1 \pm 7.64$  kg/m<sup>2</sup>. This cluster reported being less healthy, with a higher (although non-significant) percentage reporting a major illness over the past 6 months than Cluster 2 (Table 4.6-3).

**Cluster 2:** "more successful" participants (N =145, 46.2% of participants) This cluster included participants who were generally older and generally healthier than those in Cluster 1. This cluster also included more males than Cluster 1. Those in Cluster 2 were less heavy than those in Cluster 1 at both 3 and 6 months prior to their last weight loss attempt. This cluster had an average current BMI of  $27.81 \pm 5.17$  kg/m<sup>2</sup> reduced from a heaviest BMI of  $33.26 \pm 6.11$ kg/m<sup>2</sup>. Their average reported BMI 6 months previously was  $30.63 \pm 5.8$  kg/m<sup>2</sup>. The members of Cluster 2 can thus be described as "more successful" with respect to self-reported weight loss and characterised as scoring low in emotional and external eating, low in hunger and disinhibition, being less depressed, less anxious, and less stressed, having higher eating self-efficacy, higher restraint and greater satisfaction with their diet (see Table 4.6-5).

	Cluster 1 (N=169)	Cluster 2 (N=145)	
	Less successful	More successful p value	21
Diet Satisfaction (D-SAT)	137.05 (18.86)	167.16 (15.62) <0.00	1
Body Shape Perception (BSQ)	140.09 (39.44)	89.95 (30.64) < <i>0.00</i>	1
Dietary Restraint (TFEQ)	11.88 (4.51)	12.92 (4.34) <0.0	5
Disinhibition (TFEQ)	11.02 (2.86)	6.42 (2.63) <0.00	1
Hunger (TFEQ)	7.49 (3.51)	3.43 (2.18) <0.00	1
Depression (DASS)	15.42 (11.01)	4.57 (4.68) <0.00	1
Anxiety (DASS)	9.27 (7.8)	3.42 (3.97) <0.00	1
Stress (DASS)	15.99 (9.63)	7.35 (5.84) <0.00	1
Eating Self-efficacy (WEL)	4.96 (1.46)	6.94 (1.26) <0.00	1
External Eating (DEBQ)	3.84 (0.60)	2.96 (0.51) <0.00	1
Emotional Eating (DEBQ)	3.5(2.53)	1.89 (0.64) <0.00	1

 Table 4.6-5 Behavioural and psychological characteristics (means and standard deviations) of participants by cluster assignment

Note: <sup>1</sup>p values are based on independent t-tests

#### 4.6.1 Differences in self-monitoring and weight loss strategies

Participants in both clusters used a variety of weight loss methods and selfmonitoring strategies to lose weight. These methods and strategies and differences in self-reported uptake across Cluster 1 and Cluster 2 are presented in Table 4.6-6.

		01	
	Cluster 1	Cluster 2	р
	(N=169)	(N=145)	value <sup>1</sup>
	Less	More	
	successful	successful	
low calorie diet	56.1	43.9	0.1
weight loss method	66.7	33.3	0.13
keeping food diaries	56.7	43.3	0.09
reduced snacking	53.4	46.6	0.88
portion control	52.2	47.8	0.23
low fat diet	52.6	47.4	0.98
healthy eating	54	46	0.76
self-weighing	54.9	45.1	0.31
meal replacement	69.8	30.2	<0.05
joined gym	55.6	44.4	0.61
exercise class	52.1	47.9	0.75
weighed food eaten	58.3	41.7	0.13
walking	53.9	46.1	0.91
swimming	56	44	0.76
cycling	49	51	0.25
running	55.2	44.8	0.61
GP referred diet	80	20	<0.05
dietitian	75	25	0.29
commercial diet	71.4	28.6	<0.05

### Table 4.6-6 Weight loss methods and self-monitoring strategies used (%)by cluster group

Abbreviation: GP: general practitioner; <sup>1</sup> p values are based on chi-square tests

Those in Cluster 1 reported using a maximum of fifteen, and those in Cluster 2 fourteen, weight loss methods and/or weight loss strategies. Around 65% of the whole sample used 9 different methods/strategies to lose weight. The most popular commercial diets used were the Atkin's diet (3.9%), the ketogenic (2.5%), the South Beach (1.3%) and the paleo diet (1.2%). The most popular weight loss programmes reported were Weight Watchers (19.3%) and Slimming World (6%). There was a significant difference between those in Cluster 1 and those in Cluster 2 in terms of weight loss strategies used. Those in Cluster 1 followed more GP

referred diets, meal replacement plans and commercial diets than those in Cluster 2 (p<0.05). There were no significant differences between clusters in terms of exercise activities and self- monitoring strategies.

#### 4.7 Summary of findings

This study aimed to identify unique characteristics of successful weight losers using cluster analysis. Differences in self-monitoring, exercise and weight loss strategies were also explored. Two clusters of individuals were identified: less successful (Cluster 1) and more successful (Cluster 2). Cluster 2 reported losing more weight (8.17  $\pm$ 7.58 kg) over the previous 6 months than Cluster 1 (5.38  $\pm$  8.78 kg). More weight loss success (Cluster 2) was associated with lower emotional, external eating and lower disinhibition. Cluster 2 were significantly less depressed, anxious and stressed, had significantly higher eating self-efficacy, higher restraint and a significantly greater satisfaction with their diet than Cluster 1. In addition, Cluster 1 were significantly more likely to engage in more commercial diets, meal replacement plans and GP referred diets than those in Cluster 2.

#### 4.8 Discussion

There is a growing interest in research examining individual differences in response to weight management programmes with a view to improving weight loss and sustaining weight loss maintenance. This study used cluster analysis to explore characteristics in individuals who used a variety of different weight loss methods and/or strategies to lose weight. Two distinct clusters of participants varying in weight loss success emerged. Both clusters used a variety of strategies to manage their weight, but still struggled with their weight and this was more evident for those in Cluster 1. The proportions of those who gained weight or experienced no change during their most recent weight loss attempt were low in Cluster 2 as compared with those in Cluster 1. On average over the last 6 months, those in Cluster 2 lost significantly more weight (8.17kg) than those in Cluster 1 (5.32kg). Similarly, weight loss since being at their heaviest weight was significantly greater for those in Cluster 2 than those in Cluster 1.

Those who were more successful at weight loss were more likely to show control over their eating behaviours. Eating behaviour in relation to weight loss

interventions has been mainly investigated using the TFEQ (Stunkard and Messick, 1986), measuring dietary restraint, disinhibition and hunger. Definitions of disinhibition, dietary restraint and hunger have been previously described in Chapter 2 (Section 3.4.5). Eating behaviours have been consistently found to predict weight loss and weight loss maintenance in diet/exercise and/or behavioural interventions (Wing and Phelan, 2005; Batra et al., 2013; Delahanty et al., 2011; Teixeira et al., 2010). However, some studies failed to predict weight loss based on baseline TFEQ scores (Hainer et al., 2008). It has also been suggested that the combination of high dietary restraint and low disinhibition might be a better predictor of weight loss and/or weight loss maintenance than each of these factors alone (Vogels, Diepvens, & Westerterp-Plantenga, 2005).

Lower levels of depression, anxiety and stress were other characteristics of those most successful at weight loss. Depression has been linked with overeating and weight regain. However, many weight loss studies exclude participants with clinical depression or other psychopathologies, suggesting that this variable might not be an appropriate measure to predict weight loss, due to heterogeneity of samples and lack of variance in participants' scores (Teixeira et al., 2005; Stubbs et al., 2012). Although taking part in weight loss trials might lead to positive changes in mood, changes in depression over time might covary with weight changes and more research is needed to investigate the relationship between depression and weight loss (Teixeira et al., 2005; Stubbs et al., 2012). Anxiety is a more stable construct than depression, but it has received little attention as a weight loss predictor (Teixeira et al., 2004). Additionally, despite the conceptual distinction between depression and anxiety, clinically differentiating the two constructs has proven difficult, as anxiety and depression are commonly comorbid and people who experience anxiety are often depressed as well (Mergl et al., 2007).

Research suggests that people tend to eat in response to stressful or negative events and also eat to regulate mood (Elfhag & Rössner, 2005; Ohsiek & Williams, 2011). Elder et al. (2012) found that lower baseline stress scores as measured by the Perceived Stress Scale (PSS) predicted greater weight loss and that changes in weight during the weight loss program were linearly associated

with changes in both depression and stress. It has also been suggested that the coping strategies that people use to deal with stressful events are more important than the number of the stressors or the stressors themselves in relation to stress related weight gain/loss (Elfhag & Rössner, 2005; Stubbs et al., 2012).

Successful weight loss was associated with high eating self-efficacy. Self-efficacy is defined as the beliefs that people hold regarding whether they are capable in achieving and maintaining behavioural changes (Lazzeretti et al., 2015). The General Self-Efficacy Scale (GSES; (Schwarzer, & Jerusalem, 1995) measuring general self- efficacy, the Eating Self-Efficacy Scale (Glynn and Ruderman, 1986) and the WEL questionnaire (Clark et al., 1991) have been widely used in obesity research. Most of the studies on self-efficacy have concluded that high self-efficacy towards eating behaviours is associated with positive weight management outcomes (Delahanty et al., 2011; Bernier and Avard, 1986; Annesi and Gorjala, 2010; Lasikiewicz et al., 2014). Presnell et al. (2008) found that high levels of eating self-efficacy and depression predicted subsequent decreases in BMI for men, but not for women. Some studies argue that changes in self-efficacy may be more predictive of weight loss success than baseline self-efficacy. Martin et al. (2002) found that greater pre-treatment eating self-efficacy predicted less weight loss and that larger improvements in self-efficacy during treatment were associated with greater weight loss. Other studies have also found that increases in diet self-efficacy scores during treatment were associated with greater weight loss (Bas & Donmez, 2009; Burke et al., 2006; Warziski et al., 2008).

Those who were more successful at weight loss showed a greater satisfaction with their diet. Satisfaction with weight loss programmes is generally an understudied subject (Van Wormer & Lutze, 2010). Diet satisfaction may be associated with factors that make the adoption of new dietary behaviours easier and more successful, such as whether a diet is affordable, convenient, or acceptable to a family (Ello-Martin, et al., 2004). However, there is a lack of reliable tools assessing diet satisfaction; those available are either population or intervention-specific (Corle et al., 2001). The D-SAT has been developed to assess diet satisfaction across multiple types of interventions at different time points. The D-SAT is a promising tool in assessing factors contributing to

satisfaction with a dietary programme and to provide additional insight into reasons for drop outs in clinical trials (Ello-Martin, et al., 2004). It is likely that greater satisfaction with the diet, might have helped people to engage in any weight management intervention easier and consequently resulted in greater weight loss than others who felt less satisfied with their diet. Additionally, the D-SAT questionnaire may be used in clinical or practical settings when counselling patients on dietary approaches to identify barriers patients may have incorporating new dietary behaviours into their lifestyles.

Successful weight loss was also associated with less GP referred diets, less use of commercial diets and fewer meal replacement plans. Dombrowski et al. (2014) conducted a systematic review and meta-analysis of 42 randomised trials examining the effectiveness of different weight management interventions on 12 month weight loss. Five studies included in the review involved meal replacement plans and no evidence that adding a meal plan to a dietary intervention is more beneficial than a dietary intervention alone was found (Dombrowski, Knittle, Avenell, Araújo-Soares, & Sniehotta, 2014). Similarly, in a review of 7 RCTs of the efficacy of meal replacement plans on weight loss reported inconclusive results with four of the studies showing a major weight loss in meal replacement groups, but no significant difference in weight loss in the other four studies. On the contrary, Franz et al. (2007) in his review of weight loss interventions found that meal replacement interventions (a total of 7 studies) resulted in greater weight loss than diet-alone studies at 6 and 12 months. Noakes et al. (2005) argued that meal replacements are as effective for losing weight as conventional weight-loss diets, over different time frames but the degree of success depends on whether professional support from either a dietitian or a physician is included in the intervention (Noakes et al., 2005). Similar conflicting findings regarding the efficacy of commercial diets have been reported with few studies showing reliable evidence of success (Gudzune et al., 2015).

In the present study, there was a tendency for those who were less successful with weight loss to keep more food-diaries than those who were more successful in losing weight. Self-monitoring consists of recording dietary intake and physical activity so that individuals are aware of their current behaviours (Burke et al., 2011). Burke et al. (2011) conducted a systematic review on the effect of selfmonitoring diet, physical activity, and weight on weight loss in behavioural treatment studies. They found a significant association between self-monitoring and weight loss. Although the evidence supports the effect of self-monitoring on weight loss, one question not answered in the literature, and in the present study, relates to the intensity and/or frequency of self-monitoring required for successful outcomes. More frequent self-monitoring has been significantly associated with weight loss compared to less frequent self-monitoring (Burke et al., 2011) and the frequency of keeping food records as well as adherence over time was unknown in the present study. A recent study by Abildso et al. (2013) found that selfweighing (at least once a week but not daily) predicted 1 year weight loss. In addition, there is research suggesting that self-monitoring may promote increases in psychological distress and attrition (Dionne and Yeudall, 2005). Ideally researchers and clinicians should focus on enhancing individuals' selfmonitoring adherence and provide additional encouragement.

The strengths of the present study included the use of cluster analysis to explore characteristics of successful weight loss. Cluster analysis is a promising approach to understand obesity-management and might be a useful technique to inform the design of future interventions. Another strength of the present study was that the assessment of weight loss strategies was contiguous with weight loss reports, whereas in the study by Madigan et al. (2014) these were assessed some considerable time (9 years) before the weight loss and it remains unknown whether these strategies were maintained or changed in the intervening period. The present study confirms previous findings by Ogden et al. (2012) that individuals use different strategies to manage their weight. Nevertheless, different measures/variables were used in Ogden's (2012) cluster analysis and the present one making comparisons amongst studies difficult. The present study added more information in terms of differences in psychosocial factors between successful and unsuccessful weight losers, which were not considered in Ogden's study.

### 4.9 Limitations of the present study

The major limitation of the current study was the reliance on self-reported data. Women underestimate their weight and this is more prevalent amongst overweight and obese women (Merrill & Richardson, 2009). Under-reporting of weight may reflect psychological factors or social norms for slimness, recall bias, lack of access to weighing scales and lack of recent measurements taken at home or at clinics (Akhtar-Danesh, Dehghan, Merchant, & Rainey, 2008). For some populations, perceived weight and body size appears to contribute to under-reporting of body weight (Akhtar-Danesh et al., 2008).

Another limitation is that, although several weight loss methods and different psychological characteristics were assessed, there may be other discriminating factors that were not. Genetic, environmental or metabolic factors have been proposed to affect weight loss (Lyla & Blazer, 2006), but were not measured in the present study. Additionally, any physiological differences in response to weight loss between these clusters of individuals remain unknown. Studies have highlighted the role of different gastrointestinal hormones (e.g. peptide YY (PYY)), glucagon-like, peptide 1 (GLP-1)) on appetite and food intake (le Roux et al., 2007; (Troke, Tan, & Bloom, 2014). There is conflicting evidence that obese individuals experience satiety (Rolls et al., 1994) and satiation differently (Bell and Rolls, 2001) and compensate for energy intake less accurately than do lean individuals (Lyla & Blazer, 2006). In the present study, those who were less successful at weight loss scored significantly higher on the TFEQ hunger factor. This may indicate a greater physiological response to weight loss making it harder for them to follow their diet, for example. Also, since those who were less successful at weight loss felt hungrier in general, as reflected by TFEQ, they may have felt more depressed, anxious or stressed and less able to exercise restraint than those who were more successful, as a consequence.

One important limitation of the current study concerns generalisability of findings to other overweight and obese adult populations. While recruitment methods resulted in a relatively large sample (954 participants commenced the study), recruitment nonetheless relied on non-probability (convenience) sampling. Participants came to know about the survey through social media platforms and as part of studying at University of Leeds. For these reasons, the sample tended to over-represent well-educated people. In addition, there is a tendency for some individuals to respond to invitations to participate in online surveys and are more likely to complete them, while others ignore them, leasing to a systematic bias (Wright et al., 2005).

The abovementioned limitations are an acknowledgement that the clusters identified might differ in some ways if the research is repeated on an even larger scale. Future researchers can test the accuracy of the presented clusters by administering the same questionnaires to a larger and more representative sample.

### 4.10 Conclusions

The present study highlighted that it is possible for different people to use different strategies for successful weight loss, although some may also struggle substantially more than others in doing so (Ogden et al., 2012). For example, while most successful weight-reduced individuals seem to require very high amounts of physical activity to maintain their weight, some do not (Catenacci & Wyatt, 2007). The identification of distinct subgroups of obese individuals is a first step in better understanding how to provide tailored strategies to help with weight loss and weight loss maintenance. Future studies should examine whether characterising individuals and promoting tailored interventions, which could place them in the more successful category, results in sustainable weight loss outcomes. Moreover, future studies should aim to investigate the characteristics of these clusters using a larger sample.

In summary, obesity is recognised as a heterogeneous condition and different physiological, environmental and psychological factors might interact contributing to successful weight loss and/or weight loss maintenance. Understanding this heterogeneity is an essential step in developing different interventions for those with different psychological and behavioural characteristics. Further exploration of the differentiating features of these clusters could be useful for tailoring future weight loss and weight maintenance programmes to the specific characteristics of an individual.

### 4.11 Towards an understanding of putting the person back into weight loss and weight loss maintenance

The present chapter used cluster analysis and identified two groups of successful weight losers. Those who were more successful in their most recent weight loss attempt (Cluster 2) reported losing more weight (8.17 ±7.58 kg) over the previous 6 months than those who were less successful at losing weight Cluster 1 (5.38 ± 8.78 kg). Cluster 2 was associated with lower scores on questionnaires assessing behavioural factors (i.e. low emotional and external eating and lower disinhibition), lower scores on questionnaires assessing affective factors (i.e. less depression, anxiety, stress and higher diet satisfaction) and higher scores on questionnaires assessing motivational factors (i.e. eating efficacy) than those in Cluster 1. In addition, those in Cluster 1 were significantly more likely to engage in more commercial diets, meal replacement plans and GP referred diets than those in Cluster 2. All factors presented in the conceptual framework in Chapter 2 (section 2.28) were associated with successful weight loss in free-living individuals who had tried to lose weight using a variety of weight loss methods. Additionally, affective (i.e. depression) and behavioural factors (i.e. eating behaviour) were consistent predictors of weight loss in the present study and the LWW study presented in Chapter 3.

# Chapter 5- Factors associated with weight loss in obese and severely obese adults following an NHS weight management programme: a pilot study

### 5.1 Overview

The previous chapter (Chapter 4) explored affective, cognitive, behavioural and motivational factors which are associated with successful weight loss in free living individuals who had attempted to lose weight using a wide range of weight loss methods. Successful weight loss was associated with lower scores on questionnaires assessing behavioural factors (i.e. low emotional and external eating and lower disinhibition), lower scores on questionnaires assessing affective factors (i.e. less depression, anxiety, stress and higher diet satisfaction) and higher scores on questionnaires assessing motivational factors (i.e. eating efficacy). The present study will extend previous findings and examine personal characteristics associated with weight loss in a clinical setting, by evaluating the efficacy of a weight management programme, for obese and severely obese adults offered by the NHS.

### 5.2 Introduction

The online survey presented in Chapter 4 assisted in expanding on previous research, confirmed predictors of weight loss identified in the SRR (Chapter 2) and identified two distinct clusters of successful weight losers. The LWW study presented in chapter 3 allowed the examination of predictors of weight loss and weight loss maintenance following a dietary intervention in a carefully monitored free living setting. In all of these studies, it is apparent that although people might be successful in terms of following a weight management intervention, some clearly struggle more than others (Ogden et al., 2012). This chapter examines weight management in a further setting, namely Kirklees Adult Weight Management Service for obese and severely obese adults. A collaboration with the weight management team (Kirklees Adult Weight Management Service for adults) at Dewsbury and District Hospital (part of the Mid Yorkshire Hospitals NHS Trust) enabled the design of a pilot study to examine the efficacy of a 12 week weight management programme and explore potential predictors of weight loss in a community setting.

The National Health Service (NHS) primary care setting, is for many individuals who struggle with weight issues, the first step to non-surgical, non-pharmacological weight management treatment (Birnie et al., 2016). Currently at least 10 million UK adults are suitable for weight management interventions to reduce their risk of morbidity and mortality and many patients are identified daily through NHS initiatives for obesity, cardiovascular management and diabetes prevention (Birnie et al., 2016).

### 5.2.1 Local rates of obesity in Yorkshire and related behaviour?

Between 1994-96 and 2000-02, the prevalence of obesity in Yorkshire and the Humber increased from 17.3% to 22.4%. In 2003, the regional prevalence of male obesity was 24.6%, higher than the UK average of 22.2% and the highest across all English regions. The prevalence of obesity in females was 23.8% in the region, slightly higher than the UK average of 23.0%, and the second highest across all regions. Within Yorkshire and the Humber, only 40% of men and 26% of women engage in physical activity. This region has the fourth lowest rate of fruit and vegetable consumption in the country, with only 23% of adults and 15% of children eating five portions or more a day. Obesity in women (at 23.8%) is the second highest across all regions in the UK. By 2050, it is predicted that nearly 70% of people in Yorkshire and the Humber will be obese, compared with 60% nationally. Reducing obesity is a key public health priority for the NHS in Yorkshire and the Humber and most NHS trusts offer weight management programmes though the detail of each varies. The evaluation of the weight management programmes is vital to inform evidence-based commissioning of weight management services and bariatric surgery. Given the high prevalence of obesity and high relapse risk it is essential to identify treatments, personal characteristics, physiological and psychological predictors of weight loss and how they can be used to further improve the weight management programme outcomes. Identifying predictors of weight loss from community based programmes will enable a more informed and individualised approach to weight loss interventions with greater likelihood of long term success.

### 5.2.2 Key features of Kirklees NHS weight management service

NHS Kirklees has commissioned a weight management service for Kirklees. This service offers advice, help and support to adults living within Kirklees with a Body Mass Index (BMI) of 35 kg/m<sup>2</sup> and above who are motivated to attend a weight

management programme. The service is made up of the following three elements: (a) a single point access service, (b) community weight management programmes and (c) primary care multi-disciplinary team. The service is based on a tiered approach with tier 1 being a community weight management programme through to tier 3 being specialist treatment services. The model is underpinned by a range of universal programmes to support the general population maintain a healthy weight, those with a BMI of 35 and above to reduce weight and for clients who have accessed the weight management service who require support to maintain their weight loss.

As mentioned in Chapter 1 (section 1.11), although many NHS Hospital Trusts and NHS Primary care trusts commission weight management programmes across the UK, only a few of these have been evaluated with most of them reporting outcomes based on commercial programmes and a lack of high quality evidence (National Obesity Observatory, NOO, 2009). Evaluation is therefore important as it can produce new knowledge which can then be used to change how a programme is run and potentially lead to policy changes.

The aim of the present study was therefore to evaluate the efficacy of the 12 week weight management programme provided by the Mid Yorkshire Hospitals NHS Trust and to identify participants' characteristics and behaviours which are related to weight loss. The research aimed to understand the relationships and interactions between psychological and behavioural factors to inform best practice in the provision of advice to obese and overweight individuals in order to promote weight loss and prevent weight (re)gain.

The primary aim of the study was to evaluate the efficacy of the 12 week weight management programme provided by Mid Yorkshire Hospitals, NHS Trust, by examining the effect of the programme on body weight, since this is the key performance indicator for the Trust. Secondary aims were to examine changes in psychological and behavioural factors as a result of the weight management programme. An additional aim was to identify psychosocial factors that are related to weight loss.

### 5.3 Methods

The 12 week weight management programme provided by the Kirklees Adult WM Service is primarily designed to help people to achieve a weight loss of 5-10% of their baseline body weight. The programme combines advice on diet, physical activity and lifestyle modification. It consists of 11 group sessions, each lasting 2 hours and 1 optional one to one session for further support. After having been referred to the programme by their consultant, participants are asked to attend an initial session (session 0) where they meet the research team and different psychological measures are assessed via validated questionnaires.

### 5.3.1 Participants

### 5.3.2 Inclusion/exclusion criteria

Service users (SUs; men and women) who had been referred by their consultant to follow the 12-week weight management programme or those who had already completed the weight management programme were included in this study. SUs with a BMI over 35kg/m<sup>2</sup> and those who could understand verbal and written English were referred to the 12-week weight management programme by the consultant.

Service users who had completed the 12 week weight management programme were approached by the Chief Investigator by letter. They were provided with the Participant Information Sheet (PIS; Appendix 5.1) and asked to give consent for the research team to access their medical records and questionnaires completed during the programme for the purpose of this research. They were provided with a contact number of the CI in case they wished to discuss the research. They were provided with a stamped addressed envelope for return of the signed consent form. No data were used until consent forms were received.

### 5.3.3 Design

This study applied a one-group pretest-posttest design. The design examined changes in physiological and psychological outcomes as a result of completing the 12 week weight management programme.

### 5.3.4 Weight management programme

The weight management programme included dietary, physical activity and behavioural change components (e.g. self-monitoring) which aimed to establish behaviour changes by building participants' confidence and abilities to make changes in their diet and physical activity. The weight management programme included 12 group sessions (one session per week) and one final one to one session at the end of the intervention. Each session was run by dietitians at Oakwell Centre, Dewsbury and District Hospital or Brian Jackson House at Huddersfield. Each session lasted 2 hours. An overview of each session is detailed below:

1. Session 0: Meeting the team and Questionnaires:

During this session participants had the opportunity to meet the team, ask questions about the programme and were asked to complete validated questionnaires assessing different psychological factors.

2. Session 1: Introduction to the programme

The aim of this session was to give participants the chance to get to know each other and understand what the programme had to offer. They were given the opportunity to explore expectations and possible fears about joining the group and ask questions. They were also introduced to self-monitoring and they were given the task of keeping a food diary for a week, in order to raise awareness of current eating habits.

3. Session 2: Introduction to regular eating

In this session, the participants were taught about the benefits of regular eating patterns. The aim was to help them understand the cycle of dieting, explore barriers to regular eating and goal setting.

4. Session 3: Portion Control

During this session participants were taught about portion control and balanced eating. They were given information based on the EAT WELL plate and provided with portion control guides (see Appendix 5.2).

5. Session 4: Healthy balanced eating and SMART goals

This session aimed to support session 3 more and introduced participants to the SMART goals model. This model is based on assisting participants to set goals which are specific, measurable, attainable, relevant and time-bound.

6. Session 5: Session with Psychologist

This session was run by a psychologist who discussed models of behaviour change and psychological barriers to weight management.

7. Session 6: Physical activity

This session introduced physical activity for healthy living and weight management.

8. Session 7: One to one Support session

This session gave individuals the opportunity to discuss any issues they may have had but felt uncomfortable discussing in a group setting. The session provided 20 minutes slots for individual consultations.

9. Session 8: Triggers and Unhelpful thoughts

This session introduced participants to the triggers and unhelpful thoughts that shape behaviour. It also helped participants to identify their own triggers and techniques to manage them.

10. Session 9: Food labels

This session introduced participants to food labelling and helped to increase awareness of food content, traffic lights etc.

11. Session 10: Staying motivated after the programme

This session referred to evidence regarding weight loss and weight loss maintenance according to the National Weight Control Registry (NWCR).

12. Session 11: Final group session

This session was an open discussion session allowing people to reflect back over the past 12 weeks, on their achievements and areas that they felt they still needed to work on.

13. Session 12: Final one to one review

This was the final meeting with group members. A dietitian met participants individually for 20 minutes to provide feedback and to address any concerns.

### 5.4 Study Measures

The following measures were assessed as part of the 12 week weight management programme. These, apart from one questionnaire (Diet Readiness Scale), were also repeated at the end of the programme as part of their routine clinical care.

### 5.4.1 Anthropometric measures

Height and weight was initially measured by the consultant to enable the accurate calculation of their BMI (kg/m<sup>2</sup>). Height was measured using a free standing height measuring unit (Seca, Leicester Height Measure, Birmingham, Ltd) with participants barefoot. Body weight was measured without shoes on a calibrated electronic weighing scale to the nearest 0.1kg (MSP200P, Adam Equipment Co.Ltd) at the beginning of the programme (Session 0) and at the end of the programme (Session 12).

### 5.4.2 Eating Behaviour Assessments

The Dutch Eating Behaviour Questionnaire (DEBQ; van Strien et al., 1986) (see Appendix 3.11) and the Three Factor Eating Questionnaire (TFEQ; Stunkard and Messick, 1985) (see Appendix 3.12) described in Chapter 3, section 3.4.5 were administered to provide measures of dietary restraint and other aspects of eating behaviour.

### 5.4.3 Body Shape Questionnaire

Participants were asked to complete the Body Shape Questionnaire (BSQ-34; Cooper et al., 1987) (Appendix 3.13) which allows an assessment of any changes in body shape perception during the weight management programme (see section 3.4.6, Chapter 3).

### 5.4.4 Diet Satisfaction Questionnaire

Participants were asked to complete a diet satisfaction questionnaire (D-SAT; Ello-Martin et al., 2004; Appendix 3.15) to assess overall satisfaction with current diet (see section 4.2.3, Chapter 4).

### 5.4.5 Depression and Anxiety

Participants were asked to complete the Hospital Anxiety and Depression Scale (HADS; (Zigmond & Snaith, 1983), Appendix 5.3). The questionnaire is a 14 item self-report measure assessing anxiety (7 items) and depressive states (7 items). This questionnaire is designed especially for people with chronic diseases. It

does not include items which relate to somatic symptoms such as fatigue and trouble sleeping, which individuals with chronic diseases are likely to experience (Quittner, Modi, Lemanek, levers-Landis, & Rapoff, 2008).

### 5.4.6 Dichotomous Thinking in Eating Disorders Scale-11 (DTEDS-11)

The Dichotomous Thinking in Eating Disorders Scale (DTEDS-11; (Byrne et al., 2004), Appendix 5.4) scale is a revised self-report questionnaire of the original DTEDS (DTEDS-16; Byrne, Cooper & Fairburn, 2004) consisting of 11 items. It generates scores on an eating subscale (4 items) assessing dichotomous thinking about eating, dieting and weight and a general subscale (7 items) assessing dichotomous thinking more generally. Items are rated on a 4-point Likert scale ("not at all true of me" to "very true of me"). Higher scores indicate a greater degree of dichotomous thinking.

### 5.4.7 Diet Readiness Test (DRT)

The goals and attitudes scale (6 items) from the 23 item Diet Readiness Test (DRT; (Brownell, 1990), Appendix 5.5) was used to assess participants' readiness to start a weight loss programme. The scale measures motivation and commitment to weight loss as well as how realistic one's goals are (e.g. "Compared to previous attempts, how motivated to lose weight are you this time?"). Items are scored on a 5 point Likert scale. High scores indicate higher readiness. A total score is calculated by summing scores for each section. The Cronbach's  $\alpha$  estimate has been reported .58 for the DRT.

### 5.4.8 Weight Efficacy Lifestyle Questionnaire (WEL)

The weight efficacy lifestyle questionnaire (WEL; Clark et al., 1991; Appendix 4.2) described in Chapter 4, section 4.2.3 was administered to assess dimensions of efficacy for weight management.

### 5.4.9 Binge eating scale (BES)

The Binge Eating Scale (BES; (Gormally, Black, Daston, & Rardin, 1982), Appendix 5.6) was used to assess the presence and severity of the symptoms of binge eating; relating to feelings, cognitions and behaviours. The scale includes 16 items, each reflecting a characteristic of the binge eating trait, with a different weight attached to each response. The resulting weights are summed to give a total score; with high scores indicating more severe symptoms. The scale has high internal consistency. The Cronbach's  $\alpha$  estimate reported for the BES was .85.

### 5.5 Procedure

Participants attended the weekly group sessions described in section 5.2.4 led by the dietitians. Participants' weight was measured to enable the accurate calculation of their BMI. Participants completed the psychological measures described in section 5.3 and a service satisfaction questionnaire at the end of the 12 week weight management programme rating their overall satisfaction with the programme.

#### 5.5.1 Optional support group sessions

The optional support group sessions were run monthly in the community centres where the 12 week weight management sessions took place. These were available for each participant who had completed the 12 week weight management programme at no cost. During these sessions, external speakers were invited to give talks about various issues, which were related to weight management.

### 5.6 Statistical Analysis Plan

All data were entered, processed and checked in Excel. Statistical analysis was performed using SPSS 17.0. All data were examined for outliers and assumptions checked for each inferential analysis. Differences between pre- and postprogramme measurements were compared by paired sample *t*-tests. Independent sample *t*-tests were used to compare differences between those who scored higher in the diet readiness scale and those who scored lower. Pearson's Product Moment correlation coefficients were used to assess relationships between variables. Assumptions of multicollinearity. homoscedasticity were assessed prior to regression analysis. Multiple regression models using the enter method were employed to evaluate the best predictors of each outcome variable.

### 5.7 Ethical Considerations

Ethical approval was obtained from the NHS South Humber and Yorkshire Research Ethics Committee (Reference No: 14/YH/1128). All responses to the questionnaires and information provided by participants were anonymised. All data were recorded safely using unique identification codes. The link between participants' names and other personal data and their unique identity code were maintained and stored securely in Dewsbury and District Hospital, NHS Trust and were only accessible to the University research team. Unique identification codes were assigned upon inclusion to the study (after consent had been obtained) and stored securely in the participant enrolment log.

### 5.8 Results

### 5.8.1 Participants

A total of 98 obese and severely obese adults who had completed the 12 week intervention were approached to give consent for their data records to be used as part of the 12 week evaluation. A total of 22 participants who completed the 12 week weight management programme (13 female, 9 male; mean age= 47.96 (SE=1.87) responded and returned their consent forms. There were significant differences between males and females in terms of baseline body weight, with males being heavier than women at the start of the weight management programme (t=3.96, df=20, p<0.01). There were no differences between males and females in terms of baseline body df=22, p=0.34). Baseline body weight and BMI for both males and females and the whole sample are shown in Table 5.8-1.

	Female	Male	Total	
	(min,max)	(min,max)	(min,max)	
Age (yr)	49.4 (2.23)	48.62 (3.83)	49.1 (1.95)	
	(35.5, 70.1)	(38.2, 73.7)	(35.5, 73.7)	
Body weight (kg)	120.59 (5.47)	165.52 (11.14)	137.44 (6.94)	
	(80.7, 151)	(119.2, 208.4)	(80.7, 208.4)	
BMI (kg/m2)	47.12 (1.5)	50.04 (2.96)	48.22 (1.44)	
	(37.08, 56.91)	(39.32, 63.58)	(37.08, 63.58)	

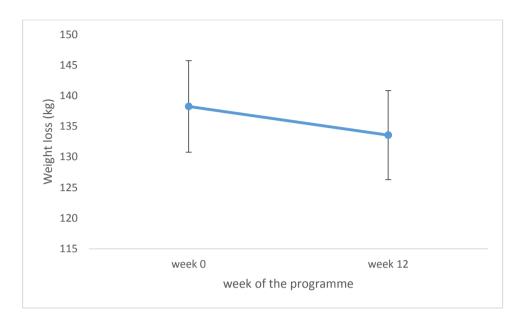
### Table 5.8-1 Participants' characteristics at baseline (N=22).

Participants completed a battery of questionnaires assessing different psychological and behavioural factors. Participants' baseline scores in these questionnaires are shown in Table 5.8-2.

### 5.8.2 Weight loss over the 12 week weight management intervention

Body weight at week 12 was significantly lower than body weight at the start of the programme (t=5.56, df=21, p<0.001). Similarly, there was a significant

difference in BMI before and after the programme (t=5.69, df=21, p<0.001). The average weight loss was 4.68kg (SE=0.84). The average BMI loss was 1.62 (SE=0.28kg/m<sup>2</sup>). Figures 5.8-1 shows mean (SE) change in body weight during the 12 week weight management programme.



### Figure 5.8-1 Means (SE) body weight before and after the 12 week weight management programme

There was great variability in the amount of weight lost with some participants losing up to 12.6 kg, one participant gaining weight (4.3kg) and two experiencing no change. Only 7 participants achieved the aim of the 12 week weight management programme and lost 5% of their initial body weight. Figure 5.8-2 shows the amount of weight lost by each participant.

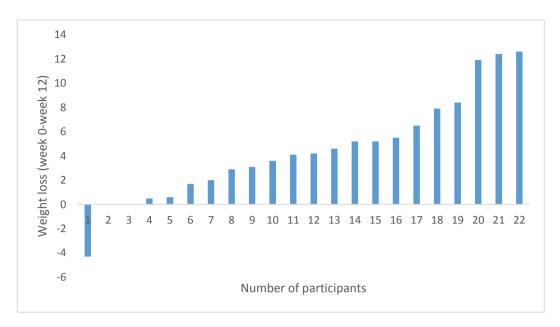


Figure 5.8-2 Mean weight loss/gain achieved during the 12 week weight management programme by each participant (N=22); positive values indicate weight loss

### 5.8.3 Differences in weight loss between participants differing in the amount of readiness to start the weight management programme

Based on participants' scores on the Diet Readiness Scale (DRS), which indicates the degree to which a person is ready to start a weight management programme, the sample was split into two groups (1= "may be close to being ready to begin a programme but should think about ways to boost their attention before they begin" and 2= "ready to begin"). An independent t-test was performed to examine if there are differences between participants who were ready to start the weight management programme (or not) and weight loss. There was a significant difference between participants who were ready (M=7.3, SE=1.25kg) and those who were not (M=2.16, SE=0.66) in the amount of weight lost (t= -3.91, df=17, p<0.01).

### 5.8.4 Changes in psychological measures over the 12 week weight management programme

Several paired t-tests were conducted to see if there are any differences in psychological measures assessed before and after the 12 week weight management programme. Table 5.8-2 shows changes in psychological measures during the 12 week weight management programme.

	Baseline (week 0)	Week 12	p value
Anxiety (HADS)	8.26 (1.13)	7.63 (1.05)	0.17
Depression (HADS)	7.32 (0.96)	6.68 (0.88)	0.25
DEBQ emotional eating	2.84 (0.26)	2.61 (0.24)	<0.05
DEBQ external eating	2.8 (0.17) 2.43 (0.17)		<0.01
BSQ score	117.32 (10.66)	104.05 (11.73)	0.15
TFEQ restraint	8.16 (0.9)	10.74 (0.8)	<0.01
TFEQ disinhibition	8.11 (0.91)	6.68 (0.74)	<0.01
TFEQ hunger	5.53 (0.93)	4.63 (0.65)	0.11
Binge eating (BES)	16.11 (2.18)	14.58 (2.09)	0.18
DTS eating	2.66 (0.19)	2.49 (0.21)	0.35
DTS general	2.61 (0.2)	2.53 (0.23)	0.44
D-SAT	144.26 (3.81)	156.63 (3.55)	<0.001
WEL	5.41 (0.47)	6.49 (0.35)	<0.001

Table 5.8-2 Psychological characteristics of participants assessed before and after the 12 week weight management programme (N=22)

There were significant differences in DEBQ emotional eating, external eating, TFEQ restraint, and disinhibition, diet satisfaction and weight efficacy. Emotional eating, external eating, and disinhibition were significantly lower at week 12 than week 0. TFEQ restraint, diet satisfaction and eating self-efficacy (WEL) significantly increased over the 12 week weight management programme.

### 5.8.5 Relationship between baseline psychological variables and body weight at week 12

There were no significant correlations between any psychological variables and body weight at the end of the 12 week weight management programme (largest r=0.33, n=21, p=0.14). Only body weight at baseline was significantly associated with body weight at week 12 (r=0.99, n=22, p<0.001).

## 5.8.6 Relationship between baseline psychological variables and weight change from baseline to week 12 of the weight management programme

There was a significant positive correlation between baseline diet satisfaction score (D-SAT) and weight loss (r=0.654, n=21, p<0.05). A multiple regression using the enter method and including baseline diet satisfaction and baseline body weight was conducted to predict weight loss. The model was significant and explained 39% of the variance in weight loss (F(2,18)= 7.4, p<0.01, Adjusted  $R^2$ =0.39). Both baseline diet satisfaction ( $\beta$ =0.6, t=3.4, p<0.01) and baseline body

weight ( $\beta$ =0.4, t=2.27, p<0.05) were significant predictors of weight loss. Higher diet satisfaction and body weight at baseline predicted greater weight loss.

### 5.8.7 Relationship between changes in psychosocial variables (week 0week 12) and body weight at week 12

There were no significant correlations found between changes in psychosocial variables and body weight at week 12 (largest r=-0.35, n=19, p=0.14).

### 5.8.8 Relationship between changes in psychosocial variables (week 0week 12) and weight change (week 0-week 12)

There was a significant correlation between changes in body shape perception and weight loss (r=0.49, n=14, p<0.05). A simple linear regression was calculated to predict weight loss from changes in body shape perception during the weight management programme. A significant regression model was found explaining 19% of the variance in weight loss (F(1,17)=5.3, p<0.05, Adjusted R<sup>2</sup>=0.19). Changes in body shape perception significantly predicted weight loss ( $\beta$ =0.49, t=2.3, p<0.05). A reduction of body shape perception during the weight management programme was associated with greater weight loss.

### 5.8.9 Summary of findings

- Body weight at week 12 was significantly lower than body weight at the start of the weight management programme
- BMI at week 12 was significantly lower than BMI at the start of the weight management programme
- There was great variability in the amount of weight lost with some participants losing up to 12.6 kg, one participant gaining weight (4.3kg) and two experiencing no change
- Only 7 out of 22 participants achieved the aim of the 12 week weight management programme and lost 5% of their initial body weight
- Those who were ready to start the weight management programme (based on their scores on the DRT) lost significantly more weight than those who were not completely ready to start
- DEBQ emotional eating, external eating and TFEQ disinhibition significantly decreased during the 12 week weight management programme
- TFEQ restraint, diet satisfaction (D-SAT) and weight efficacy (WEL) significantly increased over the 12 week weight management programme

- There were no significant correlations between any baseline psychological variables and body weight at the end of the 12 week weight management programme
- Body weight at baseline was significantly positively correlated with body weight at week 12
- There was a significant positive correlation between baseline diet satisfaction scores (D-SAT) and weight loss during the programme
- Baseline diet satisfaction was a significant predictor of weight loss, such that higher diet satisfaction predicted greater weight loss during the programme
- Baseline body weight was a significant predictor of weight loss, such that higher body weight predicted greater weight loss during the programme
- There were no significant correlations between changes in psychosocial variables during the weight management programme and body weight at week 12
- A reduction of body shape perception during the weight management programme was associated with greater weight loss

### 5.9 Discussion

### 5.9.1 Summary of main findings

The aim of the study reported in this chapter was to explore the efficacy of a 12 week weight management programme incorporating both dietary and exercise advice and behaviour modification. This study allowed the exploration of psychological characteristics related to successful weight loss in a sample of obese/severely obese patients participating in a weight management programme provided by the NHS. The 12 week weight management programme resulted in a significant weight loss. However, only 29% (n=7) of the sample achieved weight loss which amounted to 5% of initial body weight. However, there was great individual variability observed in the amount of weight loss with some people losing more weight than others, whilst others lost no weight or gained weight.

These positive changes in weight loss were mirrored by changes in psychological outcomes. Emotional and external eating assessed via the DEBQ plus disinhibition assessed via the TFEQ significantly decreased during the 12 week

weight management programme. Furthermore TFEQ restraint, diet satisfaction (D-SAT) and weight efficacy (WEL) significantly increased over the 12 week weight management programme. Additionally, there was a significant positive correlation between baseline diet satisfaction scores (D-SAT) and weight loss during the 12 week weight management programme. Finally, diet satisfaction at baseline was a significant predictor of weight loss, such that higher diet satisfaction at baseline programme. Baseline body weight was a significant predictor of weight loss during the 12 week weight management programme. Finally, the the text weight management programme. Finally, diet satisfaction at baseline predicted greater weight loss during the 12 week weight management programme. Baseline body weight was a significant predictor of weight loss, such that higher body weight predicted greater weight loss during the programme. Furthermore, an improvement in body image during the weight management programme assessed using the BSQ predicted greater weight loss.

### 5.9.2 Potential screening tests to identify those who are more motivated towards behaviour change

Accurate assessment of readiness to change is critical as it is one of the most promising factors promoting behaviour change in individuals who need to modify their lifestyle for health reasons (Ceccarini, Borrello, Pietrabissa, Manzoni, & Castelnuovo, 2015). For many patients, readiness for change differs dramatically and interventions may need to be tailored more precisely. Providers may need to use more active, behaviourally focused interventions for those who are more ready to start a weight management programme whilst implementing more cognitively focused interventions for the less prepared ones (Boudreaux et al., 2003). However, assessment of stage of change for weight-related behaviours can be time consuming in clinical practice (Wee et al., 2005).

Successful screening of individuals who are more likely to drop out and less likely to meet weight loss goals would limit their experience of any disappointment and make it possible to offer them alternative approaches (Teixeira et al., 2002). It might also be advantageous to study these individuals separately to understand better the factors that limit their weight reduction. Matching interventions to patients, saving resources, and increasing programme efficacy are potential benefits of adopting readiness/profiling approaches (Teixeira et al., 2002).

Research has also highlighted that low eating self-efficacy and poor confidence in one's ability to control eating in challenging situations can be a barrier for successful weight loss (Ames, Heckman, Diehl, Grothe, & Clark, 2015).

Readiness to change and a person's self-efficacy for a weight loss intervention has been shown in the literature to affect successful lifestyle changes and weight loss (Kong, et al, 2010; Linde et al., 2006; Warziski, Sereika, Styn, Music, & Burke, 2008). The Weight Efficacy Lifestyle Questionnaire (WEL), which measures patients' confidence in their ability to control eating behaviour and was developed as a measure for use in research and clinical practice (Ames, Heckman, Grothe, & Clark, 2012) has the potential to improve patient screening and care, was also used in the present study. However, other important instruments which are often used in the clinical practice to evaluate weightmanagement motivation in overweight or obese individuals may have been omitted such as the Treatment Self-regulation Questionnaire (TSRQ: (Levesque et al., 2007). The TSRQ examines autonomous and controlled motivation on entering a weight-loss programme and on continuing the programme participation (follow-up). This questionnaire evaluates the motivational level of people engaged in weight-management treatments, and the reasons why they enter, follow and continue weight-loss programs. It assesses the degree to which a person's motivation for their health behaviour is relatively autonomous (Levesque et al., 2007).

### 5.9.3 Lack of psychological input during the 12 week weight management programme

Psychological and behavioural issues play significant roles in both the development and consequences of obesity. The importance of addressing the psychological aspects of the treatment of obesity has become more explicit over the last two decades. The role of a psychologist in the treatment of obesity is not only important during a weight management programme, but also following completion of the programme to help people adjust to the new lifestyle changes and subsequent emotional, behavioural, and social changes that might occur (Collins & Bentz, 2009).

Most of the patients attending the 12 week weight management programme described in this chapter were severely obese, with the vast majority seeking bariatric surgery. One requirement before being referred for bariatric surgery is that they complete the 12 week weight management programme and achieve a minimum 5% weight loss. Psychological co-morbidities are prevalent and substantial among severely obese people and especially amongst those

considering bariatric surgery (National Obesity Observatory, NOO, 2011). However, the psychological input offered within NHS weight management programmes is limited. Greater psychological input is therefore required by most participants. Most of the participants in the present study stated in the service evaluation form that they felt the session with the psychologist was too short and that they felt they needed more psychological support.

Severely obese patients are often the targets of stigmatization and discrimination, not only in social situations and at work, but even in medical settings (Vallis et al., 2001). Their obesity problem is often seen as the result of a character flaw and attributed to themselves rather than to their condition (Vallis et al., 2001). This consequently leads to patients feeling misunderstood, neglected, discriminated and rejected (Kaminsky & Gadaleta, 2002). In addition, psychopathology is very common in severely obese individuals with studies suggesting that morbidly obese people seeking bariatric surgery have significantly more psychological problems, abnormal eating behaviour and impaired quality of life than the normal population (Van Hout & Van Heck, 2009), highlighting the need for additional psychological support and better screening of these individuals before commencing any weight loss treatment.

#### 5.9.4 Group versus individual treatments for weight loss

Both group and one to one sessions are available for obesity treatment. Groupbased interventions offer the promise of being more resource-effective and the opportunity for enhanced social support and are mostly used in clinical settings such as the NHS (Paul-Ebhohimhen & Avenell, 2009). However, within groups there may be fewer opportunities for attending to more specific individual needs.

Avenell et al. (2004) conducted a systematic review of RCTs examining differences between group and individually delivered weight management interventions and found no significant differences in weight loss at 12 and 18 months, but significant effects in favour of individual treatment at the 24-month follow-up (Avenell et al., 2004). However, Paul-Ebhohimhen and Avenell (2009) in a systematic review of RCTs found greater weight change at 12 months in group-based over individual-based treatment, and this increased effectiveness was associated with the use of financial reward and psychologist-led

interventions. It is likely that interventions that promote peer support are more successful that those that do not. The present study focused on a programme, which was group based and led by dieticians. It is unknown to what degree the group dynamics affected weight loss. Befort et al. (2010) showed that participants assigned to group treatment had greater weight loss than those assigned to individual treatment and reported that support, accountability and information sharing were the most helpful treatment components. Those who identify with their group have reported a greater willingness to contribute to discussion and self-exploration and have demonstrated higher attendance rates (Nackers et al., 2015). In addition, treatment preference might play an important role in outcomes and should be taken into consideration. However, there are mixed findings for the effect of patient treatment preferences on therapy outcome. Some studies report that client preference for different types of treatment improves therapy outcomes and dropout rates (Swift & Callahan, 2009) whilst others argue that matching preference with treatment has no beneficial effect over no matching. More studies are therefore needed to examine whether group based interventions and matching participants with their treatment preferences are more effective for weight loss.

### 5.9.5 Challenges encountered when evaluating weight management programmes offered within the NHS

This study highlighted some of the challenges encountered when evaluating weight management programmes. Clinicians' commitment to the service, limited funding and lack of academic infrastructure are just a few of these challenges. Services should be available to patients who need structured support to lose weight and commissioned accordingly. These services should also be monitored and evaluated to ensure that they are delivering good patient outcomes based on evidence based protocols. Service providers need to have sufficient capacity and support from local clinicians to ensure patients can be effectively identified and streamed into the weight management service.

Clinicians' extensive commitment to weight management service is difficult. This is especially true if there is no funding to support development time and no guarantee of long-term funding. This time needs to be included and costed when preparing plans to provide and evaluate a service. During the evaluation reported in this chapter, and while participants who had completed the weight

management programme were being contacted, a decision was made based on convenience and cost rather than evidence to reduce the weight management programme from a 12 week programme to a 6 week programme. Furthermore, before this evaluation was completed the service had ceased completely as no more funding for practitioner delivery time was available.

Primary care does not have the financial or academic infrastructure to subsidise the significant administrative burden of collecting a large scale of data and organising long-term follow-up to assess the true efficacy of these services (Hughes, 2015). Partnerships with academic centres and robust clinical assessment, could therefore increase the value of weight management services to the NHS. Effective management of data requires dedicated administrator time and a large continuously fed database. The cost of evaluating a weight management service is suggested to be around 10% of the budget by the National Obesity Observatory (2010) but, in practice, this is rarely reflected in the actual budget.

Increases in NHS funding came to an end after 2011 following the impact of economic recession. Analysis by the King's Fund and researchers from the Institute for Fiscal Studies (IFS) suggest increases in NHS funding in real terms, would require significant cuts in other areas or increases in taxation (Appleby, Thompson, & Galea, The Kings Fund, 2012). Funding of services is crucial in order for the maintenance and progression/development of services. Changes in government budgets are likely to affect investment potential, with funding being focussed towards interventions where evidence for costeffectiveness is the strongest (Brizell et al., 2012). However, in the case of many lifestyle behaviour change interventions, and their effects on people's health and wellbeing, change is not always instant and noticeable and may not be apparent for some time after the end of the programme, by which time funding has been withdrawn. The evaluation of health treatment interventions is therefore important so that there is an evidence based approach from which to inform policy and practice.

#### 5.9.6 Clinical implications for primary care

Although the primary-care setting provides an important medium for obesity intervention and prevention, increased effectiveness will need well-structured

interventions within large health-care systems that extend to settings where patients spend most of their time, which is mainly their homes and communities (Dietz et al., 2015). Transition from efficacy to effectiveness will require substantial and challenging changes in how primary care is delivered (Dietz et al., 2015). Practices often lack the organisational structure, such as patient registries and methods for systematic tracking to assess clinical interventions, care teams to manage patients with chronic illnesses, or health information systems that support the use of evidence-based practices at the point-of-care to provide longitudinal care for chronic illnesses (Crabtree et al., 2010). In addition to this, health professionals often lack the necessary skills to deal with obesity and are generally biased with unfounded attitudes towards patients with obesity. which also impedes care offered to patients. In the UK, the training of health professionals to prevent and treat overweight and obesity was recommended in a 2010 report presented by the Royal College of Physicians. However, reports suggested that the implementation of this training was patchy. Consequently, training of health-care providers to treat obesity needs to address their biases about patients with obesity, ability to use behaviour change strategies and ability to work collaboratively with multidisciplinary teams (Dietz et al., 2015).

#### 5.9.7 Strengths and limitations of the present study

The strengths of this study was that this was one of the first evaluations of a specialist weight management service for complex and severe obesity within a UK NHS setting including patients in a UK region with significant levels of obesity. This was only a pilot study reporting preliminary findings on the efficacy of the 12 week weight management programme in a small sample of those who took part in the programme. Hence these results should be treated with caution and may not be generalisable to other populations and other settings.

There are a number of additional limitations to this study. Firstly, this study was a non-randomised pragmatic service evaluation. The quantitative evaluation of the 12 week weight management programme undertaken was based on a one group pre-post design within which it is not possible to determine whether secular changes (something other than the programme itself) occurred between the pre-test and post-test assessments to influence the outcome (Shadish, Cook & Campbell, 2002).

In addition, long-term data were not available which would have been useful to demonstrate maintenance of weight loss following the initial 12 weeks. In addition, a more formal evaluation of the programme's aim regarding education and patient self-management is required. Further evidence is required from a randomised control study to assess the short-term and long-term clinical and cost-effectiveness of the 12 week weight management programme. Future work should explore and identify the complex patient and intervention-related factors that determine attrition rates.

It was also known that many team members ran the weight management programme on top of their existing duties and that the evaluation of such a programme requires extra time and effort, which most of the time is not possible. A common situation with health promotion interventions is that evaluation systems are set up and data collected, but the data are never analysed, so there is no ongoing feedback or learning about the project fed into and used to revise the programme.

#### 5.9.8 Future research and recommendations

More psychological measures should be incorporated into weight management programmes provided within the NHS. Also funding for additional psychological input for severely obese individuals is essential. More follow-ups and greater involvement and interest of consultants is also necessary.

The weight management programme may need additional outcome measures, as absolute weight loss may not reflect all the appropriate clinical goals, These include appropriate treatment before referral to bariatric surgery, improved diabetes control or detection of undiagnosed co-morbidities such as obstructive sleep apnoea (Jennings et al., 2014). The current classifications of obesity based on body mass index, waist circumference and other anthropometric measures, although useful, have important limitations when applied to individuals in clinical practice as they do not provide information on presence or extent of comorbidities or functional limitations that would guide decision making in an individuals' treatment (Sharma & Kushner, 2009). Sharma and Kushner (2009) proposed the Edmonson Obesity Scoring System as a new clinical and functional staging system that allows clinicians to describe the morbidity and functional limitations associated with excess weight. They argued that this system, when used in

conjunction with the present anthropometric classification, will provide a simple framework to aid decision making in clinical practice.

Evaluation and patient feedback is key to help inform and improve clinical practice and has been used to help other weight management programmes to become more patient focused (Brown & Kuk, 2015). Regular feedback is essential to gain information about content, length of session, whether the sessions met expectations and areas where improvements could be made. Feedback on performance is also important as a way of monitoring progress, plus revising and setting new goals if required. This could possibly assist in improving retention rates.

Patient educational materials should be integral to the programme to support and reinforce the topics covered (Brown et al., 2015). This was also highlighted by some participants on the service evaluation form. Participants stated that they would have liked some handouts and notes to take back home so that they could go back and see what had been discussed during the sessions. Materials given to patients after each session could help in consolidating the learning points from each session and prepare the patient for the next session's topics. These could incorporate both visual and written elements to aid learning and information retention.

#### 5.9.9 Conclusions

The current pilot study indicated that this 12 week weight management programme was effective in terms of weight loss, with 29% of participants losing 5% of their initial body weight. Weight loss was also accompanied by beneficial changes in psychological and behavioural factors during the intervention. More studies are needed to evaluate the efficacy of weight management programmes offered within NHS in the short and long term. However, this might not be easy in practice nor feasible and this could explain the few published papers reporting evaluations of weight management programmes offered by the NHS

### 5.9.10 Towards an understanding of putting the person back into weight loss and weight loss maintenance

In addition to baseline body weight, the affective component diet satisfaction was found to be a significant predictor of weight loss. In addition, improvements in affective factors such as body image during the programme predicted greater weight loss. However, the small sample studied limited the ability to identify other predictors of weight loss. Motivational factors (such as diet readiness) appeared to be useful measure in screening people prior starting a weight management programme and could be used in future interventions to identify participants that might need additional support to engage in any weight loss programme and consequently assist in minimising attrition rates. The inclusion of psychological measures during weight management programmes is essential to help clinicians identify individuals who are more likely to benefit from different types of treatment. Cumulative, across all three empirical studies, affective factors appeared to be consistently associated with weight loss across all three settings (lab-based, real-life and clinical).

### **Chapter 6 – General Discussion**

### 6.1 Overview of thesis findings

This final chapter summarises the key findings of this thesis in relation to the original aims set out in Chapter 1, which were to identify predictors of weight loss and weight loss maintenance in different settings. This thesis has presented a systematic review and three studies in order to address these aims. The systematic review presented in Chapter 2 provided an up to date review, which identified factors that are associated with weight loss and weight loss maintenance following behavioural and/or dietary (with or without exercise) weight loss interventions in overweight/obese populations. Chapter 3 aimed to identify predictors of weight loss and weight loss maintenance (1 and 12 month follow-up) following a 12 week dietary intervention in free-living individuals (LWW study). The study reported in Chapter 4 explored, via online survey methodology. the psychological and behavioural characteristics associated with successful weight loss amongst free-living individuals who had attempted to lose weight using different weight loss methods/strategies. Chapter 5 reports the results of a 12 week NHS delivered weight management programme incorporating both dietary and exercise advice. This study allowed the exploration of psychological characteristics related to successful weight loss in a sample of obese/morbidly obese patients.

Here, the strengths and limitations of this work are explored and original contributions to the field of obesity are discussed. The implications of the thesis findings, in terms of future research and real-world implications are also examined alongside methodological recommendations for future research in this area.

### 6.2 Towards an understanding of putting the person back into weight loss and weight loss maintenance

A summary of the affective, cognitive, behavioural and motivational predictors of weight loss and weight loss maintenance assessed and identified across the three studies and the systematic review is shown in Table 6.2-1.

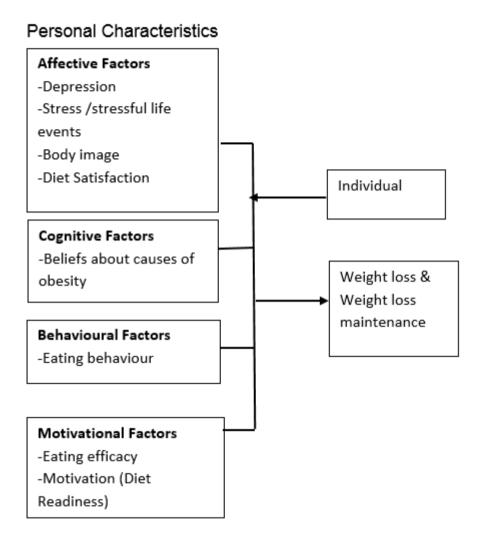
	Systematic Review	Healthy (overweight/ obese)	Free living	Clinical sample (Obese/severely obese)
Affective				
Body image (BSQ)	х	v	V	V
Binge eating (BES)	х	0	0	Х
Depression (DASS; HADS)	х	v	V	Х
Anxiety (DASS; HADS)	V	Х	V	Х
Stress (DASS)	Х	V	V	Х
Stressful life events (SRRS)	0	v	0	Х
Diet-Satisfaction (D-SAT)	0	0	V	V
Cognititive				
Beliefs about causes of obesity	V	v	0	0
Dichotomous Thinking in Eating Disorders (DTEDS-11)	V	0	0	Х
Behavioural				
Self-monitoring	V	0	Х	0
Dietary Restraint (DEBQ, TFEQ)	V	Х	V	Х
Disinhibition (TFEQ)	V	v	V	Х
Hunger (TFEQ)	V	Х	V	Х
Emotional Eating (DEBQ)	V	v	V	Х
External Eating (DEBQ)	V	Х	V	Х
Intuitive eating (IES)	0	Х	0	0
Motivational				
Diet Readines (DRT)	х	0	0	V
Eating Self-Efficacy (WEL)	V	0	V	Х
Physiological				
Age	0	v	0	0
Initial body weight	V	v	0	V
Leptin	0	v	0	0
Triglycerides	0	v	0	0
Insulin	0	V	0	0

Table 6.2-1 Summary of the evidence for candidate affective, cognitive, behavioural, motivational and physiological predictors of body weight loss assessed across the systematic review and the three studies presented in this thesis

Key:  $\sqrt{}$  indicates that the predictor was assessed and there was supporting evidence for its predictive value; o indicates that the predictor was not assessed; X indicates that the predictor was assessed but there was no evidence to suggest it may have predictive value

Abbreviations: BES: Binge Eating Scale; BSQ: Body Shape Questionnaire; DASS: Depression, Anxiety, Stress Scale; DTEDS-11: Dichotomous Thinking in Eating Disorders; D-SAT: Diet Satisfaction; DEBQ: Dutch Eating Behaviour Questionnaire; HADS: Hospital Anxiety and Depression Scale; IES: Intuitive Eating Scale; TFEQ: Three Factor Eating Questionnaire; SRRS: Social Readjustment Rating Scale; WEL: Weight Efficacy Lifestyle; WMP: Weight Management Programme

Based on the findings of this thesis the conceptual framework model presented in Chapter 2 (Section 2.28) has been refined to show the affective, cognitive, behavioural and motivational factors which emerged from the systematic review and the three empirical studies (see Figure 6.2-1).



### Figure 6.2-1 A refined conceptual model to illustrate the different personal characteristics associated with weight loss and weight loss maintenance.

Affective (depression, body image and diet satisfaction), cognitive (beliefs about causes of obesity), behavioural (eating behaviour) and motivational factors (eating self-efficacy and motivation) were consistent significant predictors of weight loss and/or weight loss maintenance across the three empirical studies. Physiological factors, although not being the primary aim of this thesis were also explored. Initial weight loss was a consistent significant predictor of weight loss and/or weight loss that need to be considered in order to put the individual

back into weight loss and weight loss maintenance and highlights that different individual characteristics will determine the degree of success in any different weight loss intervention.

### 6.3 Affective Factors

### 6.3.1 Body image

Although the systematic review found mixed evidence in terms of body image, the results from chapter 3 showed that body shape perception assessed using the BSQ predicted greater weight loss. Furthermore, changes in body shape perception from the end of the intervention to 1 month follow up predicted greater weight loss maintenance. Two studies reported in the systematic review also found that body image was a significant predictor of weight loss maintenance (Collings et al., 2008; Palmeira et al., 2010). The fact that no psychological predictors were found for weight loss maintenance (12 month follow-up) could be explained by the smaller sample at 12 month follow-up. Loss to follow up is a very common finding in many intervention studies and might explain why the evidence for predictors of weight loss maintenance is less strong than for predictors of weight loss. Additionally, during the weight loss maintenance there was a greater variability in weight outcome and less compliance with the changes implemented during the active intervention phase. An improvement in body shape perception was also associated with greater weight loss during the 12 week weight management programme, which is consistent with findings by other studies (Kiernan et al., 1998; Lynch et al., 2009; Teixeira et al., 2002; Traverso et al., 2000). Inconsistencies found in terms of body image in the systematic review might be explained by the vast range of instruments (a total of 13 different measures) used to assess body image and the multidimensionality of the construct itself (Teixeira et al., 2004).

#### 6.3.2 Depression

Depression assessed at 12 month follow-up in the LWW study was also predictive of 12 month body weight and weight loss maintenance, such that higher depression at 12 month follow-up predicted higher body weight at week 12 and greater weight regain. The results from the systematic review showed that depression was predictive of weight loss in 6 out of 16 studies which assessed depression but no corresponding evidence was available for weight loss maintenance. However, most of the studies included in the review assessed depression using the BDI and none of the included studies assessed depression using the DASS, which was used in LWW follow-up study and the online survey. The BDI differs from the DASS depression scale primarily in that the BDI includes items such as weight loss, insomnia, somatic preoccupation and irritability, which fail to discriminate between depression and other affective states (Lovibond, 1995). Successful weight loss was associated with lower levels of depression in the online study. However, depression assessed using the HADS was not a significant predictor of weight loss in the NHS delivered 12 week weight management programme. Teixeira et al. (2005) argued that the BDI does not adequately identify subjects with low likelihood of success for weight management and Somerset et al. (2011b) suggested the DASS score to be a more informative and useful measure on the basis of including another psychological measure and having higher Cronbach values than the other two scales (Sukantarat, Williamson, & Brett, 2007). However, more studies are needed to examine depression, anxiety and stress using this measure and the specificity and sensitivity of each widely used measure of depression assessed for utility in weight loss interventions and studies of weight loss maintenance.

#### 6.3.3 Stress and stressful life events

Stress was found to be a significant predictor of weight loss in the online survey, such that those who were more successful at weight loss experienced less stress. Stressful life events during the 12 month follow-up period after the 12 week dietary intervention were also associated with poorer weight loss maintenance, such that fewer stressful life events predicted better weight loss maintenance. Stressful life events were not assessed in any of the studies included in the systematic review. A previous review by Elfthag and Rossner (2005) reported three studies which found that stressful life events were associated with weight regain (DePue, Clark, Ruggiero, Medeiros, & Pera, 1995; Dubbert, 1984; Sarlio-Lahteenkorva, Rissanen, & Kaprio, 2000). However, these studies did not meet the inclusion criteria of the systematic review as they only reported correlations and were not included. Weight regain was associated with more psychosocial crises including major illnesses and bereavements (Dubbert, 1984) and personal or family stress and a busy schedule (DePue et al., 1995). Tinker and Tucker (1997) interviewed people who had successfully maintained their weight loss and

found that their weight maintenance was due to stable circumstances after the active behaviour changes (Tinker & Tucker, 1997). Stress was frequently assessed in the studies included in the systematic review, but the evidence was inconsistent. Responses to stress and/or stressful life events differ not only between people, but also within people at different times (Epiphaniou & Ogden, 2010).

### 6.3.4 Diet Satisfaction

Satisfaction with the current diet was not identified as a predictor of weight loss and/or weight loss maintenance in the systematic review but was assessed in the online survey using a relatively new measure (D-SAT; Ello-Martin, Miller, & Rolls, 2004). Baseline diet satisfaction was also a significant predictor of weight loss in the NHS delivered 12 week weight management programme, such that higher baseline diet satisfaction predicted greater weight loss during the 12 week weight management programme. Similar results were found in the online survey. Satisfaction with diet and weight loss programmes is generally an understudied area and this promoted the use of the D-SAT as a measure in the online study. The absence of measurement of diet satisfaction in the studies included in the systematic review may reflect the lack of instruments available to assess diet satisfaction and the relatively low priority afforded to it by researchers and clinicians.

# 6.4 Cognitive Factors

## 6.4.1 Beliefs about the causes of obesity

Beliefs about the causes of obesity also emerged as a predictor of weight loss maintenance. Having stronger beliefs that causes of obesity are due to medical reasons (e.g. genes, hormones) assessed at 12 month follow-up was associated with more weight loss maintenance. In the systematic review, beliefs about the causes of obesity were assessed using the Obesity Cognition Questionnaire, whilst Ogden's scale (2001) was used to assess beliefs about the causes of obesity in the LWW follow-up study. People hold beliefs about the causes and consequences of many phenomena (Wyer, 2004). Although these beliefs are sometimes based on scientific evidence and sometimes not, they can influence judgment and behaviour (Dweck, 2000). McFerran and Mukhopadhyay (2012) found that people who believed that their obesity was due to a lack of exercise

were more likely to be obese than those who believed their obesity problem was due to poor diet. They highlighted that the beliefs that people hold about their obesity are very powerful and have systematic influences on individuals' body weight and food consumption (McFerran & Mukhopadhyay, 2013).

# 6.5 Behavioural Factors

# 6.5.1 Eating Behaviour

Consistent with the findings from the systematic review in chapter 2, eating behaviour was found to be a significant predictor of weight loss and weight loss maintenance in the LWW study (Chapter 3). Greater reductions in disinhibition during the 12 week intervention predicted greater weight loss. Also, emotional eating at the end of the intervention and changes in emotional eating during the 12 week intervention predicted body weight at 1 month follow up. Lower disinhibition and hunger and increased dietary restraint were also identified as characteristics of successful weight losers in the online survey. Eating behaviour was not found to be a significant predictor of weight loss in the NHS weight management programme (Chapter 5). However, DEBQ emotional eating, external eating and TFEQ disinhibition significantly decreased and TFEQ restraint significantly increased during the 12 week NHS weight management programme. Present findings were consistent with previous studies which also have found that eating behaviour predicts weight loss (Batra et al., 2013; Bryant et al., 2012; Canetti et al., 2009; Delahanty et al., 2013; Delinsky et al., 2006) and weight loss maintenance (Fogelholm et al., 1999; Hoiberg et al., 1984; Lejeune et al., 2003; Teixeira et al., 2010; Vogels et al., 2005).

## 6.5.2 Treatment adherence/attendance

Treatment adherence/ attendance was found to be the most consistent predictor of weight loss and weight loss maintenance out of all 26 predictors presented in the SRR (Chapter 2). Treatment adherence was only assessed at the LWW study with the degree of engagement that participants showed by their completion and return of the food diary records, consumption of the test products and, in the high fibre group, by completion of WBDs in which fibre points were recorded. However, treatment adherence was not assessed as a predictor of weight loss or weight loss maintenance. Many studies suggest that attendance or degree of engagement with a weight loss intervention is associated with weight loss (Johnson et al., 2011; Stubbs et al., 2012). The mechanisms by which attendance translates into weight loss are not clear but it appears that attendance may be related to greater adherence to and use of programme components (i.e. self-regulatory behaviours, behaviour change techniques, support mechanisms) which may well differ for different people (Stubbs, Morris, Pallister, Horgan, & Lavin, 2015). Attendance appears to be an index of engagement with the multiple components of weight management programmes, which is related to rate and extent of weight loss (Stubbs et al., 2015). Further studies are needed to assess which methods most encourage engagement in weight management programmes and hence weight outcomes.

# 6.6 Motivational Factors

### 6.6.1 Self-efficacy

Self-efficacy assessed using the WEL was a consistent predictor of weight loss and weight loss maintenance in the studies reported in the systematic review and this was confirmed in the findings from the online survey. Those who were more successful at weight loss had greater eating self-efficacy. The WEL was developed as a measure for use in research and clinical practice (Ames et al., 2012) and has the potential to improve patient screening and care, However, other important instruments which are often used in the clinical practice to evaluate weight-management motivation in overweight or obese individuals such as the Treatment Self-regulation Questionnaire (TSRQ; Levesque et al., 2007) were not included in the studies within this thesis nor the systematic review and so the sensitivity of these measures to predict weight loss and weight loss maintenance has not been established.

Shin et al. (2011) suggested that assessments of self-efficacy made prior to treatment could be used to determine which participants are likely to be more successful in response to a weight loss intervention. Self-efficacy is an essential element of motivation and future interventions should aim to include approaches that strengthen both people's confidence to resist eating when foods are readily available and motivation to change (Shin et al., 2011). A useful technique to increase people's motivation and assist them in sustaining healthier lifestyle is

motivational interviewing (Christie & Channon, 2014) and is discussed in further detail in section 6.14.

Self-efficacy is consistent with the Health Belief Model (HBM; (Rosenstock, Strecher, & Becker, 1988) which proposes that the likelihood of a person performing a health-related action is motivated by a series of perceptions (e.g. severity, perceived susceptibility, perceived threat or perceived risk, benefits, perceived barriers, self-efficacy and cues to action). perceived Although, this model can predict behaviours, it has received criticism over its constructs not being clear (Abraham & Sheeran, 2005). Self-efficacy is also reflected in the Theory of Planned Behaviour Model (TPB), which also tries to explain the determinants of a person's intention to change behaviour and has been applied to explain dietary change (Contento, 2011). The TPB includes perceived behavioural control (PBC) and studies have related self-efficacy and PBC to exercise and dietary behaviours, supporting the separation of these two constructs (Armitage & Conner, 1999; Terry & O'Leary, 1995).

### 6.6.2 Motivation as a key factor for successful weight loss

Although motivation appears to be a significant predictor of weight loss and/or weight loss maintenance the evidence from the systematic review was inconsistent. Motivation was measured by readiness to change at the start of the NHS delivered 12 week weight management programme and findings showed that those who were "ready to start" lost significantly more weight than those who were not. Readiness to change seems to be one of the most promising factors promoting behaviour change in individuals who need to modify their lifestyle for health purposes (Ceccarini et al., 2015). Not everyone commencing a weight loss programme has the same motivation or self-efficacy (see section 6.7 above). It is therefore recommended that people are screened for readiness to change before entering any intervention and receive additional support based on the stage they are in.

Motivation has been defined in psychology as 'the psychological forces or energies that impel a person towards a specific goal' (Sheldon, Williams, & Joiner, 2003, p.45). Personal motivation can influence treatment adherence and effectiveness as well as the choice of intervention (Resnicow et al., 2008). Several studies have pointed out that motivational techniques promote weight loss by favouring adherence to weight-loss and weight management programmes, with positive results (Pietrabissa, Manzoni, & Castelnuovo, 2013; Ryan & Deci, 2000; Vanvoorhis & Morgan, 2007).

These theories i.e. readiness to start a diet and motivation per se are reflected in Prochaska and Di Clemente's Transtheoretical Model (TTM) which considers readiness to change and the stages of change (SOC; (Prochaska & Velicer, 1997). The TTM of health behaviour change is a multiple construct framework for understanding health behaviour and promoting behaviour change (Prochaska & Velicer, 1997). The model suggests that people change behaviour as they progress through five stages: precontemplation, contemplation, preparation, action and maintenance. People are classified into a stage based on their current behaviour and readiness to change that behaviour. Stages of change have been used as an investigation tool to determine estimates of and changes in motivational readiness for different populations (Nigg et al., 2005). The stage of change construct can assist in tailoring of interventions by matching intervention strategies to individuals' motivational readiness (Jordan & Nigg, 2002). Steptoe et al. (2001) found that a stage-matched intervention for at-risk participants (either overweight and sedentary or active smoker) was superior to a non-stage matched intervention in increasing the odds of becoming more physically active, decreasing fat intake or quitting smoking (Steptoe, Kerry, Rink, & Hilton, 2001).

# 6.7 Physiological factors associated with weight loss and/or weight loss maintenance

Other factors beyond the scope of the systematic review reported in Chapter 2 were identified as predictors of weight loss. These were physiological factors such as age, initial body weight and biomarkers such as fasting leptin and insulin. These findings are consistent with previous studies which have identified these physiological factors as potential predictors of weight loss and/or weight loss maintenance (see section 3.28.1, 3.28.2 and 3.31 in Chapter 3).

# 6.8 Strategies associated with weight loss

An additional aim of the online survey study was to examine strategies associated with weight loss. Previous studies have highlighted a range of strategies used by people in order to manage their weight issues. Both clusters identified in this study used a variety of strategies to manage their weight, but still struggled with their weight and this was more evident for those in the less successful group (Cluster 1). Interestingly, within these two distinct groups of weight losers, those who were more successful at weight loss were less likely to use GP referred diets, commercial diets and meal replacement plans. There was also a tendency for those who were more successful at weight loss to keep more food-diaries than those who were more successful in losing weight. This contradicts the findings of the systematic review which supported the beneficial effect of self-monitoring on weight loss. Although the evidence supports the effect of self-monitoring on weight loss, there is research suggesting that self-monitoring may promote increases in psychological distress and attrition (Dionne & Yeudall, 2005). Furthermore, one question not answered in the literature, and in the present thesis, which needs further investigation is the intensity and/or frequency of self-monitoring required for successful weight loss.

# 6.9 Why is changing behaviour and sustaining behaviour change so difficult?

There are many different ideas about the factors which affect whether someone will change (and maintain) lifestyle behaviours. Most of the main theories include a concept relating to self-efficacy (i.e. belief in one's ability to perform the behaviour; see section 6.7 above) and to motivation (i.e., one's desire or will to engage in the behaviour; see section 6.12) (Dixon, King's Fund, 2008). In a review of the psychological literature on behaviour change, Michie et al. (2005) identified 12 domains including: knowledge, skills, social/professional role and identity, beliefs about capabilities, beliefs about consequences, motivation and goals, memory, attention and decision process, environmental context and resources, social influences; emotion, behavioural regulation and nature of the behaviours (Michie et al., 2005).

Powell et al. (2007) has argued that the idea of participants completing an intervention and sustaining the changes implemented beyond the intervention phase is outdated (Powell, Calvin, & Calvin, 2007). People require sustained ongoing support to maintain lifestyle changes. Previous literature has highlighted that duration of treatment was an independent predictor of weight loss (Jeffery et al., 2000). Longer treatment times may be important as they allow for continued support and provide patients with a greater opportunity to practice the behaviours

necessary for long term weight management success (Jiandani, Wharton, Rotondi, Ardern, & Kuk, 2016). However, offering long term treatment for obese people is not cost-effective or feasible. Instead of demanding that people make changes and follow certain diet/physical activity regimes (i.e. promote controlled motivation) people should accept the regulation of change as one's own responsibility (Teixeira, Mata, Williams, Gorin, & Lemieux, 2012). This would require internalisation of relevant behaviours and integrating these with one's sense of self and one's values and goals, so they can become the basis of autonomous regulation. In line with the self-determination theory, a behaviour is personally endorsed and engaged in with a sense of choice and volition (autonomous motivation), as opposed to being associated with a need to comply or with feelings of pressure and tension (Teixeira et al., 2012). Individuals participating in any weight loss programme, have particular goals in mind associated with a reduced weight, whether these are to improve appearance, for health and fitness reasons, or to please others. Self-determination theory differentiates between behaviours that are associated with more extrinsic goals (i.e. physical attractiveness) and those regulated by controlled reasons and more intrinsic goals (i.e., health, affiliation, personal growth) (Ingledew, Markland, & Ferguson, 2009). The latter are connected to the satisfaction of basic psychological needs and are typically regulated by more autonomous forms of motivation (Ingledew et al., 2009). In self-determination theory, the concept of autonomy is central to understanding goal pursuit and why not all goals are the same (Ryan & Deci, 2000). Autonomy (or self-determination) is seen as an innate human psychological need, along with needs for competence and relatedness (belonging) with others (Ryan & Deci, 2000).

Motivational interviewing (MI) and self-determination theory can both be seen as complementary approaches to understanding behaviour change and informing health-related interventions. MI is defined as a method of strengthening personal motivation for change (Resnicow & McMaster, 2012) and future interventions should include both MI and instruments to assess self-determination theory constructs such as measures of perceived support for autonomy and measures of autonomous and controlled regulation of behaviour (Teixeira et al., 2012). This could further assist in examining whether interventions are perceived by participants as autonomy-supportive rather than controlling and whether interventions lead to increased autonomous motivation for change and consequently to greater adherence to adaptive behaviours and greater weight loss and weight loss maintenance.

### 6.10 Weight stigma as a de-motivator of weight loss

Research has shown that weight stigmatization reinforces unhealthy lifestyle behaviours and is detrimental to motivation (Puhl & Heuer, 2010). Individuals who experienced and internalised negative weight stigma reported more frequent binge eating and were less likely to follow a diet (Puhl et al., 2007) and more likely to avoid exercise (Vartanian & Shaprow, 2008). Lillis, Hayes, Bunting and Masuda (2009) examined a 1-day intervention that taught patients mindfulness and acceptance-based strategies to cope with obesity related stigma and found that these strategies were effective in improving body mass, quality of life, perceived weight-related stigma, and psychological distress at 3-month follow-up. These authors argued that a model which can reduce distress related to weight stigma whilst promoting weight control seems a promising treatment approach and should be further examined (Lillis, Hayes, Bunting, & Masuda, 2009).

Weight related stigma and discrimination has been identified in three important areas: employment, education, and health care (Puhl & Brownell, 2001). In addition, stigma and discrimination toward obese persons are pervasive and consequently, affect their psychological and physical health (Puhl & Heurer, 2010). Research has found that health care settings are a significant source of weight stigma, which challenges obese patients' opportunity to receive effective medical care (Puhl & Heurer, 2010). Studies have shown that health care providers and fitness professionals often hold negative stereotypes and attitudes toward obese, including views that obese patients are lazy, lacking in selfdiscipline, dishonest, unintelligent, annoying, and noncompliant with treatment (Puhl & Heurer, 2009). Studies have also found that health care providers spend less time in appointments with and provide less health education to obese patients compared with thinner patients (Bertakis & Azari, 2005). Consequently, obese individuals frequently report experiences of weight bias in health care settings (Puhl & Brownell, 2001), often feel disrespected, and believe that they will not be taken seriously because of their weight. As such they may be less

motivated to address their weight issues with health care providers (Anderson & Wadden, 2004). All of these findings point to suboptimal health care experiences for obese individuals.

# 6.11 Individual variability in weight loss and weight loss maintenance

A common finding across both intervention studies (the LWW study and NHS the weight management programme) was the great individual variability in weight loss with some people losing weight, some gaining and some maintaining their baseline weight during the active intervention phase. Differences in weight loss may be explained by individual differences in psychological factors mentioned earlier as well as differences in physiological and environmental influences. This individual variability demonstrates the need to treat people as individuals (King, Hopkins, Caudwell, Stubbs, & Blundell, 2008) and to determine whether people would benefit from individual or group based treatments. It also highlights the importance of examining the mechanisms that may explain this variability. In this regard, the main aim of a successful intervention should be to try and change the more resistant individual profile for weight management to a more susceptible one for weight management.

# 6.12 Group versus individual based interventions for weight loss

In the present thesis, the LWW study was delivered on an individual basis with patients being seen regularly by the dietitian or a member of the research team. In contrast, the delivery of the 12 week weight management intervention provided by NHS was group based. Although, comparison between these two studies is difficult as they included different samples in different settings, they both resulted in significant weight loss during the same time period. This confirms the previous findings of a review by Avenell et al. (2004) who found no significant differences between group and individually delivered weight management interventions in weight loss at 12 and 18 months. However, other studies have found that obese women randomized to face-to-face group treatment lost significantly greater weight than those randomized to face-to-face individual treatment, regardless of their expressed preference for individual or group counselling (Renjilian et al., 2001).

Group based treatment is an alternative approach to individual sessions allowing participants to interact with each other in real time while still providing reduced participant and provider burden (Befort, Donnelly, Sullivan, Ellerbeck, & Perri, 2010). Group based benefits include factors such as interpersonal learning, imparting information to others, and developing optimism and hope for change (Yalom, 1995). In behavioural obesity treatment, features of group counselling such as support, accountability to one another, building alliances with those who have the same problem, and group problem-solving are believed to be important for sustaining difficult lifestyle changes (Donnelly et al., 2007; Perri et al., 2001; Stubbs, Whybrow, & Lavin, 2010). This could also explain the similar weight loss across both diet groups in the LWW study. Although the intervention was a face to face treatment, the monthly meetings with the dietitian and the ongoing support might have accounted for the successful weight loss in both groups.

The NHS delivered weight management programme was group based and led by dietitians. However, the degree to which the group dynamics affected weight loss is unknown. Group dynamics may play a positive or negative role in weight loss outcomes during weight management programmes and they need to be taken into consideration (Nackers et al., 2015). Greater perceived conflict in terms of friction and anger between participants was associated with lower weight loss and poorer rates of attendance and self-monitoring adherence during the intensive treatment phase (Nackers et al., 2015). In addition, greater desire to identify with and be accepted as a group member, was associated with greater attendance. Therefore, effectively addressing conflicts and encouraging positive interactions among group members may be useful strategies to promote better treatment outcomes (Nackers et al., 2015). Health care professionals delivering weight loss interventions should be aware of these factors and try to identity tension, distrust, and withdrawal among group members and be able to manage conflict effectively.

# 6.13 Consideration of other treatment outcomes in weight loss interventions

Treatment outcomes following weight loss interventions should not exclusively depend on reporting weight change. Selected psychological and behavioural outcomes should also be routinely considered as successful outcomes following different weight management programmes. Both study participants and health professionals may experience pressure about achieving particular outcomes (i.e. weight loss), with consequences for their motivation. This pressure could affect how health care professionals interact with their patients and involuntarily interfere with patient autonomy (Teixeira et al., 2012). Health professionals working with obese patients need to have an understanding of their own motivations related to treatment, and how much control they feel from external incentives (e.g. by their health care organisations, external funding bodies) or driven by internalised outcome contingencies, such as feeling that their own professional and/ or self-worth is dependent on their patients' weight loss success (Teixeira et al., 2012).

# 6.14 Strengths of this thesis

### 6.14.1 Analytical approach

This thesis aimed to examine predictors of weight loss and weight loss maintenance in different study populations within different settings (lab-based, and free-living) using an appropriate statistical analysis approach. The LWW study is the first study to examine the effects of fibre consumption on various daily physiological and psychological symptoms of wellbeing, using a robust statistical method (OLS accounting for daily changes over the 12 weeks). Logistic regression is a more complex method than linear regression models. The use of this method is rare in the public health area (Abreu, Siqueira, & Caiaffa, 2009). This may be attributed to its complexity and. is the relatively small number of modelling options offered in commercial statistical packages used in psychology and public health, such as SPSS (Abreu, Siqueira and Caiaffa, 2009). Even if more complex packages are used, such as SAS and Stata, OLS is difficult to programme and selection of the appropriate commands and interpretation of the output requires advanced training.

Regression modelling using the AIC criterion and the weighted AIC was used within this thesis and is a useful technique to identify the best fitting model amongst competing models (Wagenmakers & Farrell, 2004). AIC is a popular method of comparing multiple models, taking both descriptive accuracy and parsimony into account. The AIC has been used as a measure of model adequacy in structural equation modelling (Joreskog & Sorbom, 1996), time series analysis (McQuarrie & Tsai, 1998), factor analysis (Akaike, 1987), regression (Burnham & Anderson, 2002) and latent class analysis (Eid & Langeheine, 1999)

Finally, cluster analysis was used to examine the characteristics of free living individuals who had previously attempted to lose weight using different weight loss methods. The purpose of cluster analysis is to arrange observations into relatively homogeneous groups based on multivariate observations, maximising the distance (which reflects differences in the combination of scores) between the clusters (Gore, 2000). Although researchers in the social and behavioural sciences are often interested in clustering people, nowadays they rarely use this method preferring discriminant function analysis if at all (Stoker, 2016). Both cluster and discriminant function analyses are concerned with the characteristics of groups of objects, but there is an important conceptual difference between the two procedures (Gore, 2000). Discriminant analysis is used to identify an optimal subset of variables that is capable of distinguishing among discrete predetermined groups, while cluster analysis begins with undifferentiated groups and attempts to create clusters of objects based on the similarities observed among a set of variables.

## 6.15 Limitations of the present thesis

Sampling issues and generalizability, loss to follow-up, seasonal effects on weight loss, failure to account for physical activity and reliance on self-reported data are some of the limitations of this thesis and are discussed below.

### 6.15.1 Sampling issues

Sample characteristics should be taken into account when drawing conclusions from the three studies presented in this thesis. Participants in Study 1 (LWW study) were ostensibly healthy, overweight and obese British women and so the results cannot be generalised to individuals with health problems and may not generalize to other cultures. The online survey was based on a convenience sample and participants came to know about the survey through social media platforms and as part of studying at the University of Leeds. For these reasons, the sample tended to over-represent well-educated people. Finally the NHS delivered 12 week weight management programme was based on a small sample

of obese/severely obese patients in a relatively deprived region with different comorbidities. Studies have shown that severely obese individuals suffer stigmatization, discrimination (Kaminsky & Gadaleta, 2002) and major psychosocial disturbance which may cause or aggravate depression more than less obese counterparts (Dixon, Dixon, & O'Brien, 2003) and this may be compounded by social deprivation. The findings might therefore not be generalised to other populations and other settings.

#### 6.15.2 Loss to follow-up

Loss to follow-up is inevitable with time, even with the best study design and conduct (Fewtrell et al., 2008). Attrition is a common problem in weight loss interventions with attrition rates ranging from 10 % to more than 80 % depending on the type of intervention (Moroshko, Brennan, & O'Brien, 2011). Understanding factors that influence early attrition and weight loss success in overweight and obese individuals seeking medical treatment is important, as it may lead to the implementation of alternative strategies, which may improve retention and ultimately health and weight-related comorbidities. Factors influencing follow-up rates include participants' age, the nature and perceived benefit of the follow-up, the degree of inconvenience involved and the ability to trace and contact participants (Fewtrell et al., 2008). Attrition is also important to consider statistically for three principal reasons; its effect on study power, bias and generalisability (Shadish, Cook, & Campbell, 2002; Tabachnick & Fidell, 2007). Reduced sample size can affect the power of the study to detect a hypothesised difference. Attrition introduces a form of selection bias, since loss to follow-up is rarely a truly random event. Attrition can also affect the extent to which research findings can be applied to settings other than the study sample in which they were tested. However, generalisability is an issue even in trials with excellent follow-up rates and a low risk of bias (Tabachnick & Fidell, 2007).

An important potential barrier to participation in follow-up from a weight loss program is embarrassment due to weight regain (DePue et al., 1995). Such a barrier could produce a sample biased in favour of the successful weight maintainers. Those who do not attend are probably the ones who were not successful and feel embarrassed. They might also feel that the intervention was not effective and/or the support they received was less than expected or anticipated. Therefore, they may feel disinclined to attend for follow-up visits. In addition, repeated failed attempts to lose weight are the norm in obese people, and this failure accompanied by thoughts of guilt, hopelessness, and poor selfesteem might discourage them from returning for follow-ups (Dixon, Dixon & O' Brien, 2003). Furthermore, their expectations might have been different to actual outcome. Hence advice and interventions need to be tailored to match expectations, motivation stage and self-efficacy levels. Identification of those who are highly depressed or have many incidents of binge eating would also be beneficial in order to minimise dropouts and decrease attrition rates.

Jiandani et al. (2016) found that certain baseline comorbidities such as depression or hypertension were associated with both greater early attrition and lower weight loss success. However, other studies have failed to find an association between comorbidities and differential attrition or weight loss (Greenberg, Stampfer, Schwarzfuchs, & Shai, 2009). Depression is a significant comorbidity of severe obesity and has been associated with poor quality-of-life scores for all SF-36 domain scores, especially those related to social functioning, emotional problems, and mental health (Dixon, Dixon & O' Brien, 2003). Symptoms of depression correlate significantly with body image dissatisfaction (Friedman, Reichmann, Costanzo, & Musante, 2002) and severely obese subjects, especially women with poor body image, are at high risk for depression (Dixon, Dixon & O' Brien, 2003). Severely obese people also suffer stigmatization (see section 6.13, Chapter 6), discrimination, and major psychosocial disturbance, which may cause or intensify depression (Kaminsky & Gadaleta, 2002). Depression may interfere with weight management as it is often associated with symptoms such as fatigue and lack of motivation or uncontrolled eating and substance abuse, which may make weight loss or attendance more difficult (Jiandani et al., 2016).

The demands of a weight loss program may feel overwhelming for participants with greater depressive symptoms, especially given the reduced energy, motivation, and concentration that characterise this condition. Therefore, participants may require more flexible treatment options and a more tailored approach, based on their comorbid conditions, in order to improve weight loss success and reduce early attrition. Encouraging depressed participants to obtain treatment for their mood before or during their enrolment in a weight loss program may reduce attrition. Alternatively, such participants might need additional support or structure from their weight loss programme to maximize their level of participation.

#### 6.15.3 Seasonal effects on weight loss

Another issue that needs to be addressed is the fact that not all participants completed the weight management programmes reported in this thesis at exactly the same time of the year. Some participants started their intervention during spring, others during the summer or autumn. Studies have investigated the association of seasonality with food intake and have reported that eating behaviour can be affected by seasonal variation. de Castro (1991) investigated eating behaviours and seasonal variations over a 6 year period using 7-day food diary records. He found that food intake increased during autumn and this was due to an increase in carbohydrate intake (de Castro, 1991). Daily food intake was higher in the autumn compared to spring. Similar findings were observed in a longitudinal observational study over 1 year using 24-h dietary recall interviews (Ma et al., 2006). Small seasonal variations with people increasing food intake during autumn versus the winter, accompanied by a small increase in body weight during the winter were observed (Ma et al., 2006). However, other studies have failed to document seasonal changes in food intake (Hackett, Appleton, Rugg-Gunn, & Eastoe, 1985; Van Staveren, Deurenberg, Burema, De Groot, & Hautvast, 1986). Inconsistencies in the literature are mainly due to different study populations and different measures used to capture people's diets. Studies of body weight and seasonal variation have been more consistent and tend to show an increase in body weight during the winter and a decrease during the summer (Ma et al., 2005; Sasaki, Sakamoto, Akaho, Nakajima, & Takahashi, 1998; Van Staveren et al., 1986).

Seasonal variation of recreational physical activity also has been reported in several studies (Haggarty et al., 1994; Van Staveren et al., 1986). Ma et al. (2006) argued that the lowest physical activity level is observed in the winter (which may

explain the increase in body weight during winter noted above) and the highest in the spring with greater seasonal variation observed in male, middle aged, nonwhite, and less educated participants. These seasonal variations in energy intake and physical activity might also impact on the success of weight loss interventions.

### 6.15.4 Failure to control for physical activity

Physical activity was not controlled or assessed during the LWW study presented in Chapter 3 or the NHS delivered weight management programme presented in Chapter 5. Volunteers exercising more than four times a week were excluded at screening in LWW study and were instructed to maintain their usual activity levels throughout the study and inform the research team in the event that they made any changes to their daily routine. Participants in the weight management programme were not excluded on the basis of physical activity since the majority, due to being severely obese, were typically inactive. They were informed about the benefits of exercise during the 12 week programme and attended a one to one session with the physiotherapist who gave them advice based on their physical abilities. However, there was no follow-up assessment of their physical activity either during the active phase of the programme or after completing it.

It is possible that the weight loss observed in the LWW study and/or the NHS delivered 12 week weight management programme could have been due to an increase in exercise levels (increased energy expenditure). However, it is unknown if those who were successful in maintaining body weight at 1 and 12 month follow-up in the LWW study engaged in any physical activity. Physical activity was found to be a significant predictor of weight loss maintenance in the systematic review presented in Chapter 2. Participants who completed the online survey (Chapter 4) reported engagement with different physical activities as a strategy to lose weight. However, there were no differences between those who were more or less successful in weight loss in terms of any type of physical activity reported. Research suggests that physical activity plays an important role in the amount of weight regain following successful weight loss (Swift, Johannsen, Lavie, Earnest, & Church, 2014). However, individuals who have

successfully lost weight require a substantial amount of physical activity to maintain weight loss (200 minutes per week) (Donnelly et al., 2009).

### 6.15.5 Reliance on self-reported data

A limitation of the present thesis was the reliance on self-report (subjective) measures through the use of questionnaires, food diaries and the online survey. These less invasive measures are frequently used due to their practicality, low cost, low participant burden, and general acceptance (Prince et al., 2008). Although self-reports are useful for gaining insight into participants' behaviours they are prone to errors of recall (i.e. inaccurate memory) and response bias (i.e. social desirability) such that respondents report behaviours that they perceive to be desirable rather than accurate (Prince et al., 2008). For example, although food diary records, are considered the best method for assessment for diet, they can still show over reporting of healthier foods and under reporting of less healthy foods (Richardson, Cavill, Ells, & Roberts, 2011). Despite these limitations, self-report tools remain the most cost-effective and the most practical option for public health evaluations of diet and physical activity in relation to weight management interventions (Richardson, Cavill, Ells, & Roberts, 2011).

### 6.16 Future research and recommendations

The relationship between seasonal variation in body weight and seasonal changes in diet and physical activity, and how this may affect weight change has not been studied. Hence it may be helpful for future studies to examine periods where people eat more, exercise less, and add weight (Ma et al., 2006). In addition, the presence of seasonal variation should be taken into account when counselling patients about healthy habits as well as when designing studies involving observation of diet and physical activity.

Individual physiological and psychological factors, often genetically influenced, interact with social and environmental factors, giving a multitude of individual responses to both the magnitude and rate of weight change. There is no evidence in the research literature of a single variable that strongly predicts weight loss and/or weight loss maintenance (Teixeira et al., 2005). Rather, many different variables account for a small amount of the variance in weight loss and/or weight

loss maintenance (Teixeira et al., 2005; Stubbs et al., 2011). More research is therefore needed to elucidate physiological and psychological factors that predict weight loss and/or weight loss maintenance in different settings using sophisticated analyses so that interventions can be targeted to optimize results. Additionally, more studies are needed to examine the aforementioned psychosocial/behavioural predictors in weight loss maintenance studies due to the paucity of studies implementing a weight loss maintenance phase.

Future research should also further examine diet satisfaction, beliefs about the causes of obesity, stressful life events, locus of control and dichotomous thinking as potential predictors of weight loss and weight loss maintenance. There is paucity of research examining these psychological factors in both the short and long term. In order to achieve diet satisfaction, dietary interventions must be simple to administer and acceptable to or tolerable by participants. The 12 week dietary intervention (LWW study) reported in this thesis was a successful simple strategy to assist participants to reach the recommended daily fibre intake (25g/d) that might have implications for public health recommendations for gastrointestinal health and chronic disease prevention. Increases in fibre intake were associated with improved bowel pain and reduced constipation. Functional constipation is a significant factor in health care utilization. It leads to impairment in quality of life, lost work productivity and increased costs spent in medical treatments (Schmier et al., 2015). Dietary modification via the addition of high fibre cereals presents a safe, effective and economical option for improving gut health that can be a natural alternative to medical treatment.

Future studies should examine whether screening individuals based on depression, eating efficacy, readiness to change and diet satisfaction and offering additional support to those who are more likely to struggle with these issues would result in sustainable changes. Successful screening of individuals who are more likely to drop out and less likely to meet weight loss goals would limit their experience of any disappointment and make it possible to offer them alternative approaches (Teixeira et al., 2002). However, a wide range of instruments are used to assess similar psychological constructs. This is especially the case for

measures of body image. Hence researchers and clinicians should aim to use the most psychometrically sound and well validated instruments.

For many patients, readiness for change differs dramatically and interventions may need to be tailored more precisely. Providers may need to use more active, behaviourally focused interventions for those who are more ready to start a weight management programme whilst implementing more cognitively focused interventions for the less prepared ones (Boudreaux et al., 2003).

The identification of distinct subgroups of obese individuals is a first step in better understanding how to provide tailored strategies to help with weight loss and weight loss maintenance. Future studies should examine whether characterising individuals and promoting tailored interventions, which could place them in the more successful category, result in sustainable weight loss outcomes. Moreover, future studies should aim to investigate the characteristics of the clusters identified in Chapter 4 using a larger sample. In addition, motivational components for dietary and physical activity change in order to increase intrinsic motivation and self-efficacy and emotion regulation and stress coping components through a non-judgemental and de-shaming environment of social support should be incorporated and investigated in future interventions.

Weight changes are only a part of the many health-related outcomes of weight management programmes. Outcome variables can also include quality of life, specific healthy behaviours, body image, self-esteem, social functioning and many other variables. Recent evidence suggests that not all obese persons are negatively affected by their weight and that weight loss does not necessarily always improve health (Brown & Kuk, 2015). An emphasis on maintaining a healthy lifestyle that includes a high level of physical activity and physical fitness may be a more appropriate recommendation for some obese populations than just focusing on the goal of weight loss alone (Brown & Kuk, 2015). Given the documented difficulties many individuals have with weight loss even when provided with evidence-based and comprehensive interventions, determining individual psychosocial variables associated with success (or lack of it) is particularly important.

Health care professionals working with obese individuals should receive additional training and education in order to feel confident working in health areas such as nutrition and obesity. Some health professionals might need support to strengthen their communication skills in order to understand individuals' attitudes and behaviours that underlie their health conditions and influential factors such as family and culture (Soni & Bailey, NHS Future Forum, 2012). Furthermore, training should address their biases about patients with obesity, ability to use behaviour change strategies and ability to work collaboratively with multidisciplinary teams (Dietz et al., 2015). These are essential if the NHS is to help people make healthier and sustainable changes and reduce health inequalities.

A critical feature missing in many attempts at promoting lifestyle change is the implementation of solutions that are practical for consumers, which involve continuing support, so that they can effectively adopt and maintain new and healthier patterns of behaviour (Stubbs et al. 2011, Elfthag and Rossner, 2005). Assisting people in putting advice into practice and transforming healthy choices into habits requires expertise in engaging, motivating and guiding people in weight control practices, and in coping with lapses to support behaviour change until they become the basis of a healthy lifestyle (Stubbs et al., 2012).

### 6.17 Conclusions

The present thesis has confirmed and extended previous findings by demonstrating that affective (diet satisfaction, stressful life events and depression), cognitive (beliefs about causes of obesity), behavioural (eating behaviour) and motivational factors (eating efficacy and motivation) are predictors of weight loss and/or weight loss maintenance. The refined conceptual model which emerged from this thesis highlight different personal characteristics related to weight loss and weight loss maintenance. The refined model presented is not a definitive model and more studies are needed to provide the evidence base to refine it further and to explore other constructs related to affect cognition, behaviour and motivation that might assist in the design of future weight loss/maintenance interventions. In addition, findings from the pilot study (Chapter 5) might encourage NHS delivered weight management services to incorporate and examine the efficacy of at least some screening tests prior referring patients

to the weight management programme and to use this information to better tailor their programmes to improve patient outcomes. This thesis identified two distinct clusters of successful weight losers and future studies are needed to further confirm these findings. New techniques of motivational interviewing, selfmonitoring and behavioural counselling offer promise for promoting behaviour change for weight loss. However, little research has been done to evaluate how the application of these techniques may influence behaviour and motivation in the short and long term. More research needs to be done to identify other constructs relat4ed to individual behaviour that motivational constructs that influence behaviour change and consequently lead to a healthier lifestyle. A multidisciplinary approach to tackle obesity which addresses psychological, social, environmental, and biological factors is therefore critical to ensure comprehensive care, best practice and outcomes for individuals struggling with WL and WLM (Collins & Bentz, 2009).

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### APPENDICES

#### **Appendix 3.1 Randomisation Schedule**



# Quadt Consultancy B.V.

Adviesbureau voor statistische proces- en kwaliteitbeheersing

Prof. Louise Dye BSc PhD CPsychol Chair in Nutrition and Behaviour Human Appetite Research Unit Institute of Psychological Sciences University of Leeds

Geelgieterhol 11 \$123 PB Schiedam

Telefson 010-4715038 Tel. mob. 06-53722189 e-mail: frits.guadt@wanadoo.nl Bankrelatie ABN-AMRO Bek. po : 41.0435.073

Our Ref: LD/90001/PA

#### Power Analysis

Schiedam, 7 July 2009

#### Introduction.

Quadt Consultancy BV has been requested to calculate the number of subjects needed to power an experiment for the primary parameter Weight Loss after 12 weeks intervention such that at a power of 80% a weight loss of 2.5 kg can be detected as statistically significant at the 5% significance level.

The estimated standard deviation of the weight loss is 3.63 kg as taken from a previous similar sample recruited for a study of improving health via exercise. The actual mean weight at the start of the study was 85.5 kg at a standard deviation of 8.15.

#### Analysis.

The power analysis has been done using the PROC POWER procedure of the SAS software (version 9.1.3). The input data are the expected mean difference in weight loss (2.0 or 2.5 kg), the expected standard deviation (3.63 kg), the type of test (one sided two sample t-test for independent samples), the required significance level (0.05) and the required power of the experiment (0.80).

#### Results.

For a one-sided test and an expected weight loss of 2.0 kg the required sample size per group is 42 subjects, i.e 84 subjects in total. For a one sided test and an expected weight loss of 2.5 kg the required sample size is 27 subjects per group or 54 in total.

For a two-sided test and an expected weight loss of 2.0 kg the required sample size per group is 53 subjects, i.e 106 subjects in total. For a two sided test and an expected weight loss of 2.5 kg the required sample size is 35 subjects per group or 70 in total.

#### Conclusion.

The suggested sample size of 55 subjects will give sufficient power for a two-sided significance test at the lowest expected weight loss and allows for a small number of dropouts.

J.F.A. Quadt Quadt Consultancy BV

Op al onze transacties en diensten zijn onze leveringsvoorwaarden van toepassing, welke op verzoek worden verstrekt. Appendix 3.2 Participant Information Sheet and Informed Consent form



Human Appetite Research Unit

#### Institute of Psychological Sciences

University of Leeds

Leeds LS2 9JT

Telephone: 0113 343 5753

Fax: 0113 343 5749

#### PARTICIPANT INFORMATION SHEET

### Leeds Women's Wellbeing Study: A study to compare the effects of two 12-week healthy eating interventions on body weight, body composition, appetite control, biomarkers of health and wellbeing in overweight women

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and talk to others about the study if you wish. One of our team is available to go through the information sheet with you and answer any questions you have. Please take your time to decide whether or not you wish to take part.

Part 1 tells you the purpose of this study and gives a summary of what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Ask us if anything is unclear or if you would like more information.

#### PART 1

#### What is the purpose of the study?

This study has been designed to compare the effects of two different healthy diets on the overall wellbeing of women over a period of 12 weeks. The results of this study will be used to advise women on the most effective dietary changes that they could make to improve their health and wellbeing and to maintain a healthy body weight. Women who are overweight and in good health and who do not have a cardiac pacemaker fitted can take part.

Both study diets will encourage healthy eating, but are not 'fad' diets and will not involve the use of any supplements or medicines. You will be asked to follow one of the

two study diets. You will be encouraged to increase your consumption of healthy foods and provided with recipes and commercially available foods to help you do this. Our study dietitian will give you advice on getting started on the diet and will support you with dietary advice during the 12 week diet. In order to provide a fair comparison of the effects of the two diets, you will only be given information about the diet we ask you to follow. It is important that this is the only diet you follow during the 12-week period. However, at the end of the study we will offer you full information about the diet that you did not follow, to give you the opportunity to try this out yourself. Some results from the study will be used towards an educational qualification by a member of the research team.

#### Study Summary

The study will be carried out in The Human Appetite Research Unit (HARU) in the Institute of Psychological Sciences, University of Leeds under the supervision of Professor Louise Dye and Dr Clare Lawton.

The duration of the study is 16 weeks for each participant although the whole study will run for approximately 12 months (with over 100 women taking part). During the first 4 weeks, we will assess your current health, wellbeing and dietary habits. You will be asked to complete a 7-day food diary and a short wellbeing diary each day (more details are given in Part 2). If you are eligible to continue you will then start on one of the 12-week diets.

You will need to visit our research unit 6 times. There will be 4 short visits (each of which should last no more than 1 hour) and 2 longer visits (test meal days, each lasting about 8 hours). During each visit we will measure your body weight, body composition and waist circumference. We will also ask you to complete some questionnaires about your eating habits, feelings about your body shape and sleep quality. At each visit our study dietitian will give you some dietary advice, recipes and other tips to help you follow the study diet. We will also give you some commercially available foods to consume at home. You will be asked to complete a 3-day food diary 4 times during the 12-week diet and a short wellbeing diary each day (more details are given in Part 2). On 2 of the study visits (12 weeks apart) we would like to take some blood samples from you. These will be taken by qualified staff at the HARU and at Leeds General Infirmary (LGI). More details about what is involved at each study visit are provided in Part 2.

#### Why have I been invited?

You are invited to participate in the study because you are a woman aged between 18-48 years, reporting good health and a Body Mass Index (BMI) of between 26-35kg/m<sup>2</sup> (overweight and above). BMI is a number calculated from your weight and height that provides a reliable indicator of body fatness for most people. It is calculated by dividing your weight in kilograms by the square of your height in metres.

#### Do I have to take part?

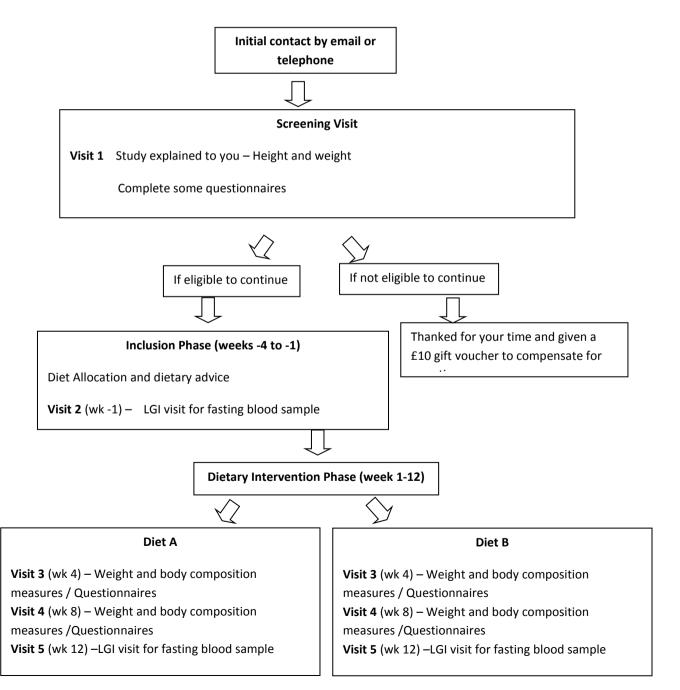
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you

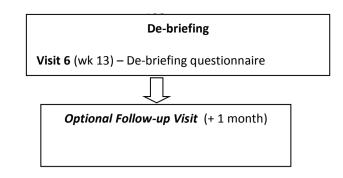
decide to take part you are still free to withdraw at any time and without giving a reason.

#### What will happen to me if I take part?

This study is a randomized controlled trial. This means you will be randomly allocated into one of the two diet groups. Allocation will be decided by chance – rather like tossing a coin. There is an equal chance that you will be put into either of the two diet groups. Neither you nor the researcher will be able to choose which of the diet groups you are put into. However, after you have completed the study you can have access to the information about the other diet if you wish. If you do decide to participate in the study and remain eligible you will need to follow the diet prescribed to you for a period of 12 weeks and attend the HARU six times. A diagram of the study schedule is provided on page 3 of this information sheet.

### A diagram of the study schedule





### What do I have to do if I agree to take part?

Participating in a research study can be an inconvenience to your daily life. When considering taking part you should think carefully about the time commitments and responsibilities required by the study. For two of your visits (test meal days) you will be asked to attend the HARU for about 8 hours and you should consider any other commitments before agreeing to do this. However, we will try to be flexible and accommodate your schedule as far as is possible. You must carefully follow any instructions given to you concerning the study. It is important that you follow the advice given to you by the research team.

#### What are the possible disadvantages and risks of taking part?

The risks associated with cannulation and blood sampling include; infection, fainting, bruising and discomfort. All researchers taking blood samples will be fully trained, competent, first aid trained and will take every step to minimise any of the risks associated.

#### What are the possible benefits of taking part?

Participants, who follow either of the study diets for 12 weeks duration, should improve their nutritional and health status. Taking part in this research study may also improve your understanding of what is a healthy diet and how to maintain it. Taking part may also lead to modest weight loss and improved feelings of general wellbeing. The results from the study may provide important new information regarding the effects of the two study diets on the health and wellbeing of women of your age and BMI.

#### What if something goes wrong?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

#### 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. The details are included in Part 2.

#### Will I receive anything for taking part?

Upon completion of the study, a payment of £120 (taxable) will be paid to each participant to compensate you for the time that you have invested in the study. Participants will also receive a £10 gift voucher for completing the inclusion phase. If you decide to withdraw before completing the study you will be compensated in

accordance with the number of visits that you have completed (at the rate of £20 per visit).

Thank you for reading 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 to me if I take part?

Detailed information about each study visit is provided below:

#### Screening Visit (Visit 1)

If you choose to take part you will be asked to come to the HARU for a screening visit which should take no more than an hour. We will explain the study procedures to you and show you round the unit. You will be free to ask any questions you may have about any aspects of the study. After signing the informed consent form (giving your consent to take part in the study), your height and weight will be measured by a researcher (to accurately calculate your BMI) and you will be asked to complete three questionnaires, one to assess your general health and to check that you meet the study inclusion criteria, one to assess your usual eating habits and one to assess your eating attitudes. If you do not remain eligible at this stage you will be informed of this and thanked for your time.

If you do remain eligible we will ask you to complete a 7-day food diary record at home and to post this back to us as soon as possible (a freepost envelope will be provided). The study dietitian will explain how to fill in the food diary. We will also ask you to complete a short wellbeing diary (asking how you have felt that day) every day (for approximately 4 weeks). This will only take a few minutes each evening. You should start completing the wellbeing diaries on the day that you start completing the food diary and then continue completing them every day until we re-contact you. The wellbeing diaries will be provided in the form of a small weekly booklet each containing seven pages (one for each day). We will provide you with freepost envelopes so that you can return your completed wellbeing diary booklets to us on a weekly basis. When we have analysed your food diary we will be able to confirm your full eligibility to take part in the study. If you remain eligible we will contact you to arrange your next study visit. If you are not eligible to continue at this stage you will be informed of this, thanked for your time, and sent a £10 gift voucher to compensate you for your time and effort.

#### Test Meal Days (Visits 2 and 5)

If you are eligible to participate in the 12-week dietary intervention you will be asked to attend the HARU to be briefed on your 12-week diet plan by the study dietitian. You will be given detailed information on the diet we would like you to follow, along with recipes to try, and given some commercially available foods appropriate to your diet. You will also be given a set of scales, measuring spoons and a measuring cup to keep and to enable you to measure quantities and help you follow the recipes. The dietitian will give you advice on getting started on the diet and will support you over the next 12 weeks. This information will be provided on the first of your two test meal days.

On both test meal days you will also be required to consume a standard breakfast (cereal and milk plus tea or coffee) followed by a test meal (a moderate portion of ice cream) at lunch. The first test meal visit will take place in the week before you start the diet (week -1) and the second test meal visit will take place in the final week of the diet (week 12). Each test meal visit runs from approximately 8.30am to 4.00pm.

On the day before each test meal visit we will ask you to have nothing to eat or drink (except water) after 10pm. On the morning of each test meal day, after having had an overnight fast, you will need to visit the Phlebotomy Outpatient Clinic at Leeds General Infirmary (LGI) to have a fasting blood sample taken (the amount of blood needed will be less than two teaspoons). You will be given a study request card to show the staff at LGI. This blood sample will be used to measure your fasting levels of glucose, insulin, cholesterol (total cholesterol plus LDL and HDL), triglycerides (blood fats) and leptin (an appetite hormone which varies with body weight).

After the blood sample has been taken, you will need to come to the HARU before you eat or drink anything (except water). At the HARU we will measure your weight and waist circumference. We will also measure your body composition in two ways. The first method uses a technique called bioimpedance and requires you to stand on a machine, dressed but in your bare feet and to hold two hand-grips. This machine measures the amount of fat and muscle you have in your body by passing a small electric current through your body and measuring the resistance. This is completely safe, provided that you do not have a cardiac pacemaker fitted, and you will not be able to feel anything. The bioimpedance machine in the HARU is very similar to those which you might find in a commercial gym. The second method uses a machine called a 'BodPod'. This machine measures the amount of fat and muscle you will be required to wear a swimming costume (or other very tight-fitting clothing) and sit in the carbon fibre 'BodPod' whilst relaxing and breathing normally for 5 minutes. We will show you the 'BodPod' when you come for screening.

# Please remember to bring some tight-fitting clothing with you to this visit – a swimming costume is ideal. We will provide dressing gowns.

After having your body composition measured you will be asked to eat the breakfast provided. We will also ask you to complete four questionnaires; two questionnaires to assess your usual eating behaviour; one questionnaire to assess your sleep quality and one questionnaire on your feelings about your body shape. On your second test meal day (Visit 5, week 12) we will also ask you to complete a further questionnaire to assess your eating habits.

Before lunch on both test meal days, you will have a cannula fitted into a vein in your arm, in order to give 5 small blood samples (5mls per sample – equivalent to one teaspoon per sample) at specified times, before (1 sample) and after lunch (4 samples). These blood samples will be used to measure appetite hormones. At the same time as blood sampling we will also ask you to complete some ratings of your appetite (e.g. hunger). You will be taken to a room where a research nurse or a trained researcher will fit the cannula and take the first blood sample. Cannulas are designed to stay in the arm

in order to take multiple samples therefore minimising the number of times you need to have a needle put in. The cannula (a flexible tube, not a needle) will be fixed securely so you can move your arm and still move around as normal. You are advised to wear comfortable clothing which allows access to the arm (e.g. a short sleeved shirt/top). You will be asked to consume all of the test lunch after which the four blood samples will be taken (via the cannula) at 30 minute intervals for a period of 2 hours. Each blood sample is about a teaspoon and the total amount taken (25ml) is less than a quarter of what you would give if you are a blood donor. After the last of these measurements, the cannula will be removed by a research nurse or a trained researcher. Cannulation is usually a painless procedure, however there may be some minor discomfort or bruising at the cannulation site.

Before you leave the HARU on the first test meal day (Visit 2) we will provide you with food products tailored to the diet group to which you are randomised. The study dietitian will give you some dietary advice, recipes and other tips to help you follow the diet. We will also provide you with a 3-day food diary and ask you to complete and return this the following week. The 3-day food diary should be completed on 2 weekdays and 1 weekend day (ideally Thursday to Saturday or Sunday to Tuesday). You will be provided with more wellbeing diary booklets so that you can continue to complete these every day for the duration of the study. You will then be free to leave the HARU.

Before you leave the HARU on the second test meal day (Visit 5) we will provide you with a 3-day food diary and ask you to complete and return this the following week. The 3-day food diary should be completed on 2 weekdays and 1 weekend day (ideally Thursday to Saturday or Sunday to Tuesday as before). You will be provided with another wellbeing diary booklet if required and we will ask you to complete a page each day for the duration of the study (12 weeks).

#### Interim Visits (Visits 3 and 4)

On two occasions during the diet (weeks 4 and 8) you will need to visit the HARU for additional weight, waist and body composition (using bioimpedance) measurements. We will also ask you to complete two questionnaires, one to assess your sleep quality and one on your feelings about your body shape. You will also be provided with more food products and dietary advice and a further 3-day food diary to be completed and returned the following week. More wellbeing diary booklets will be provided at Visit 3 (for completion in weeks 5 to 8) and at Visit 4 (for completion in weeks 9 to 12). Each of these visits should not take more than an hour.

#### De-briefing Visit (Visit 6)

On completion of the study, after returning the last food diary and wellbeing diary booklets, you will be asked to complete a de-briefing questionnaire. If you wish, you will be given the details of the diet that you did not follow. This visit will take about 30mins.

#### **Optional Follow-up Visit**

One month after completion of the study you will be invited to an optional follow-up visit of about 30mins duration. If you choose to attend this visit, you will be weighed and have your waist circumference measured. We will also measure your body composition using the bioimpedance method. You will be asked to complete five questionnaires, one questionnaire to assess your eating habits, two questionnaires to assess your usual eating behaviour; one questionnaire to assess your sleep quality and one questionnaire on your feelings about your body shape.

#### What if something goes wrong?

In the unlikely event of a study-related bodily injury or harm, signing the consent form will protect your rights to compensation. If you wish to make a claim for compensation then please ask the researchers for information on how to proceed. If you are harmed due to someone's negligence you may have grounds for legal action, but you may have to pay for this. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study you should contact the principal investigators (Professor Louise Dye or Dr Clare Lawton) who will investigate your complaint. If you remain unhappy and wish to complain formally, this can be done through the University complaints procedure.

#### Will my taking part in the study be kept confidential?

All information that is collected from you during the course of the study will be treated in the strictest of confidence at all times and will only be used for the purposes of this research. After initially completing the consent form and recruitment questionnaire you will be given a unique study identity code. All data will then be recorded safely using this code and not your name. The link between your name (and other personal data) and your unique study identity code will be maintained and stored securely in the HARU at The University of Leeds and will only be accessible to the University research team. Anything that you say will be treated in confidence and no names will be mentioned in any reports of the study. Some results from the study will be used towards an educational qualification by a member of the research team. Individuals will not be identifiable from any details in reports, presentations or scientific publications based on the results of the study. With your permission, we will inform your GP that you are taking part in this study.

#### What will happen to the results of the research study?

Once all participants have completed the study, the information obtained will need to be collected and analysed before any results are published. This is likely to take at least one year to be finalised. If you would also like to know the results of the study, the research team will be able to give this information to you when it becomes available. You will not be identified in any report or publication.

#### What will happen to the blood samples I give?

The blood samples that you give will be separated into plasma or serum and will be analysed by our collaborators at Leeds General Infirmary and Imperial College London. Any unused plasma or serum and all the red blood cells will be destroyed. There will be no genetic testing carried out on the samples. Your samples will only be labelled with your unique study identity code, date and time so you will not be identifiable from these samples. The researchers analysing your blood samples will not have access to the link between your name and your unique study identity code.

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

If you decide at any time that you no longer wish to take part in the study, you will be free to withdraw without having to give a reason for this. If you decide to drop out before completing the study you will be invited to a final visit at which we would like to obtain some final data from you (i.e. your body weight, composition and waist circumference). Attendance at this final visit is entirely optional and you may decline to attend without having to give a reason.

We would like to use the data and the blood samples that you provide, up until the point at which you drop out but we will give you the opportunity to withdraw your data and samples from the study analysis if you so wish.

#### Who is organising and funding the research?

The research is a collaboration between the HARU, University of Leeds and colleagues at Leeds General Infirmary and Imperial College London. The research will be carried out with financial support from a food manufacturing company.

#### Who has reviewed this study?

All research is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by South Humber NHS Research Ethics Committee.

### Who do I contact for further information?

If you want further information about this study or information regarding this research or in the event of an emergency or if you need extra advice please contact one of the following researchers:

Diana Camidge (d.c.camidge@leeds.ac.uk; 0113 3435753)

Iria Myrissa (<u>k.myrissa@leeds.ac.uk</u> 0113 3435753)

Fiona Croden (f.c.croden@leeds.ac.uk; 0113 3435753)

Dr Clare Lawton (c.l.lawton@leeds.ac.uk; 0113 3435741)

Professor Louise Dye (<u>I.dye@leeds.ac.uk;</u> 0113 3435707)

Finally, thank you for taking the time to read this informa

## Appendix 3.3 Demographic Information Questionnaire (DIQ)

# DEMOGRAPHIC INFORMATION

CONT	ACT INFORMATION	
	Other	
	Word of Mouth	
	Poster advert	
How did you find out about the study?	Contacted by us	
Date of contact / /	Researcher	

Name	
Address	
Contact phone number	
E-mail	
Dept	
Date of Birth//	Age
Measured height	Measured weight

Measured BMI
Name of GP
Address of GP Practice

With your permission, we will use this information to inform your GP that you are taking part in the study

	G	ENERA	L INFORMATI	ON		
Occupation	Employed		Unemployed			
	Retired	pus	ewife			
	Student		Other			
Hours of work	<ul><li>Full time/ Pa</li></ul>	rt time				
Night shifts - `	Yes/No Details					
Holidays planned or booked over next 6 months? Yes/No						
Dates						
			HEALTH			
How would you rate your general health? Do you have or have you had any medical conditions? (i.e. heart condition, asthma,						
diabetes)						
Current medi	cations					
Do you have a	a cardiac pacem	naker fitte	ed?	Yes/No		

	4	11					
	Yes						
	Given up	How I	ong ago?				
EXERCISE							
Do you do regular exercise	e? Yes / No						
If yes, how many times a v	week do you exercise?	? One to four					
		More	than four				
What type of exercise do	you do?						
If none, are you planning t	to start doing regular	exercise in the	next 4 month	s?			
Details							
PREGNANCY							
Are you currently pregnan	nt or planning a pregn	ancy this year?	Yes / No				
Have you had a baby or ha	ave you been pregnan	nt in the last 6 r	nonths? Yes/	No			
Date of delivery (if applica	ble) / /						
Have you breast fed in the	e last 6 months?	Yes / No					
MENOPAUSAL SYMPTOM	IS						
Do you think you have rea							
period for 12 months of m	nore)						
Are you taking/ have you	taken hormone replac	cement therapy	/ (HRT)?				
What was the date of your last period?							
How many periods have you had in the last 12 months?							
Are you experiencing hot	flushes?	Yes / No	How often .				
Are you experiencing nigh	t sweats?	Yes / No	How often .				
DIET							

Are you vegetarian	Yes / No	If yes are you Vegan	Yes / No
		o not like or could not ea	
	••••••		
Do have any food sensit	tivities or food a	Illergies?	
Do you normally consur	ne breakfast?	Yes / No	
Are you willing to eat b	reakfast as part	of the study? Yes / N	۷٥
How many times per we	eek do you cons	ume breakfast?	
What do you normally o	consume for bre	akfast	
Does it differ at the wee	ekends? Yes / N	١o	
Details			
How many units of alco	hol do you usua	lly drink per week?	
N.B. 1 small (125mls) gl	ass of wine or h	alf a pint of lager or 1 sh	ot of spirits = 1 unit
Has your weight varied	within the last 3	3 months? Yes / No	
If yes by how much?			
Are you currently on an	y form of a wei	ght loss diet? Yes / No	
Details			

## **OTHER INFORMATION**

Can we keep this information on file and contact you about future studies? Yes / No

Inclusion visit arranged for Date \_\_\_\_\_ / \_\_\_\_\_

ADDITIONAL NOTES

# Appendix 3.4 Standard operating procedures for introducing Diet A at inclusion phase (week -1)

#### Introduction

Bring the Study LWW bag containing products (list of products and allergies), Jill Dupleix recipe book, British Heart Foundation booklet, measuring cups, spoons, scales, WDBs (for Diet A) and a 3 day food diary and freepost return envelope. Thank you for coming in today. This study bag is for you to keep and it contains things that will help you to follow the diet. As you know we have developed two healthy eating diets for this study and we are asking participants to follow one of them for 12 weeks and I'll just explain to you about your allocated diet. I can't give you any details about the other diet now but we can give you this diet information once you have finished the study.

• Allocation

You have been allocated by chance to Diet A. An independent statistician randomly allocated you to Diet A using a computer programme and we have no control over which diet you are allocated to. So by being allocated to Diet A means that you will need to follow our healthy eating advice for 12 weeks.

• Diet A and the BHF booklet

The booklet highlights the benefits of eating a healthy diet in order to reduce the risk of developing heart disease, some cancers, obesity, diabetes, arthritis and high blood pressure. It contains sample eating plans, advice on shopping and cooking, together with a selection of healthy eating recipes.

# Show the BHF booklet to the ppts and talk through and expand on the BHF healthy guidelines:-

According to the British Heart Foundation (BHF) booklet, a healthy balanced diet should

- 1. Contain plenty of fruit and vegetables (5 portions a day). Ideally 2 fruit and 3 vegetables.
- 2. Base your meals on starchy foods (Bread, cereals and potatoes). Gram for gram starchy foods contain less than half the calories of fat.
- 3. Eat more fish. Aim for at least 2 portions of fish a week (1 should be oily fish salmon, herring, trout, mackerel, fresh tuna, sardines)
- 4. Eat or drink moderate amounts of dairy foods (milk, cheese, yogurt). Choose lower fat versions e.g. use semi-skimmed milk, low fat yogurt/cheeses. Intake of saturated fat should be avoided.
- 5. Eat moderate amounts of meat. Choose lower fat versions e.g. poultry without the skin, cut off visible fat, drain fat from cooking juices and cook without added fat. Beans and pulses are a good alternative to meat.

- 6. Cut down on saturated fat and sugar. Reduce the amount of cakes, crisps, chocolate, ice-creams, biscuits, sweets and desserts. Try to eat less salt <6g per day. Don't add salt to your food or cooking water.
- 7. Drink plenty of water. Avoid drinking fizzy drinks which are high in added sugar. Cut down on your alcohol consumption. Alcohol has a high calorie content and drinking heavily can increase the risks of health problems. Women can drink up to 2-3 units of alcohol per day without significant risk to their health. A unit is half pint of beer/lager and a glass of wine is 2 units.

We'd like you to follow these dietary guidelines during the 12 week study and we'll ask you to complete a 3 day diary every 4 weeks so we can see how you're getting on. Don't be afraid to ask for help and advice whenever you need it. Its important to be as accurate and precise as possible when completing the food diaries

<u>Recipe books</u>

BHF booklet and Jill Dupleix recipe book

These are complimentary recipe books to help you prepare some healthy eating meals. Go through the books with them and ask them about their current cooking habits and encourage them to make their own recipes from the books and to follow the BHF booklet guidelines.

• <u>Products</u>

#### Show the list of products and allergies

Here is the list of products that you can choose from to consume during the 12 week study. They are breakfast cereals and snack bars. If you don't usually eat cereal for breakfast then we'd like you to do so on this study. We want you to replace your usual breakfast foods and snacks and are supplying you with free breakfast cereals for your convenience. *Talk about the importance of eating cereal for breakfast*. To help you in your healthy eating plan it's a good idea to have breakfast every day using the food products we have given you.

# Show the participant how to use the measuring cups and scales in order to get an accurate amount.

• Week 1

So you have completed the run in phase to the study and this is now Week 1 of the study and you need to start the diet from tomorrow morning. Please complete the 3 day food diary during the next week (over 2 week days and 1 weekend day) and send this back to us using the freepost return envelope or drop off at the HARU lab.

Show the participant the WDB for Diet A (they should be familiar with it but check if they had any problems completing it). You also need to complete a well being diary every day for 4 weeks. You need to start this as soon as you start the diet tomorrow. Bring them back to us on your next visit. We need to arrange another visit in 4 weeks time. Arrange a date. We will phone to remind you 2-3 days beforehand.

Please contact us at any time if you have any queries or problems from following the diet. *Make sure they have the lab/office phone number and email address.* 

# Appendix 3.5 Standard operating procedures for introducing Diet B at inclusion phase (week -1)

• Introduction

Bring the Study LWW bag containing products (list of products and allergies), scales, recipe book, measuring cups, spoons, WDBs (for diet B), BHF booklet, FIT table and a 3 day food diary and return envelope.

Thank you for coming in today. This study bag is for you to keep and it contains things that will help you follow the diet. As you know we have developed two healthy eating diets for this study and we are asking participants to follow one of them for 12 weeks and I'll just explain to you about your allocated diet. I can't give you any details about the other diet now but we can give you this diet information once you have finished the study.

• <u>Allocation</u>

An independent statistician randomly has allocated you to Diet B. So by being allocated to Diet B means that you will need to follow our healthy eating advice for 12 weeks and gradually increase your fibre intake to the recommended daily amount of 25g per day.

# Show the BHF booklet to the ppts and talk through and expand on the BHF healthy guidelines:-

The booklet highlights the benefits of eating a healthy diet in order to reduce the risk of developing heart disease, some cancers, obesity, diabetes, arthritis and high blood pressure. It contains sample eating plans, advice on shopping and cooking together with a selection of healthy eating recipes.

According to the British Heart Foundation (BHF) booklet, a healthy balanced diet should

- 8. Contain plenty of fruit and vegetables (5 portions a day). Ideally 2 fruit and 3 vegetables.
- 9. Base your meals on starchy foods (Bread, cereals and potatoes). Gram for gram starchy foods contain less than half the calories of fat.
- 10. Eat more fish. Aim for at least 2 portions of fish a week (1 should be oily fish salmon, herring, trout, mackerel, fresh tuna, sardines)
- 11. Eat or drink moderate amounts of dairy foods (milk, cheese, yogurt). Choose lower fat versions e.g. use semi-skimmed milk, low fat yogurt/cheeses. Intake of saturated fat should be avoided.
- 12. Eat moderate amounts of meat. Choose lower fat versions e.g. poultry without the skin, drain fat from cooking juices and cook without added fat. Beans and pulses are a good alternative to meat.
- Diet B and Dietary Fibre

Along with following these healthy guidelines we want you to increase your daily dietary fibre intake. The recommended intake of fibre is a minimum of 25g per day. However, most people especially women don't eat enough dietary fibre and foods rich in fibre are a very healthy choice. So in order to follow Diet B we want you to increase your dietary fibre intake to these levels.

Dietary Fibre is only found in foods that come from plants. There are two types - insoluble and soluble. Insoluble fibre cannot be digested by the body and so it passes through the gut helping other food and waste products move through the gut more easily. It keeps the bowels healthy and foods rich in this sort of fibre are more bulky and more likely to make us feel fuller. Insoluble fibre is found in wholegrain bread, brown rice, breakfast cereals and fruit and vegetables. Soluble fibre can be partially digested and may help to reduce the amount of cholesterol in the blood and it is also protective against cardio vascular disease and diabetes. Good sources of soluble fibre include fruit, oats and pulses such as beans and lentils. By increasing your dietary fibre intake you may experience an increase in flatulence. Your body will adapt to this increase and drinking more water will help.

• Participants current dietary fibre intake

### Refer to their baseline 7 day food diary, DINE, LWW DINE and FIT table.

From looking at your food diary your current fibre intake is ....g per day which is quite low / not bad / but there is room for improvement. We need you to increase your dietary fibre gradually over the 12 weeks and aim to reach 25g/day by week 8. It is important to increase your fibre intake gradually to minimise flatulence and discomfort. (*this will depend on the participants baseline intake and we can use the FIT to advise them – check before the participant arrives and plan the next 4 weeks fibre increase*). *Give them their own FIT table to follow.* 

• Fibre Points

To help you increase your dietary fibre and to calculate how much you are eating we want you to count and record your fibre points every day. One gram of fibre equals one fibre point. To help you calculate this if you look at the nutritional information on a food product you will always find information about fibre measured in grams either per 100g of the product or per slice or per serving. E.g. one slice of wholemeal bread contains 3 grams of fibre therefore you would get 3 fibre points. If you cannot find this information we have put together a table of foods in this recipe book for you to find it. *Show the recipe book* 

• Fibre points and recipe book

In this book we have listed food products with their fibre points. Use this table to calculate your fibre points. If you cannot find the product and the nutritional information is not listed on the packet then please write down in the wellbeing diary booklet on the appropriate day as much information about the food product as possible or bring the packet to us if you can. *Show the dietary fibre nutritional information on some packets of food and how to work out the fibre points. Encourage them to read food packets.* 

It's really important that we get all the information about the fibre that you are consuming daily so please contact us at any time if you have any queries or concerns about the food you consume. If in doubt please ask us.

Fibre products

We want you to increase your fibre intake by increasing the amount of cereal fibre that you currently consume. Here are some high fibre cereal products and bars that we would like you to have for breakfast and /or snacks during the day. The high fibre cereal can also be added to your food (see recipe book). *Show the recipe book and list of products and allow them to choose 3 cereals and give them 2 high fibre cereals which must be consumed.* 

This book contains information about fibre and also contains high fibre recipes. It is just a guide for you to see that you can increase your fibre very easily and you don't need to make big changes. A good way of achieving this is to make your own meals using some of the recipes in this book by adding fibre to the meals. Its good for all the family to have a higher fibre diet but be careful not give children under 5 too much fibre if they are not used to it. You don't need to necessarily make all the foods in the book but we'd like you to have a go at making some of them. It might be an idea to make batches of the meals and freeze them. *Go through the recipe book with them and explain about adding fibre to the recipes. Show the meal plans in the recipe book and discuss what they could do in week 1 and then how they could increase intake in weeks 3 and 4. Discuss the types of things they usually make and what they can make from the fibre recipe book. Encourage them to cook more of their own meals and rely less on pre-packed foods. Emphasise the BHF booklet guidelines.* 

- <u>Tips</u>
- 1. To help you to reach your target we recommend that you have a bowl of high fibre cereal every morning.
- Alternatively you can add some of the high fibre cereal to your usual cereal or the cereal we provide and maybe work up to a full bowl of high fibre cereal over time.
   Show the participants how to use the measuring cups and scales in order to get an accurate amount.
- 3. One 250ml cup of High Fibre cereal =19 fibre points, 125ml = 11 points, 85ml = 7 points and 65ml =5 points.
- 4. If you are still hungry and have not met your fibre points then its a good idea to have a bowl of one of the high fibre cereals at the end of the day.

# Use their baseline diary to see where/when they can replace their usual snacks with the study products

- 5. Replace your usual snacks with high fibre cereal bars but its important not to eat them as well as your usual snacks.
- <u>Week 1</u>

So you have completed the run in phase to the study and this is now Week 1 of the study and you need to start the diet from tomorrow morning. Please complete the 3 day food diary over the next week (over 2 week days and 1 weekend day) and send this back to us using the freepost return envelope or drop off at the HARU lab.

You also need to complete a well being diary every day for throughout the study. This is the same well being diary that you have completed previously but you just need to keep a track of the amount of fibre points you are having. *Show the participant the WDB for diet B and explain how and where to complete the fibre points table.* 

Show the ppt the stool form questionnaire in the WDB again and tell them not to be embarrassed by it if they have lots of stools. Please bring them back to us on your next visit. We need to arrange another visit in 4 weeks time. Arrange a date. We will phone to remind you of the visit 2-3 days beforehand.

Please contact us if you have any queries or problems from following the diet. *Make sure they have the lab/office phone number and email address.* 

#### Appendix 3.6 Fibre Intake Table

#### **Fibre table Instructions**

In order to minimise adverse responses to a high fibre diet, the fibre points consumed each day should be increased on a weekly basis following the increments in the table below.

The baseline levels (column 0) for each volunteer will be calculated from the 7 day diary.

For example, if a person's initial fibre intake is 6g/day, they should increase to 7g/day in week 1, 8g/day in week 2, 10g/day in week 3 and so on.

If a participant has a baseline level of 15 then by week 8 they will reach a maximum of 37g per day. By week 8 all participants should be on the minimum fibre intake requirement of 25g per day or above.

Participants will be trained to increase their fibre intake to a minimum of 25g per day using a points-based system.

Participants will be encouraged to eat high fibre breakfast cereals and to incorporate wheat bran fibre in other meals

Week of study												
0	1	2	3	4	5	6	7	8	9	10	11	12
15	17	18	20	22	25	29	33	37	37	37	37	37
14	15	17	19	20	23	27	30	35	35	35	35	35
13	14	16	17	19	22	25	28	32	32	32	32	32
12	13	15	16	18	20	23	26	30	30	30	30	30
11	12	13	15	16	18	21	24	27	27	27	27	27
10	11	12	13	15	17	19	22	25	25	25	25	25
9	10	11	12	13	15	18	21	25	25	25	25	25
8	9	10	11	13	15	18	21	25	25	25	25	25
7	8	9	10	12	14	17	21	25	25	25	25	25
6	7	8	10	11	14	17	20	25	25	25	25	25
5	6	7	8	10	13	16	20	25	25	25	25	25
4	5	6	7	9	12	15	19	25	25	25	25	25
3	4	5	6	8	11	14	19	25	25	25	25	25
2	3	4	5	7	9	13	18	25	25	25	25	25

#### Appendix 3.7 Wellbeing Diary Booklets (WDBs)

Wellbeing Diary Booklets

Volunteers will be shown the Wellbeing Diary Booklets at visit 1 and given a full briefing on how they should be completed. They will all be shown the Bristol Stool Form Scale (see below) and the Diet B group will also be shown examples of typical fibre points records and given advice on how to complete this section.

Instructions for Baseline/ Diet A: Healthy Eating

Please complete this booklet on a daily basis.

We suggest you complete the first section on sleep in the morning when you get up and then keep the diary with you in your handbag and fill in the bowel function section referring to the picture guide after every bowel movement.

The wellbeing section should be filled in just before you go to bed as the questions ask about how you have felt across the whole day.

**Don't forget to make a note of anything else you have experienced during the day in the** other information **section.** 

Instructions for Diet B: High Fibre and healthy Eating

Please complete this booklet on a daily basis.

We suggest you complete the first section on sleep in the morning when you get up and then keep the diary with you in your handbag and fill in the fibre points record and the bowel function referring to the picture guide after every bowel movement as the day goes on.

The wellbeing section should be filled in just before you go to bed as the questions ask about how you have felt across the whole day.

**Don't forget to make a note of anything else you have experienced during the day in the** other information **section.** 

#### Baseline / Diet A version

#### **Bowel Function**

Please refer to the diagram on the inside cover of this booklet for stool type

Day: M T W T F Sa Su Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time of completion: \_\_\_\_: \_\_\_(am/pm)

Do you have your period today No  $\ni$  Yes  $\ni$  If Yes, when did it start? \_\_\_\_/\_\_\_\_

Time	Туре	Quantity	(tick)		Comments			
		< average	average	> average				

Sleep

How long did you sleep last night?

\_\_\_\_\_ hours \_\_\_\_\_ mins

How many times did you wake up in the night last night?

Э

How easy did you find it to get to sleep last night? (please

circle)

1 2 3 4 5 6 7

Not at all easy moderately easy extremely easy

How rested did you feel when you got up this morning? (please circle)

 1
 2
 3
 4
 5
 6

 7
 Mot at all rested

moderately rested

extremely rested

Wellbeing

Please indicate the extent to which you have experienced the following feelings/symptoms today by ticking the box that best describes your experience.

0 1 2 3 4 None Minimal Moderate A lot/Very Extreme

 [2]
 [3]
 [4]

 Wind
 Preast tenderness
 Preast tenderness

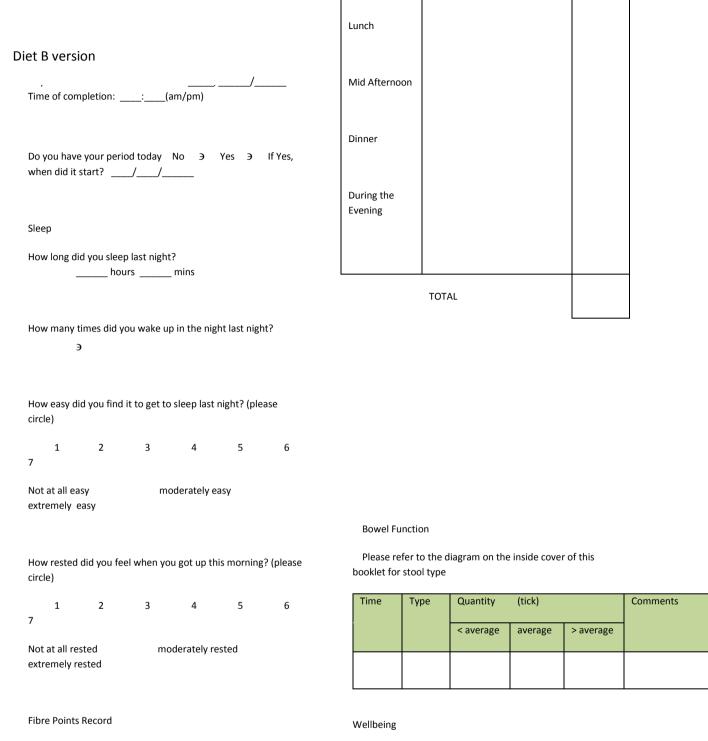
 Preast tenderness
 Preast Pr

Feeling slim				Э	Э	Э	Э	Э
Constipation	Э	Э	Э	Э	Э			
Indigestion				Э	Э	Э	Э	Э
Feeling happy	Э	Э	Э	Э	Э			
Stress	Э	Э	Э	Э	Э			
Bloating	Э	Э	Э	Э	Э			
Mental tiredness	Э	Э	Э	Э	Э			
Headaches	Э	Э	Э	Э	Э			
Feeling energetic	Э	Э	Э	Э	Э			
Feeling fat	Э	Э	Э	Э	Э			
Difficulty concentrating				Э	Э	Э	Э	Э
Bowel pain/cramp	Э	Э	Э	Э	Э			
Physical tiredness	Э	Э	э	Э	Э			

Other information

Please use this space to make a note of anything else you have felt/noticed today.

#### Diet B version



4

Time	Foods Consumed (fibre containing foods only)	Points
Breakfast		
Mid Morning		

Please indicate the extent to which you have experienced the following feelings/symptoms today by ticking the box that best describes your experience.

0 1 2 3

None Minimal Moderate A lot/Very Extreme

[2] [3] [4]							[0]	[1]
Wind	Э	Э	Э	Э	Э			
Breast tenderness	Э	Э	Э	Э	Э			
Mental alertness	Э	Э	Э	Э	Э			
Feeling slim				Э	Э	Э	Э	Э
Constipation	Э	Э	Э	Э	Э			
Indigestion				Э	Э	Э	Э	Э
Feeling happy	Э	Э	Э	Э	Э			
Stress	Э	Э	Э	Э	Э			
Bloating	Э	Э	Э	Э	Э			
Mental tiredness	Э	Э	Э	Э	Э			
Headaches	Э	Э	Э	Э	Э			
Feeling energetic	Э	Э	Э	Э	Э			
Feeling fat	Э	Э	Э	Э	Э			
Difficulty concentrating				Э	Э	Э	Э	Э
Bowel pain/cramp	Э	Э	Э	Э	Э			
Physical tiredness	Э	Э	Э	Э	Э			

#### Other information

Please use this space to make a note of anything else you have felt/noticed today.

# Bristol Stool Form Scale

Hard to	Туре 1	Separate hard lumps, like nuts (hard to pass)	
pass	Type 2	Sausage-shaped but lumpy	
• Ideal	Туре З	Like a sausage but with cracks on its surface	Charles P
consistency	Type 4	Like a sausage or snake, smooth and soft	
	Type 5	Soft blobs with clear cut edges (passed easily)	
<ul> <li>Difficult to control</li> </ul>	Type 6	Fluffy pieces with ragged edges, a mushy stool	
	Type 7	Watery, no solid pieces. Entirely liquid	

## **Eating Habits Questionnaire**

#### <u>Purpose</u>

The purpose of this questionnaire is to get an idea of your usual eating habits. For the listed foods, we would like to know how many servings you eat in a typical day or week. A serving is an average portion that would be served at a meal. If you usually eat more than one serving of the food at a time, you should count all the servings you eat.

#### **Instructions**

For each food listed, tick the box that describes the number of servings that you usually eat. If you never eat a particular food, tick the box under "None". Do not leave any line

ID number		
DF score		
TF score		
UF score		

About how many **pieces or slices a day** do you eat of the following types of bread, rolls, or chapattis? (Please tick one box on each line)

	Breads & Rolls		Less than 1 a day	1 to 2 a day	3 to 4 a day	5 or more a day
1.	White bread or rolls					
2.	Brown or granary bread or rolls					
3.	Wholemeal bread or rolls					

Г

	About how many <b>servings a week</b> do you eat of the following types of breakfast cereal or porridge? (Please tick one box on each line)								
	Breakfast cereals	None	Less than 1 a week	1 to 2 a week	3 to 5 a week	6 or more a week			
4.	<u>Sugared type</u> : Frosties, Coco Pops, Ricicles Sugar Puffs <u>Rice or Corn type</u> : Corn Flakes, Rice Krispies, Special K								
5.	<u>Porridge</u> or Ready Brek <u>Wheat type</u> : Shredded Wheat, Weetabix, Fruit 'n Fibre, Puffed								

	Wheat, Nutri-grain, Start <u>Muesli type</u> : Alpen, Jordan's			
6.	<u>Bran type</u> : All-Bran, Bran Flakes, Sultana Bran			

	About how many <b>servings a week</b> do you eat of the following foods? (Please tick one box on each line)								
	Vegetable foods	None	Less than 1 a week	1 to 2 a week	3 to 5 a week	6 to 7 a week	8 to 11 a week	12 or more a week	
7.	Pasta or rice								
8.	Potatoes								
9.	Peas								
10.	Beans (baked, tinned, or dried) or lentils								
11.	Other vegetables (any type)								
12.	Fruit (fresh, frozen, canned)								

About how many <b>servings a week</b> do you eat of the following foods? (Please tick one box on each line)									
		None	Less than 1 a week	1 to 2 a week	3 to 5 a week	6 or more a week			
13.	Cheese (any except cottage)								
14.	Beef burgers or sausages								
15.	Beef, pork, or lamb (for vegetarians: nuts)								
16.	Bacon, meat pie, processed meat								
17.	Chicken or turkey								
18.	Fish (NOT fried fish)								
19.	ANY fried food: fried fish, chips, cooked breakfast, samosas								
20.	Cakes, pies, puddings, pastries								
21.	Biscuits, chocolate, or crisps								
		None	Less than 1 a week	1 to 2 a week	3 to 5 a week	6 or more a week			

	About how much of the following types of milk do you yourself use <b>in a day</b> , for example in cereal, tea, or coffee? (Please tick one box on each line)								
Milks   None   a quarter   quarter					1 pint or more				
22.	Full cream (silver top) or Channel Islands (gold top)								
23.	Semi-skimmed (red striped top)								
24.	Skimmed (blue checked top)								

	About how many <b>rounded teaspoons a day</b> do you usually use of the following types of spreads, for example on bread, sandwiches, toast, potatoes, or vegetables?									
	Spreads	None	1 a day	2 a day	3 a day	4 a day	5 a day	6 a day	7 or more	
25.	Regular margarine or butter or Reduced fat spread such as sunflower or olive spread, Flora, Vitalite, Clover, Golden Churn, Olivio, Stork, Utterly Butterly, Pure									

	Low fat spread such as				
26	Flora Light, St. Ivel Gold, Half-fat				
26.	butter, Olivite, Flora Pro-activ, Diet				
	Clover				

	What type of fat do you usually use for the following purposes? (Please tick one box on each line)								
		Butter, lard, or dripping	Solid cooking fat (White Flora, Cookeen) Half-fat butter Hard margarine (Stork)	Soft margarine (sunflower, soya) Reduced fat spread (olive, Flora Buttery, Olivio)	Vegetable oil or Low fat spread (Flora Light, Olivite, St. Ivel Gold)	No fat used			
27.	On bread and vegetables								
28.	For frying								
29.	For baking or cooking								

Thank you for completing the Eating Habits Questionnaire.

Please go back and check that you have ticked one box on every line.

### Appendix 3.9 LWW – DINE

A new scoring system has been designed to enable us to use the DINE questionnaire as a basis to get a daily fibre intake estimate in g's using current (AOAC) fibre contents. Use this sheet as an interview guide to estimate the scores to enter into the Excel scoring file.

#### 1. Breads and Rolls

Ask about the types of bread they buy or eat on a regular basis and use the questions below to find out how much bread they eat in an average week.

What types of bread do you regularly buy?

(medium or thick sliced?)

Questions to ask	Frequency per week	Type of bread	Number & size of slices	Average per week
How many times a week do you have bread/toast at breakfast?				
How many times a week do you have bread/rolls at lunch?				
How many times a week do you have bread/rolls at dinner?				
How many times a week do you have bread/rolls in between meals?				
How often do you have other types of bread i.e. chapatti, rye, bagels, crispbreads				

**Scoring** - use the information above to estimate how many slices of each type of bread they consume each week. High fibre white or soft grain bread is scored as brown/granary. Use portion size 1 for medium bread and 1.5 for thick sliced bread. Multiply frequency by portion size to get total.

Breads & Rolls	Average per week	Portion size	Total
White			
Brown/Granary			
Wholemeal			

#### 2. Breakfast Cereal

Ask about the types of breakfast cereals they buy or eat on a regular basis and use the questions below to find out how much cereal they eat in an average week.

What types of cereals do you regularly buy?

Type of cereal	Type of cereal	Frequency per week	Portion size
Cereal eaten at breakfast?			
Cereal eaten at other times of day?			

**Scoring** - use the information above to estimate how much of each type of cereal they consume each week. Use 1 for average portion size and 1.5 for large portion size. Multiply frequency by portion size to get total (this does not need to be a whole number).

Frequency per week	Portion size	Total
	Frequency per week	Frequency per week     Portion size       Image: state

#### Other foods

Type of food	Frequency per week	Portion size	Total
White pasta			
Wholewheat pasta			
White rice			
Brown rice			
Potatoes			
Peas			
Beans (baked, tinned or dried) or lentils			
Other vegetables (any type)			
Fruit (fresh, frozen or canned)			

Use 1 for average portion size and 1.5 for large portion size. Multiply frequency by portion size to get total.

## Appendix 3.10 – Eating Attitudes Test -26

Please answer the following questions as accurately and honestly as possible. Please tick one response for each of the following statements.

	Always	Usually	Often	Sometimes	Rarely	Never
1. I am terrified about being overweight.	0	0	0	0	0	0
2. Avoid eating when I am hungry.	0	0	0	0	0	0
3. Find myself preoccupied with food.	0	0	0	0	0	0
4. Have gone on eating binges where I feel I may not be able to stop.	0	0	0	0	0	0
5. Cut my food into small pieces.	0	0	0	0	0	0
6. Aware of calorie content of foods that I eat.	0	0	0	0	0	0
7. Particularly avoid food with a high carbohydrate content (i.e., bread, rice, potatoes, etc.)	0	0	0	0	0	0
8. Feel that others would prefer if I ate more	0	0	0	0	0	0
9. Vomit after I have eaten	0	0	0	0	0	0
10. Feel extremely guilty after eating.	0	0	0	0	0	0
11. Am preoccupied with a desire to be thinner.	0	0	0	0	0	0
12. Think about burning calories when I am exercising.	0	0	0	0	0	0

13. Other people think I am too thin.	0	0	0	0	0	0
14. AM preoccupied with the thought of having fat on my body.	0	0	0	0	0	0
15. Take longer than others to eat meals.	0	0	0	0	0	0
16. Avoid foods with sugar in them.	0	0	0	0	0	0
17. Eat diet foods	0	0	0	0	0	0
18. Feel that food controls my life.	0	0	0	0	0	0
	Always	Usually	Often	Sometimes	Rarely	Never
19. Display self-control about food	Always 0	<b>Usually</b> 0	Often 0	Sometimes 0	Rarely 0	Never 0
	_	_			_	
food 20. Feel that others pressure	0	0	0	0	0	0
food 20. Feel that others pressure me to eat. 21. Give too much time and	0	0	0	0	0	0
food 20. Feel that others pressure me to eat. 21. Give too much time and thought to food. 22. Feel uncomfortable after	0 0 0 0	0 0 0 0	0	0	0 0 0 0	0 0 0 0
food 20. Feel that others pressure me to eat. 21. Give too much time and thought to food. 22. Feel uncomfortable after eating sweets 23. Engage in dieting	0 0 0 0 0 0	0 0 0 0 0 0	0 0 0 0 0	0 0 0 0	0 0 0 0 0 0	0 0 0 0 0 0 0
food 20. Feel that others pressure me to eat. 21. Give too much time and thought to food. 22. Feel uncomfortable after eating sweets 23. Engage in dieting behaviours. 24. Like my stomach to be	0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0

# Appendix 3.11 Dutch Eating Behaviour Questionnaire (DEBQ)

INSTRUCTIONS – Please answer the following questions as carefully and honestly as possible. Read each question and simply tick the circle which best applies to you.

		Never	Seldom	Sometimes	Often Very Often
1. If you have put on weight, do you eat less than you usually do?	0	0	0	0	0
2. Do you have a desire to eat when you are irritated?	0	0	0	0	0
3. If food tastes good to you, do you eat more than you usually do?	0	0	0	0	0
4. Do you try and eat less at mealtimes than you would like to eat?	0	0	0	0	0
5. Do you have a desire to eat when you have nothing to do?	0	0	0	0	0
6. Do you have a desire to eat when you are fed up?	0	0	0	0	0
7. If food smells and looks good, do you eat more than you usually do?	0	0	0	0	0
8. How often do you refuse food or drink offered because you are worried about how much you weigh?	0	0	0	0	0

•

9. Do you have a desire to eat when you are feeling lonely?	0	0	0	0	0
10. If you see or smell something delicious, do you have a desire to eat it?	0	0	0	0	0
11. Do you watch exactly what you eat?	0	0	0	0	0
12. Do you have a desire to eat when somebody disappoints you?	0	0	0	0	0
13. If you have something delicious to eat, do you eat it straight away?	0	0	0	0	0
14. Do you deliberately eat foods that are slimming?	0	0	0	0	0
15. Do you have a desire to eat when you are cross?	0	0	0	0	0
16. Do you have a desire to eat when you are expecting something to happen?	0	0	0	0	0
17. If you walk past the baker do you have a desire to buy something delicious?	0	0	0	0	0
	Never	Seldom	Sometimes	Often	Very Often
	0	0	0	0	0

18. When you have eaten too much do you eat less than usual on the following days?				
19. Do you get a desire to eat when you are anxious, worried or tense?	0	0	0 0	0
20. If you walk past a snack bar or café, do you have a desire to buy something delicious?	0	0	0 0	0
21. Do you deliberately eat less in order not to become heavier?	0	0	0 0	0
22. Do you have a desire to eat when things are going against you or when things have gone wrong?	0	0	0 0	0
23. If you see others eating, do you also have a desire to eat?	0	0	0 0	0
24. How often do you try not to eat between meals because you are watching your weight?	0	0	0 0	0
25. Do you have a desire to eat when you are frightened?	0	0	0 0	0
26. Can you resist eating delicious foods?	0	0	0 0	0
27. How often in the evening do you try not to eat because you are watching your weight?	0	0	0 0	0

28. Do you have a desire to eat when you are disappointed?	0	0	0 0	0
29. Do you eat more than usual when you see others eating?	0	0	0 0	0
30. Do you think about how much you weigh before deciding how much to eat?	0	0	0 0	0
31. Do you have a desire to eat when you are upset?	0	0	0 0	0
32. When you see someone preparing a meal, does it make you want to eat something?	0	0	0 0	0
33. Do you have a desire to eat when you are bored or restless?	0	0	0 0	0

## **EATING INVENTORY**

If you disagree with a statement, or if you feel that it is false as applied to you, circle the F next to the statement.

1)	When I smell a sizzling steak or see a juicy piece of meat I find			
	it very difficult to keep from eating, even if I have just			
	finished a meal		т	F
2)	I usually eat too much at social occasions, like parties			
	and picnics.	т	F	
3)	I am usually so hungry that I eat more than 3 times a day.	т	F	
4)	When I have eaten my quota of calories I am usually very good			
	about not eating any more.		т	F
5)	Dieting is so hard for me because I just get too hungry.		т	F
6)	I deliberately take small helpings as a means of controlling my			
	weight.		т	F
7)	Sometimes things just taste so good that I keep on eating, even			
	when I am no longer hungry.	т	F	

8) Since I am often hungry, I sometimes wish that while I am

eating an expert would tell me that I have had enough or that I can have something more to eat. т F 9) When I feel anxious I find myself eating. Т F 10) Life is too short to worry about dieting. Т F 11) Since my weight goes up and down, I have gone on reducing F diets more than once. Т 12) I often feel so hungry I just have to eat something. т F 13) When I am with someone who is overeating I usually overeat too. T F 14) I have a pretty good idea of the number of calories in common foods Т F 15) Sometimes when I start eating, I just can't seem to stop. т F 16) It is not difficult for me to leave something on my plate. т F 17) At certain times of the day I get hungry because I have gotten used to eating then. т F 18) While on a diet, if I eat food that is not allowed, I consciously eat less for a period of time to make up for it. F т

19) Being with someone who is overeating often makes me hungry			
enough to eat also.	т	F	
20) When I feel blue I often overeat.		т	F
21) I enjoy eating too much to spoil it by counting calories or watching my weight.		т	F
22) When I see a real delicacy I often get so hungry that I have to eat it right away.		т	F
23) I often stop eating when I am not really full as a conscious means of limiting the amount I eat.	т	F	
24) I get so hungry my stomach feels like a bottomless pit.		т	F
25) My weight has hardly changed at all in the last ten years.	т	F	
26) I am always hungry so it is hard for me to stop eating before I finish the food on my plate.	т	F	
27) When I feel lonely, I console myself by eating.		т	F
28) I consciously hold back at meals in order not to gain weight.	т	F	
29) I sometimes get very hungry late in the evening or at night.	т	F	
30) I eat anything I want, anytime.		т	F

31) Without even thinking about it I take a long time to eat. т F 32) I count calories as a conscious means of controlling my weight. т F 33) I do not eat some foods because they make me fat. т F 34) I am always hungry enough to eat at anytime. Т F 35) I pay a great deal of attention to changes in my figure. Т F 36) While on a diet, if I eat food that is not allowed, I often then splurge and eat other high calorie foods. Т F

Please answer the following questions by circling the number above the response that is appropriate to you.

37) How often are you dieting in a conscious effort to control your weight?

	1	2	3	4
	rarely	sometimes	usually	always
38)	Would a weight fluctua	ation of 5lbs affect the w	ay you live your life?	
	1	2	3	4

moderately

very much

slightly

not at all

	1	2	3		4
	only at	sometimes	ofte	n between	almost
	meal times	between meals	s mea	lls	always
40)	Do your feelings of gui	lt about overeati	ing help you to	o control your foc	d intake?
	1	2	3		4
	never	rarely	ofte	n	always
41)	How difficult would it l	be for you to sto	p eating halfw	vay through dinne	r and not
	eat for the next four h	ours?			
	1	2	3		4
	easy	slightly	moderately	very	
		difficult	difficult	difficult	
42)	How conscious are you	ı of what you are	e eating?		
	1	2	3		4
	not at all	slightly	moderately	extre	mely
43)	How frequently do you	avoid 'stocking	up' on tempti	ng foods.	
		-			
	1	2	3		4
almost	t never seldom	usually	/	almost	always
					-

2 3 1 4 unlikely slightly moderately very likely likely likely 45) Do you eat sensibly in front of others and splurge alone? 1 2 3 4 rarely often never always 46) How likely are you to consciously eat slowly in order to cut down on how much you eat? 1 2 3 4 slightly unlikely moderately very likely likely likely 47) How frequently do you skip dessert because you are no longer hungry?

1 2 3 4 seldom at least never almost once a week every day 48) How likely are you to consciously eat less than you want? 1 2 3 4 unlikely slightly moderately very likely likely likely

49) Do you go on eating binges even though you are not hungry?

44) How likely are you to shop for 'low calorie' foods?

1	2	3	4
never	rarely	sometimes	at least
			once a week

50) On a scale of 0-5 where 0 means no restraint in eating (eat whatever you want, whenever you want it), and 5 means total restraint (constantly limiting food intake and never 'giving in'). What number would you give yourself?

- **0** Eat whatever you want, whenever you want it.
- **1** Usually eat whatever you want, whenever you want it.
- 2 Often eat whatever you want, whenever you want it.
- **3** Often limit food intake, but often 'give in'.
- 4 Usually limit food, rarely 'give in'
- **5** Constantly limiting food intake, never 'giving in'.
- 51) To what extent does this statement describe your eating behaviour?

'I start dieting in the morning, but because of any number of things that happen

during the day, by evening I have given up and eat what I want, promising myself to start dieting again tomorrow.'

1	2	3	4
not like me	little like me	pretty good	describes
		description	me perfectly
		of me	

## Appendix 3.13 Body Shape Questionnaire (BSQ-34)

We should like to know how you have been feeling about your appearance over the **PAST FOUR WEEKS**. Please read each question and circle the appropriate number to the right. Please answer <u>all</u> the questions.

#### OVER THE PAST FOUR WEEKS:

		Nev	er				
		I	Rare	ly			
		I	Ι	Som	etime	es	
		I	Ι	Ι	Ofte	n	
		I	Ι	Ι	Ι	Very	y often
			I	I	Ι	I	Always
		1	Ī				
		I					I
1.	Has feeling bored made you brood about your shape?	1	2	3	4	5	6
2.	Have you been so worried about your shape that you have been feeling you ought to	1	2	3	4	5	6
	diet?	T	Z	5	4	J	0
3.	Have you thought that your thighs, hips or bottom are too large for						
5.	the rest of	1	2	3	4	5	6
	you?						
4.	Have you been afraid that you might become fat (or	1	2	3	4	5	6
	fatter)?						
5.	Have you worried about your flesh being not firm	1	2	3	4	5	6
	enough?						
6.	Has feeling full (e.g. after eating a large meal) made you feel	1	2	3	4	5	6
	fat?						
7.	Have you felt so bad about your shape that you have	1	2	3	4	5	6
	cried?						
8.	Have you avoided running because your flesh might	1	2	3	4	5	6
	wobble?						

<ol> <li>Has being with thin women made you feel self-conscious about your shape?</li> </ol>	1	2	3	4	5	6
10. Have you worried about your thighs spreading out when sitting down?	1	2	3	4	5	6
11. Has eating even a small amount of food made you feel fat?	1	2	3	4	5	6
12. Have you noticed the shape of other women and felt that your own shape compared unfavourably?	1	2	3	4	5	6
13. Has thinking about your shape interfered with your ability to concentrate (e.g. while watching television, reading, listening to conversations)?	1	2	3	4	5	6
14	1	2	3	4	5	6
Has being naked, such as when taking a bath, made you feel fat?						
15. Have you avoided wearing clothes which make you particularly aware of the shape of your body?	1	2	3	4	5	6
16. Have you imagined cutting off fleshy areas of your body?	1	2	3	4	5	6
17. Has eating sweets, cakes, or other high calorie food made you feel fat?	1	2	3	4	5	6
18. Have you not gone out to social occasions (e.g. parties) because you have felt bad about your shape?		2	3	4	5	6
19. Have you felt excessively large and rounded?	1	2	3	4	5	6
20. Have you felt ashamed of your body?	1	2	3	4	5	6
21. Has worry about your shape made you						

22.	Have you felt happiest about your shape when your stomach has been empty (e.g. in the morning)?	1	2	3	4	5	6
23.	Have you thought that you are in the shape you are because you lack self- control?	1	2	3	4	5	6
24.	Have you worried about other people seeing rolls of fat around your waist or stomach?	1	2	3	4	5	6
25.	Have you felt that it is not fair that other women are thinner than you?.	1	2	3	4	5	6
26.	Have you vomited in order to feel thinner?	1	2	3	4	5	6
27.	When in company have you worried about taking up too much room (e.g. sitting on a sofa, or a bus seat)?	1	2	3	4	5	6
28.	Have you worried about your flesh being dimply?	1	2	3	4	5	6
29.	Has seeing your reflection (e.g. in a mirror or shop window) made you feel bad about your shape?	1	2	3	4	5	6
30.	Have you pinched areas of your body to see how much fat there is?	1	2	3	4	5	6
31.	Have you avoided situations where people could see your body (e.g. communal changing rooms or swimming baths)?	1	2	3	4	5	6
32.	Have you taken laxatives in order to feel thinner?	1	2	3	4	5	6
33.	Have you been particularly self-conscious about your shape when in the company of other people?	1	2	3	4	5	6
34.	Has worry about your shape made you feel you ought to exercise?	1	2	3	4	5	6

## Appendix 3.14 Intuitive Eating Scale (IES)

For each item, please circle the answer that best characterizes your attitudes or behaviours.

# 1. I try to avoid certain foods high in fat, carbohydrates, or calories.

1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
2. I stop eating when	I feel full (not overs	stuffed).		
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
3. I find myself eating even when I'm not pl		emotional (e.g., ar	nxious, depre	essed, sad),
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
4. If I am craving a ce	ertain food, I allow r	nyself to have it.		
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
5. I follow eating rule to eat.	s or dieting plans t	hat dictate what, v	when, and/o	r how much
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
6. I find myself eating	g when I am bored,	even when l'm no	ot physically	hungry.
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
7. I can tell when I'm	slightly full.			
1	2	3	4	5

Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
8. I can tell when I'm slig	ghtly hungry.			
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
9. I get mad at myself fo	r eating something u	nhealthy.		
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
10. I find myself eating	when I am lonely, eve	n when I'm nc	ot physically	hungry.
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
11. I trust my body to te	II me when to eat.			
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
12. I trust my body to te	ll me what to eat.			
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
13. I trust my body to te	II me how much to ea	it.		
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
14. I have forbidden foo	ds that I don't allow r	nyself to eat.		
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly

15. When I'm eating, I can tell when I am getting full.

450

1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
16. I use food to help	me soothe my neç	gative emotions.		
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
17. I find myself eating hungry.	g when I am stress	sed out, even whe	n l'm not ph	ysically
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
18. I feel guilty if I eat	a certain food tha	t is high in calorie	s, fat, or car	bohydrates.
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
19. I think of a certain content.	food as "good"or	· "bad" depending	on its nutri	tional
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
20. I don't trust mysel	f around fattening	foods.		
1	2	3	4	5
Strongly Disagree Agree	Disagree	Neutral	Agree	Strongly
21. I don't keep certain lose control and eat the secontrol and eat the secontrol and eat the second	-	se/apartment beca	ause I think	that I may
1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly

Agree

#### Appendix 3.15 Diet Satisfaction Questionnaire (D-SAT)

For each of the statements listed below, circle the number that best represents your response as it applies to the way you currently eat and your current level of physical activity. Please read each statement carefully before responding.

**For example:** For the following question, **"I think I exercise a lot**," you would base your answer on your current level of physical activity. If you feel that you currently exercise a lot, you would circle **5** to indicate that you strongly agree.

	Disagree	Disagree	Neither disagree	Agree	Agree
	strongly	somewhat	nor agree	somewhat	strongly
I think I exercise a lot.	1	2	3	4	5
	Disagree	Disagree	Neither disagree	Agree	Agree
	strongly	somewhat	nor agree	somewhat	strongly
1. I have a lot of energy.	1	2	3	4	5
2. I feel good about myself.	1	2	3	4	5
3. I think I eat a healthy diet.	1	2	3	4	5
<ol> <li>I believe that I am reducing my risk for disease by the way that I eat.</li> </ol>	1	2	3	4	5
5. I believe that I am reducing my risk for disease by the way that I exercise.	1	2	3	4	5
6. I think I have a healthy lifestyle.	1	2	3	4	5
7. I am satisfied with my current diet.	1	2	3	4	5
8. The way I currently eat makes me feel guilty.	1	2	3	4	5
9. The way I currently eat prevents me from eating in restaurants frequently.	1	2	3	4	5
10. When dining out, I can easily choose foods from the menu that fit into my current diet.	1	2	3	4	5

	Disagree strongly	Disagree somewhat	Neither disagree nor agree	Agree somewhat	Agree strongly
11. Finding appropriate food choices at restaurants is difficult.	1	2	3	4	5
12. I have to prepare most of my foods from "scratch".	1	2	3	4	5
13. I find eating satisfying.	1	2	3	4	5
<ol> <li>I have difficulty finding the foods I want when eating out.</li> </ol>	1	2	3	4	5
15. I find it easy to shop for the kinds of foods I eat at my grocery store.	1	2	3	4	5
16. I limit my choice of restaurants.	1	2	3	4	5
17. I have plenty of different types of foods to choose from with my current diet.	1	2	3	4	5
<ol> <li>I feel I spend a large amount of my budget on the foods I eat.</li> </ol>	1	2	3	4	5
19. I think preparing food/meals for the way I eat now is economical	1	2	3	4	5
20. I think preparing food/meals for the way I eat now costs a lot of money	1	2	3	4	5
21. I spend a lot of money on food.	1	2	3	4	5
22. It's hard for me to afford the kind of foods I eat	1	2	3	4	5
23. I feel the way I eat now bothers my family.	1	2	3	4	5
24. My family encourages me to keep eating the way I am eating now.	1	2	3	4	5

	Disagree	Disagree	Neither	Agree	Agree
	strongly	somewhat	disagree nor agree	somewhat	strongly
25. My family supports my efforts to eat a healthy diet.	1	2	3	4	5
26. My family thinks my current diet is a healthy diet.	1	2	3	4	5
27. My family discourages me from eating the way I am eating now.	1	2	3	4	5
28. The way I currently eat causes stress within my family.	1	2	3	4	5
29. Thoughts of food are always on my mind.	1	2	3	4	5
30. I think about food between almost every meal.	1	2	3	4	5
31. I have cravings for some of my favorite foods.	1	2	3	4	5
32. I always feel like I want to snack between meals.	1	2	3	4	5
33. I often feel hungry.	1	2	3	4	5
34. I feel that my diet controls my life.	1	2	3	4	5
35. I feel deprived based on what I order when eating in a restaurant.	1	2	3	4	5
36. I feel self-conscious trying to eat my current diet at social events.	1	2	3	4	5
37. I feel embarrassed if I order specially prepared foods in a restaurant.	1	2	3	4	5
38. My family eats the same foods that I currently eat.	1	2	3	4	5
39. I feel deprived when I choose to avoid some of my favorite foods.	1	2	3	4	5

	Disagree strongly	Disagree somewhat	Neither disagree nor agree	Agree somewhat	Agree strongly
40. I have to prepare separate meals for my family and myself.	1	2	3	4	5
41. I spend a lot of time planning my meals.	1	2	3	4	5
42. I spend a lot of time shopping for food.	1	2	3	4	5
43. I think preparing food/meals for the way I eat now is time consuming.	1	2	3	4	5
44. I think preparing food/meals for the way I eat now requires a lot of effort.	1	2	3	4	5
45. I spend a lot of time looking for new food/meal ideas that fit into my current diet.	1	2	3	4	5

# Appendix 3.16 Social Readjustment Rating Scale (SRRS) or Life Events Scale (LES)

Instructions: Place a tick next to each event that has occurred to you in the last 12 months.

EVENT	YES OR NO
Death of a spouse	
Divorce	
Marital separation	
Jail term	
Death of a close family member	
Personal injury or illness	
Marriage	
Fired at work	
Marital reconciliation	
Retirement	
Change in health of family member	
Pregnancy	
Sex difficulties	
Gain of a new family member	
Business readjustment	
Change in financial state	
Death of a close friend	
Change to different line of work	
Change in number of arguments with spouse	
Taking on a large mortgage/loan	
Default of mortgage or loan	

Change in responsibilities at work	
Son or daughter leaving home	
Trouble with in-laws	
Outstanding personal achievement	
Partner begins or stops work	
Begin or end school	
Change in living conditions	
Revision of personal habits	
Trouble with boss	
Change in work hours or conditions	
Change in residence	
Change in schools	
Change in recreation	
Change in church activities	
Change in social activities	
Taking on a small mortgage/loan	
Change in sleeping habits	
Change in number of family get-togethers	
Change in eating habits	
Vacation	
Christmas	
Minor violations of the law	
	1

# Appendix 3.17 Depression Anxiety Stress Scales (DAAS)

appl	se read each statement and circle a number 0, 1, 2 or 3 which indicates h ied to you <i>over the past week</i> . There are no right or wrong answers. Do r ny statement.				
The	rating scale is as follows:				
0 D	d not apply to me at all				
1 Aj	oplied to me to some degree, or some of the time				
2 Aj	oplied to me to a considerable degree, or a good part of time				
3 Aj	oplied to me very much, or most of the time				
1	I found myself getting upset by quite trivial things	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I just couldn't seem to get going	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I had a feeling of shakiness (eg, legs going to give way)	0	1	2	3
8	I found it difficult to relax	0	1	2	3
9	I found myself in situations that made me so anxious I was most relieved when they ended	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting upset rather easily	0	1	2	3
12	I felt that I was using a lot of nervous energy	0	1	2	3
13	I felt sad and depressed	0	1	2	3
14	I found myself getting impatient when I was delayed in any way (eg, lifts, traffic lights, being kept waiting)	0	1	2	3
15	I had a feeling of faintness	0	1	2	3
16	I felt that I had lost interest in just about everything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3

18	I felt that I was rather touchy	0	1	2	3
19	I perspired noticeably (eg, hands sweaty) in the absence of high temperatures or physical exertion	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life wasn't worthwhile	0	1	2	3
22	I found it hard to wind down	0	1	2	3
23	I had difficulty in swallowing	0	1	2	3
24	I couldn't seem to get any enjoyment out of the things I did	0	1	2	3
25	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
26	I felt down-hearted and blue	0	1	2	3
27	I found that I was very irritable	0	1	2	3
28	I felt I was close to panic	0	1	2	3
29	I found it hard to calm down after something upset me	0	1	2	3
30	I feared that I would be "thrown" by some trivial but unfamiliar task	0	1	2	3
31	I was unable to become enthusiastic about anything	0	1	2	3
32	I found it difficult to tolerate interruptions to what I was doing	0	1	2	3
33	I was in a state of nervous tension	0	1	2	3
34	I felt I was pretty worthless	0	1	2	3
35	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
36	I felt terrified	0	1	2	3
37	I could see nothing in the future to be hopeful about	0	1	2	3
38	I felt that life was meaningless	0	1	2	3
39	I found myself getting agitated	0	1	2	3
40	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3

	41	I experienced trembling (eg, in the hands)	0	1	2	3
	42	I found it difficult to work up the initiative to do things	0	1	2	3
Арр	endi	x 3.18 Beliefs about the causes of obesity				

Medical: genetics/ inheritance, glands/hormone problem, slow metabolism

Psychological: Low self-esteem, anxiety/stress, depression

Behavioural: eating too much, not enough exercise, eating the wrong foods

Social: unemployment, low income

Appendix 3.19 Study Schedule	
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	Initial Contact	Screening visit	h	nclusio	n Phase	•					Int	terventi	ion Pha	se					Debrief- ing	Follow up
			-4	-3	-2	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	+ 1 month
Initial contact via telephone/email	x																			
Participant Information Sheet	x																			
Study visit		x				x				x				x				x	x	x
Informed consent		x																		
DIQ		x																		
Inclusion/ exclusion criteria	x	x				x				x				x				X		
Food Diary training		x																		
EAT-26		x																		
7-day food diary			x																	
3-day food diary							х				x				x			x		
Randomisation					x															
Eating advice						x				x				x						
Administration of food products						x				x				x						
Anthropometric measures **		X				x				x				x				X		X*
BodPod						x												x		

DINE	х																Х		X*
DEBQ					X												X		X*
TFEQ					X												X		X*
LSEQ					X				Х				Х				X		X*
BSQ					X				X				X				X		X*
FPC/VAS					x												X		
Debriefing Questionnaire																		Х	
Fasting Blood sample					X												X		
Complimentary fixed breakfast					X												X		
Appetite hormone blood sampling					X												X		
Standard fixed lunch					X												X		
Continuous glucose monitor				•	▶•											• —	▶•		
Daily symptom/wellbeing diary		X	X	х	X	х	Х	X	Х	X	х	х	х	X	Х	Х	X		
Web/ Telephone support available	X	X	X	х	X	X	х	X	Х	X	х	х	X	X	Х	Х	X		

Key: \* indicates measures to be included at an optional follow-up assessment after the study has ended to examine whether body weight has remained stable and whether the dietary intervention has been continued \*\*height and weight at screening; weight ,waist and body composition via bioimpedance at weeks -1,4, 8, 12 and at follow-up; body composition (BodPod) via ADP at weeks -1 and 12.

### Appendix 3.20 End of Study Questionnaire (Diet A)

Please complete this questionnaire and return it to us when you attend the Human Appetite Research Unit for your debriefing session. This questionnaire **should** be completed before you are debriefed.

In this questionnaire we are interested in your views of the study and your experiences as a volunteer. In order for us to learn as much as possible from the study we would appreciate you completing this questionnaire fully and honestly. All your responses will be treated in confidence.

#### Recruitment to the study

1. How did you find out about the study?

2. What made you decide to participate?

3. Did you have any concerns about taking part?

4. What were you hoping to get out of the study?

#### **Study procedures**

5. Were there any questions you were not happy with answering at any stage during the study?

6. Were there any procedures that made you feel uncomfortable or that you didn't like at any stage during the study?

7. What was it like filling in the wellbeing diary every day?

8. Did you ever miss a wellbeing diary in the evening and fill it in the next day?

Yes ightarrow No 
ightarrow

If yes, roughly how many times during the study did this happen?

1-3 > 4-6 > 7-9 > 10-12 > >13 >

#### **Blood Sampling**

11. What was your experience of having blood samples taken at Leeds General Infirmary?

12. Is there anything we could have done to make this aspect of the study easier for you?

13. What was your experience of having a cannula fitted and several blood samples taken in the research unit?

14. Is there anything we could have done to make this aspect of the study easier for you?

#### **Test Meal/Cannulation Days**

15. What was your experience of attending the research unit on the test days?

16. What did you think was the purpose of these test days?

17. Is there anything we could have done to make these test days easier for you?

#### The study overall

18. What do you think the study was trying to determine?

Not at all healthy	Э	Э	Э	Э	Э	Very healthy
		1	2	3	4	5
20. How healthy was	your di	et durin	g the stu	ıdy?		
Not at all healthy	Э	Э	Э	Э	Э	Very healthy
		1	2	3	4	5
21. How healthy do y	ou thin	k your di	iet will b	e now tl	hat the s	tudy has finished
Not at all healthy	Э	Э	Э	Э	Э	Very healthy
		1	2	3	4	5
22. What do you thir	nk are th	e benefi	its of hav	ving a m	ore heal	thy diet?

24. Will you continue to eat more healthily now the study has finished?

465

Yes ightarrow No 
ightarrow

If Yes, please give details of how you intend to do this

25. How easy did you find it to comply with all the instructions on the study? Was there any part of the study that was particularly hard to comply with?

26. Were there any aspects of the study that you particularly enjoyed?

27. Were there any aspects of the study that you didn't enjoy?

28. During the study you were given food products to take home – which of these did you like the most and why?

29. Which food products did you like the least and why?

30. Did you make any of the recipes in the cookery book Yes	Э	No	Э
If yes, which ones did you like?			
31. Did you make any of the recipes in the Eat Well book	Yes	Э	No
If yes, which ones did you like?			

32. Did you experience any discomfort throughout the study?	Yes э	№ э
If yes, please give details.		

33.	Did	you	ever	feel	like	giving	up?
-----	-----	-----	------	------	------	--------	-----

Yes  $\ni$  No  $\ni$  If yes, what was it that made you decide to continue?

Please use the space below to write any additional comments you may have about the study.

Would you like to be sent details of any further studies? Yes	Э	No	Э
---	---	----	---

We would like to thank you for taking part in this study and for all the time and effort you have put in. We have collected lots of useful data which we hope will help forward this area of research.

### Appendix 3.21 End of Study Questionnaire (Diet B)

Please complete this questionnaire and return it to us when you attend the Human Appetite Research Unit for your debriefing session. This questionnaire **should** be completed before you are debriefed.

In this questionnaire we are interested in your views of the study and your experiences as a volunteer. In order for us to learn as much as possible from the study we would appreciate you completing this questionnaire fully and honestly. All your responses will be treated in confidence.

#### Recruitment to the study

1. How did you find out about the study?

2. What made you decide to participate?

3. Did you have any concerns about taking part?

4. What were you hoping to get out of the study?

#### **Study procedures**

5. Were there any questions you were not happy with answering at any stage during the study?

6. Were there any procedures that made you feel uncomfortable or that you didn't like at any stage during the study?

7. What was it like filling in the wellbeing diary every day?

8. Did you ever miss a wellbeing diary No 🛛	y in the	evening	and fill i	t in the next day?	Yes 🛛
If yes, roughly how many times durin	g the st	udy did	this happ	en?	
1-3 2 4-6 2 7-9 2 10-1	2 🤉	> 1	3 ?		
9. How difficult did you find it to cons	sume th	ne requii	ed numb	er of points each d	lay?
Not at all difficult 1 2	3	4	5	Very Difficult	
10. Did you ever exaggerate the num	ber of p	points yo	ou had ac	tually consumed?	
(Please be honest about this – we val difficult for some people).	lue this	informa	tion and	appreciate it may l	nave been
Yes 🗆 No 🗆					
If yes, how often did this happen?		Less	than on	ce a week	
Once or twice a week					
Three or four times a week					
More than four times a week					
Blood Sampling					
11. What was your experience of hav	ing blo	od samp	les taken	at Leeds General I	nfirmary?
12. Is there anything we could have c	lone to	make th	is aspect	of the study easie	r for you?

13. What was your experience of having a cannula fitted and several blood samples taken in the research unit?

14. Is there anything we could have done to make this aspect of the study easier for you?

#### **Test Meal/Cannulation Days**

15. What was your experience of attending the research unit on the test days?

16. What did you think was the purpose of these test days?

17. Is there anything we could have done to make these test days easier for you?

#### The study overall

18. What do you think the study was trying to determine?

19. How healthy was your diet before you took part in the study?										
Not at all healthy	?	?	?	?	?	Very healthy				
		1	2	3	4	5				
20. How healthy was yo	our diet	during tl	ne study	?						
Not at all healthy	?	?	?	?	?	Very healthy				
		1	2	3	4	5				
21. How healthy do you	u think y	our diet	will be r	now that	the stu	dy has finished?				
Not at all healthy	?	?	?	?	?	Very healthy				
		1	2	3	4	5				

22. What do you think are the benefits of having a r	more healthy diet?
--	--------------------

23. Did you experience any benefits in having a more healthy diet during the study?	
24. Will you continue to eat more healthily now the study has finished? Yes I No I If Yes, please give details of how you intend to do this	
25. How easy did you find it to comply with all the instructions on the study? Was there part of the study that was particularly hard to comply with?	any
26. Were there any aspects of the study that you particularly enjoyed?	
27. Were there any aspects of the study that you didn't enjoy?	
28. During the study you were given food products to take home – which of these did yo the most and why?	ou like
29. Which food products did you like the least and why?	

30. Did you make any of the recipes su	ggested?	Yes	?	No	?
If yes, how often did you do this?	Less thar	n once a wee	k		?
Once a week	?				
Once or twice a week	?				
Three or four times a week	?				
More than four times a week	?				
31. Which were your favourite recipes	?				
32. Did you experience any discomfort	t throughou	ut the study?	Yes	☑ No	?
If yes, please give details.					
33. Did you ever feel like giving up?					
	what was i	it that made	you decir	he to con	tinuo?
			you decit		unue:
24 What do you think is the surrout re			unt of fib		
34. What do you think is the current re					
1-6g 🛛 7-12g 🖓 13-18g 🖓	-		-	-	-
35. Before you took part in the study, fibre?	what do yo	u think was	your aver	age daily	intake of
1-6g 🛛 7-12g 🖓 13-18g 🖓 19-2	24g 🛛 2	5-30g 🛛 3	1-36g 🛛		
36. What do you think was your avera	ge daily int	ake of fibre o	during the	e study?	
1-6g 🛛 7-12g 🖓 13-18g 🖓 19-2	24g 🛛 2	5-30g 🛛 3	1-36g 🛛		
37. What do you think are the benefits	s of having	more fibre ir	n your die	t?	

28	Did		norionco	anv	honofite	in	having	more	fihro	in	your diet	during	tho	ctud	v?
50.	Diu	you ex	penence	any	Denenits		naving	more	nne		your uler	uuring	guie	รเนน	y٤

	•			nore fibre now the study has finished?
Yes	?	No	?	If yes, please give details of how you intend to do this

Would	vou like to be sent	details of an	y further studies? Yes	?	No	?
<b>W</b> Ould	you like to be serie	actuns of an	y fullifier studies. Tes	<u> </u>	110	

We would like to thank you for taking part in this study and for all the time and effort you have put in. We have collected lots of useful data which we hope will help forward this area of research.

Appendix 3.22 Adverse Event Report Form (AE)

Participant ID Code.....

Date of report: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Name of reporter: .....

Source of information: .....

Description of event: Dates of event: Start: End: Ongoing: Yes • No • Any medication taken for this AE? Yes / No If YES, please specify: -

# Appendix 3.23 Ethics Certificate



# Appendix 3.24 Predicted Probabilities (PP) by rating score for week -1 (baseline) through week 12 (end of the intervention)

1. FEELING FAT

----- Li Appendix 2 Predicted Probabilities (PP) by rating score for week -1 (baseline) through week 12 (end of the intervention)

kelihood ratio test ------

Log likelihood first model: -8207.85 df= 5473

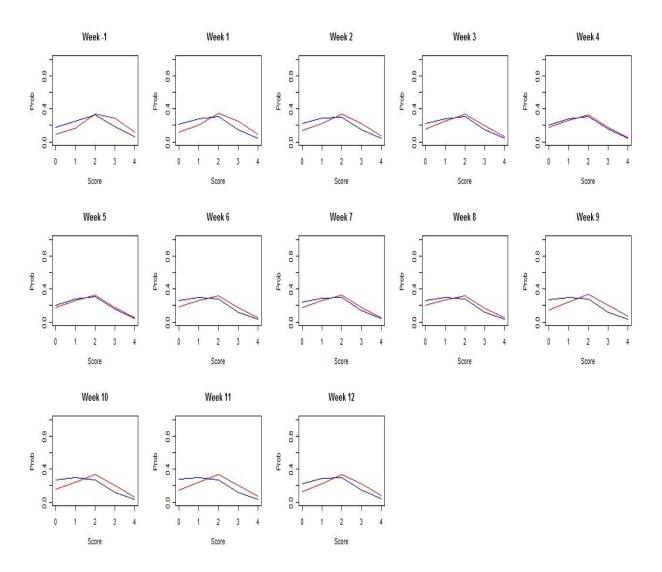
Log likelihood second model: -8207.85 df= 5473

Test statistic (Chi-square) : 190.92 df= 25

p-value= 1.694458e-27

-----End of Likelihood ratio test ------

[1] 1.694458e-27



# 2. FEELING SLIM

------ Likelihood ratio test ------

Log likelihood first model: -7106.22 df= 5508

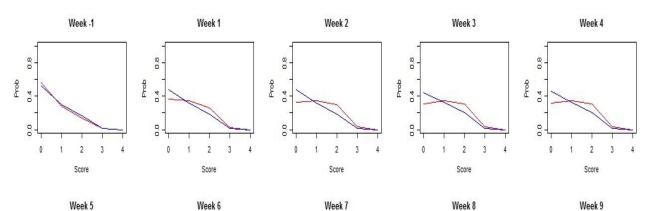
Log likelihood second model: -7106.22 df= 5508

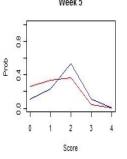
Test statistic (Chi-square) : 1390.26 df= 25

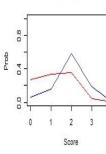
p-value= 4.609424e-278

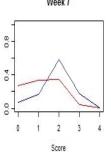
-----End of Likelihood ratio test ------

[1] 4.609424e-278



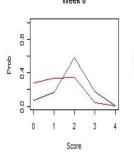


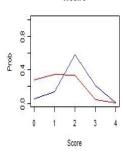


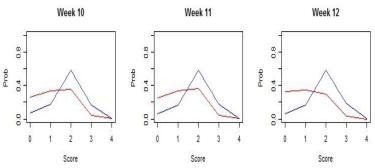


Prob

4







#### **3. FEELING ENERGETIC**

------ Likelihood ratio test ------

Log likelihood first model: -6648.79 df= 5494

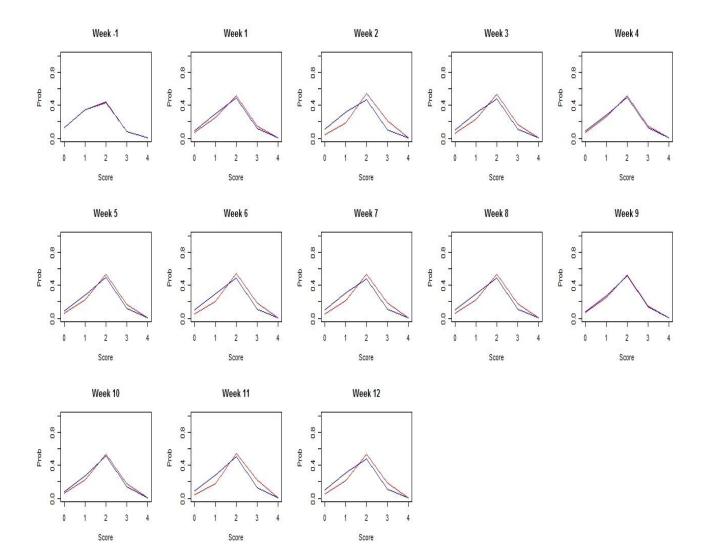
Log likelihood second model: -6648.79 df= 5494

Test statistic (Chi-square) : 155.8 df= 25

p-value= 7.131694e-21

-----End of Likelihood ratio test ------

[1] 7.131694e-21



#### 4. MENTAL ALERTNESS

- Likelihood ratio test ------

Log likelihood first model: -5896.12 df= 5523

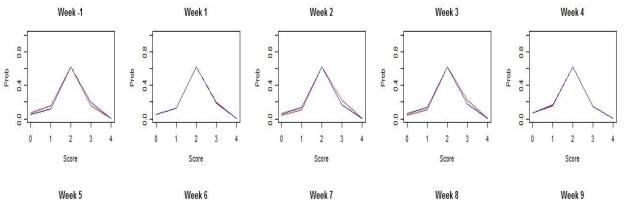
Log likelihood second model: -5896.12 df= 5523

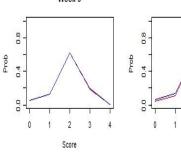
Test statistic (Chi-square) : 38 df= 25

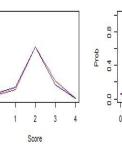
p-value= 0.04626148

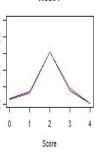
-----End of Likelihood ratio test ------

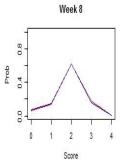
[1] 0.04626148

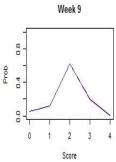


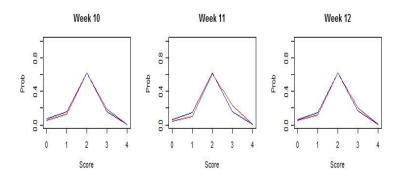












479

#### 5. MENTAL TIREDNESS

------ Likelihood ratio test ------

Log likelihood first model: -7141.3 df= 5518

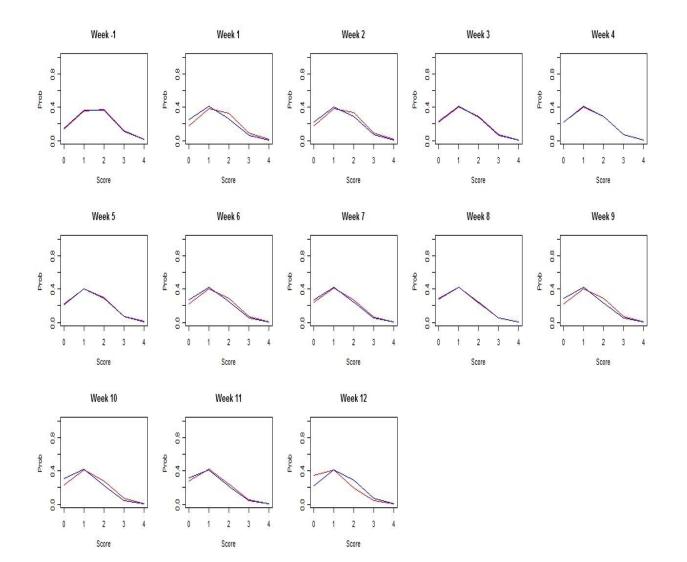
Log likelihood second model: -7141.3 df= 5518

Test statistic (Chi-square) : 121.04 df= 25

p-value= 1.450976e-14

-----End of Likelihood ratio test ------

[1] 1.450976e-14



#### 6. DIFFICULTY CONCENTRATING

>----- Likelihood ratio test ------

Log likelihood first model: -6374.86 df= 5475

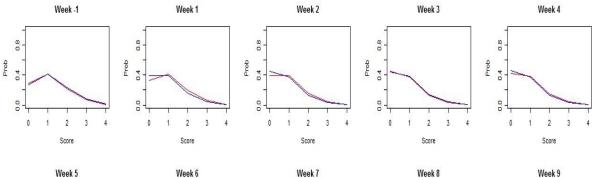
Log likelihood second model: -6374.86 df= 5475

Test statistic (Chi-square) : 145.06 df= 25

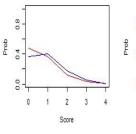
p-value= 6.82394e-19

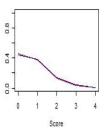
-----End of Likelihood ratio test ------

[1] 6.82394e-19

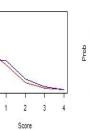






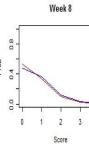


Week 11

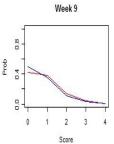


3

4



4







Week 12

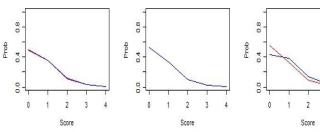
0.8

4.0

0.0

0

Prob



#### 7. PHYSICAL TIREDNESS

------ Likelihood ratio test ------

Log likelihood first model: -7638.16 df= 5558

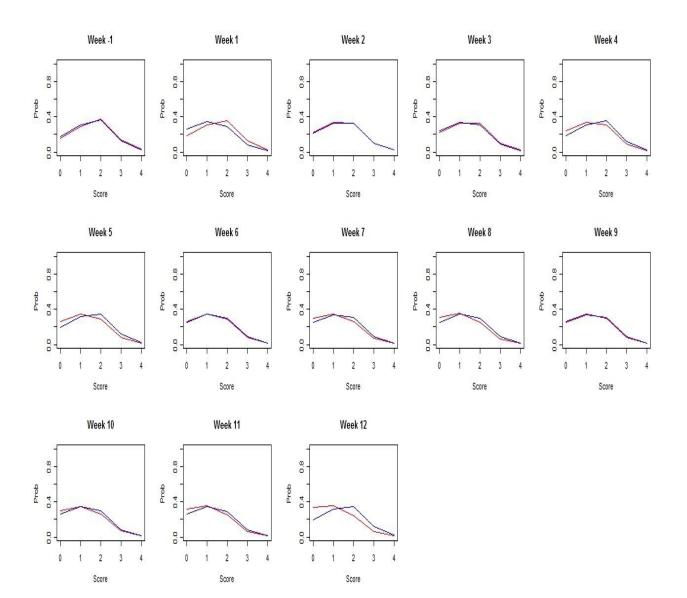
Log likelihood second model: -7638.16 df= 5558

Test statistic (Chi-square) : 101.68 df= 25

p-value= 3.265535e-11

-----End of Likelihood ratio test ------

[1] 3.265535e-11



#### 8. HEADACHES

> ------ Likelihood ratio test ------

Log likelihood first model: -4943.19 df= 5426

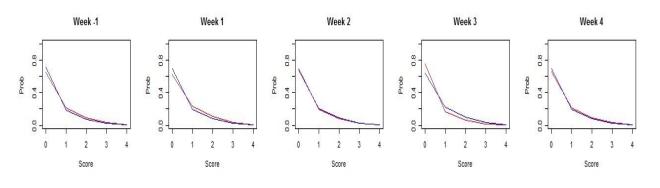
Log likelihood second model: -4943.19 df= 5426

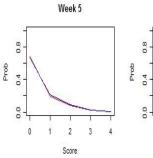
Test statistic (Chi-square) : 39.58 df= 25

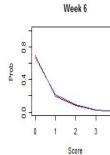
p-value= 0.03219397

-----End of Likelihood ratio test ------

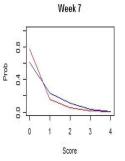
[1] 0.03219397

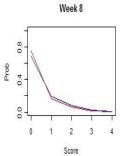


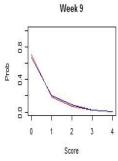


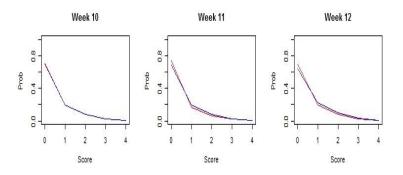


4









#### 9. BOWEL PAIN

---- Likelihood ratio test ------

Log likelihood first model: -4763.39 df= 5443

Log likelihood second model: -4763.39 df= 5443

Test statistic (Chi-square) : 96.92 df= 25

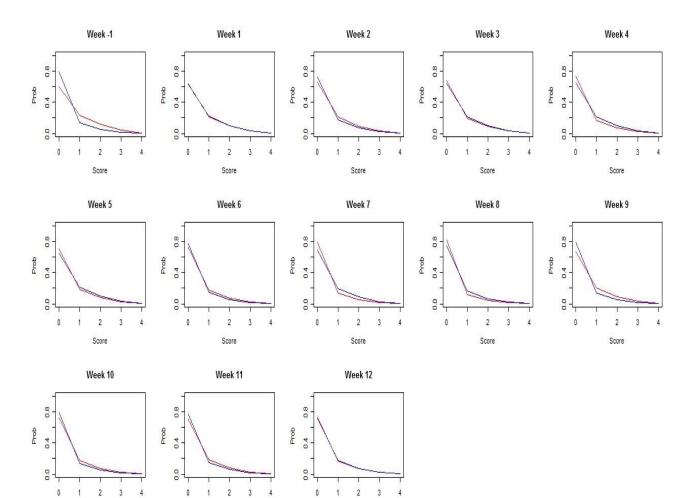
p-value= 2.060704e-10

Score

Score

-----End of Likelihood ratio test ------

[1] 2.060704e-10



Score

# **10. CONSTIPATION**

------ Likelihood ratio test ------

Log likelihood first model: -3696.61 df= 5428

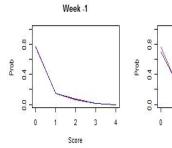
Log likelihood second model: -3696.61 df= 5428

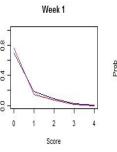
Test statistic (Chi-square) : 56.3 df= 25

p-value= 0.0003314517

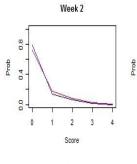
-----End of Likelihood ratio test ------

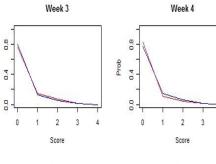
[1] 0.0003314517

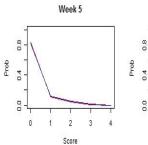


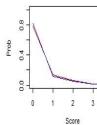


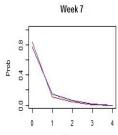
Week 6

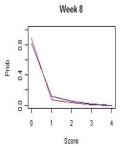


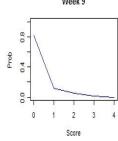














2

Score

0.8

0.0

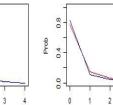
0

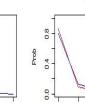
1

Prob 0.4









0

0.8

0.0

4

3

Score

4

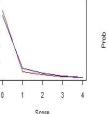


3

4

2

Score





#### **11. BLOATING**

----- Likelihood ratio test ------

Log likelihood first model: -6554.19 df= 5431

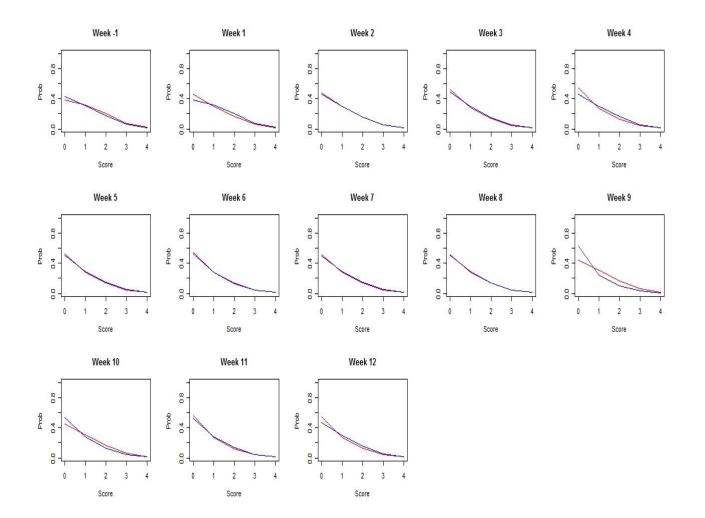
Log likelihood second model: -6554.19 df= 5431

Test statistic (Chi-square) : 71.68 df= 25

p-value= 2.159849e-06

-----End of Likelihood ratio test ------

[1] 2.159849e-06



## **12. INDIGESTION**

------ Likelihood ratio test ------

Log likelihood first model: -3468.18 df= 5421

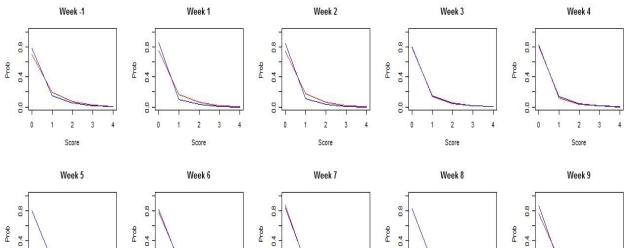
Log likelihood second model: -3468.18 df= 5421

Test statistic (Chi-square) : 67.04 df= 25

p-value= 1.048713e-05

-----End of Likelihood ratio test ------

[1] 1.048713e-05





2

Score

0.0

0 1



3 4



3 4

4

Score

0.0

0 1 2



2 3

Score

0.0

4

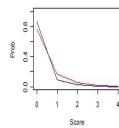
0

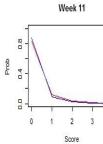
1 2 3 4

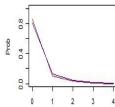
Score

0.0

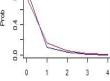
0 1







Score



Score

#### **13. WIND**

------ Likelihood ratio test ------

Log likelihood first model: -6995.15 df= 5499

Log likelihood second model: -6995.15 df= 5499

0.4

0.0

0

1

2 3 4

Score

0.4

0.0

0

1

2 3 4

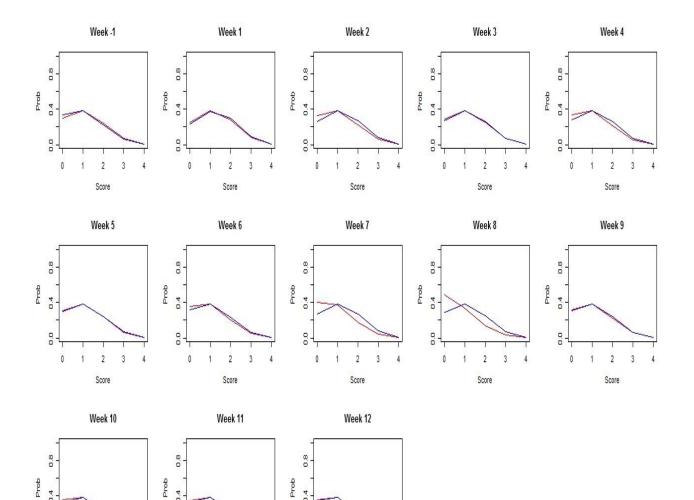
Score

Test statistic (Chi-square) : 85.78 df= 25

p-value= 1.380024e-08

-----End of Likelihood ratio test ------

[1] 1.380024e-08



0.4

0.0

0

1

2 3 4

Score

#### **14. BREAST TENDERNESS**

----- Likelihood ratio test ------

Log likelihood first model: -3543.1 df= 5449

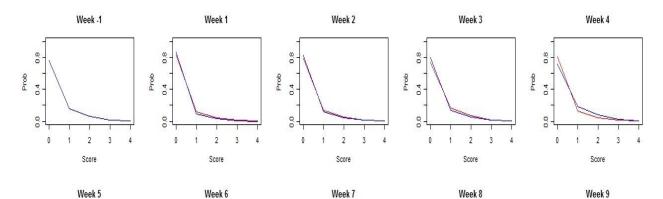
Log likelihood second model: -3543.1 df= 5449

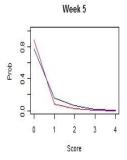
Test statistic (Chi-square) : 92.1 df= 25

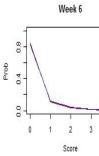
p-value= 1.295857e-09

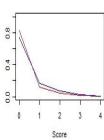
-----End of Likelihood ratio test ------

[1] 1.295857e-09









0.8

0.0

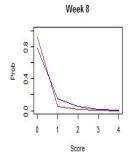
Prob

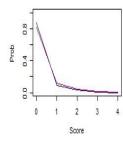
Prob

0 1

4

4

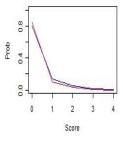


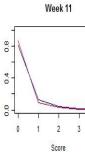


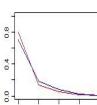


Prob









2 3

Score

4

489

#### **15. HAPPINESS**

------ Likelihood ratio test ------

Log likelihood first model: -6098.03 df= 5529

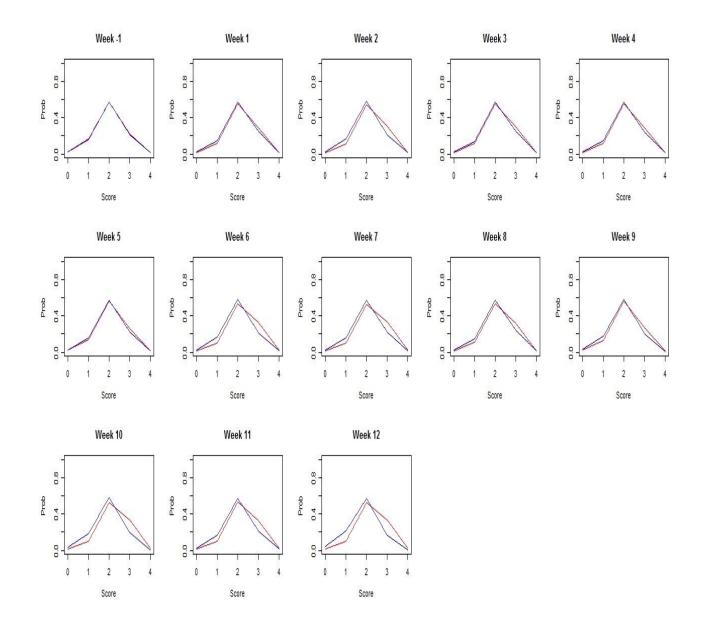
Log likelihood second model: -6098.03 df= 5529

Test statistic (Chi-square) : 101.86 df= 25

p-value= 3.044321e-11

-----End of Likelihood ratio test ------

#### [1] 3.044321e-11



### **16. STRESS**

------ Likelihood ratio test ------

Log likelihood first model: -7364.03 df= 5490

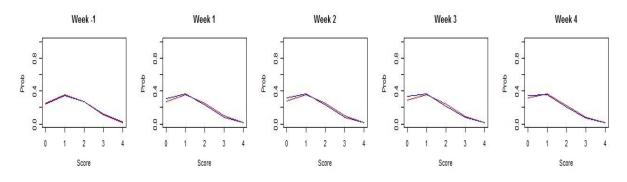
Log likelihood second model: -7364.03 df= 5490

Test statistic (Chi-square) : 62.66 df= 25

p-value= 4.451887e-05

-----End of Likelihood ratio test ------

[1] 4.451887e-05



Week 7

2 3

2 3

Score

4



0.8

0.4

0.0

0.8

0.4

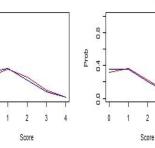
0.0

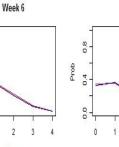
0

Prob

0

Prob





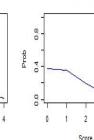
Prob

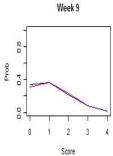
0.4

0.0

0

1



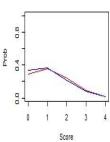




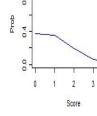
2 3 4

Score

1



Week 11

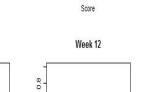


Week 8





4



Appendix 4.1 Ethical Approval Certificate



# Appendix 4.2 Weight Efficacy Life-Style Questionnaire (WEL)

Listed below are a number of situations that lead some people to eat. Please select the number that best describes your confidence about being able to resist the desire to eat in each situation according to the following scale:

	0	1	2	3	4	5	6	7	8	9
1		NFIDEN	іт					V	ERY CO	NFIDENT
1. I (	can resis	t eating	when I	am an	xious (n	ervous)	)			
0	1	2	3	4	5	6	7	8	9	
2. I	can conti	rol my e	ating o	n the we	eekend	S.				
0	1	2	3	4	5	6	7	8	9	
3. I	can resis	t eating	even v	vhen I h	ave to s	say "no'	' to othe	ers.		
0	1	2	3	4	5	6	7	8	9	
4. I (	can resis	t eating	when I	l feel ph	ysically	run do	wn.			
0	1	2	3	4	5	6	7	8	9	
5. I	can resis	t eating	when I	am wa	tching 7	ΓV.				
0	1	2	3	4	5	6	7	8	9	
6. I	can resis	t eating	when I	am de	pressed	l (or dov	wn).			
0	1	2	3	4	5	6	7	8	9	
7. I	can resis	t eating	when t	there ar	e many	differer	nt kinds	of food	available	÷.
0	1	2	3	4	5	6	7	8	9	
8. I	can resis	t eating	even v	vhen I fe	eel it's i	mpolite	to refus	e a sec	ond help	ing.
0	1	2	3	4	5	6	7	8	9	
9. I	can resis	t eating	even v	vhen I h	ave a h	eadach	e.			
0	1	2	3	4	5	6	7	8	9	
10.	l can resi	ist eatin	g when	l am re	ading.					

0	1	2	3	4	5	6	7	8	9
11. I	can res	ist eatin	g when	l am ar	ngry (or	irritable	).		
0	1	2	3	4	5	6	7	8	9
12. I	can res	ist eatin	g even v	when I a	am at a	party.			
0	1	2	3	4	5	6	7	8	9
13. I	can res	ist eatin	g even v	when of	thers ar	e press	uring me	e to eat.	
0	1	2	3	4	5	6	7	8	9
14. I	can res	ist eatin	g when	I am in	pain.				
0	1	2	3	4	5	6	7	8	9
15. I	can res	ist eatin	g just be	efore go	oing to b	oed.			
0	1	2	3	4	5	6	7	8	9
16. I	can res	ist eatin	g when	I have	experie	nced fai	lure.		
0	1	2	3	4	5	6	7	8	9
17. I	can res	ist eatin	g even v	when hi	igh-calo	rie food	s are av	/ailable.	
0	1	2	3	4	5	6	7	8	9
18. I	can res	ist eatin	g even v	when I	think oth	ners will	be ups	et if i do	n't eat.
0	1	2	3	4	5	6	7	8	9
19. I	can res	ist eatin	g when	l feel u	ncomfoi	rtable.			
0	1	2	3	4	5	6	7	8	9
20. I	can res	ist eatin	g when	l am ha	арру.				
0	1	2	3	4	5	6	7	8	

# **Appendix 5.1 Participant Information Sheet**



Human Appetite Research Unit

Institute of Psychological Sciences

University of Leeds

Leeds LS2 9JT

Kirklees Weight Management Service Diabetes and Endocrinology Department Dewsbury and District Hospital WF13 4HS

01924 816032

Tel:

Tel: 0113 343 5753

Fax: 0113 343 5749

# PARTICIPANT INFORMATION SHEET

# Factors associated with weight loss and/or weight loss maintenance following an NHS weight management programme

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Please take your time to decide whether or not you wish to take part.

#### What is the purpose of the study?

Obesity rates are currently increasing and although many different weight management programmes are successful, people find it hard to maintain any changes. Therefore, it is essential to identify factors that predict weight loss and weight loss maintenance and how they can be used to improve future interventions. These might include treatment type and also personal characteristics (physiological and psychological). The present study aims to evaluate the 12-week weight management programme provided to men and women by Mid Yorkshire Hospitals, NHS Trust. We aim to examine the overall strengths and weaknesses of the programme, to assess gaps in provision and to assess the reasons for success.

#### Why have I been invited?

You are invited to participate in this study because you have either completed the 12week weight management programme delivered by Mid Yorkshire Hospitals, NHS Trust or you are about to start it. We believe you can provide important information to us that may be help us to improve our WMP for future patients.

#### Do I have to take part?

No. 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. You have 7 days (around the time of your next visit) to decide whether you would like to take part or not in the study. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your participation in the weight management programme.

#### What will happen to me if I take part?

If you are happy to participate in the research we will ask you to read this information sheet, sign the consent form and return it to us. It would be helpful if you could return this form at your next visit which will be at least 7 days from now and indicate whether you would like to take part in the study or not. By signing the consent form you are giving permission to the Chief Investigator (Kyriaki Myrissa) to access your medical records for specific information (your body weight, height, blood pressure, and fasting glucose) and guestionnaires that you completed/ or are about to complete as part of the 12-week weight management programme. We also would like to invite you to attend a 6 month follow up where you will be asked to complete the same questionnaires that you completed at the end of the weight management programme. We will send you a letter to ask you if you would be happy to attend this follow up visit. This visit will take place either at Dewsbury hospital or in any of the centres where you attended the group sessions (Oakwell centre in Dewsbury and District Hospital or Brian Jackson House in Huddersfield). If a community centre is available and you are happy to attend one of the scheduled support group sessions, this option will be preferred. However, if you are unable or unwilling to travel to one of the community centres or if such place is not available, we will arrange a convenient meeting for you.

#### What are the possible disadvantages and risks of taking part?

There are no health risks related to this study. Whilst you may be asked to answer questions on your diet and eating behaviours, all information provided by you will be kept confidential at all times. Only members of the research team will have access to the information you provide to us. Some questions in the questionnaires may be sensitive and you might feel uncomfortable answering them. You are not obliged to answer all questions and you can skip question(s) without having to give a reason

#### What are the possible benefits of taking part?

People who have followed the weight management programme in the past have demonstrated improvements in their nutritional and health status. Taking part in the study is likely to increase your understanding of what constitutes a healthy diet and your ability to implement such recommendations. Your participation may provide important new information regarding the weight management programme and possible ways of improving it. The results from the study might also improve our understanding of the factors influencing short and long term weight loss and weight loss maintenance in overweight individuals. Your participation will increase the body of research knowledge in this area, which may help other people in the future.

### What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you feel distressed at any time (e.g. distress brought about by a failure to lose or sustain weight loss) you should contact Dr Joanne Quinn (Clinical Psychologist) or Dr Chinnadorai Rajeswaran (Consultant). If you have a complaint about the way you have been dealt with during the study, you can make a complaint to the local NHS complaints service or contact the local Patient Advice and Liaison Service.

#### Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you during the weight management programme will be handled in confidence. All information that is collected from you will be treated in the strictest of confidence at all times and will only be used for the purposes of this research. All responses to the questionnaires and information provided by them will be anonymised. All data will be recorded safely using unique identification code. The link between your name (and other personal data) and your unique identity code will be maintained and stored securely in Dewsbury and District Hospital, NHS Trust and will only be accessible to the University research team. Unique identification codes will be assigned upon inclusion to the study (after consent has been obtained) and stored securely in the participant enrolment log. All data will be stored in secure areas on computers, which are password protected. Anything that you say will be treated in confidence and no names will be mentioned in any reports of the study. Some results from the study will be used towards an educational qualification by a member of the team. Individuals will not be identifiable from any details in reports, presentations or scientific publications based on the results of the study.

#### What will happen to the results of the research study?

All information provided by you will be stored anonymously on a computer with analysis of the information obtained undertaken by a member of the research team based at Dewsbury and District Hospital. If you would also like to know the results of the study, you can email the research team and they will be able to give this information to you when it becomes available. Remember that your own results are confidential and that your name will not be associated with any information published from this study. The results from this study will be available in one or more of the following sources: scientific papers in peer reviewed academic journals, presentations at regional or international conferences/seminars. The findings will be available from the Kirklees Adult Weight Management Service for Adults, Mid Yorkshire Hospitals, NHS trust, upon completion of the evaluation.

# Who is organising and funding the research?

The research is a collaboration between the Biopsychology Group, Institute of Psychological Sciences, University of Leeds and Kirklees Adult Weight Management Service for Adults, Mid Yorkshire Hospitals, NHS Trust. The funding for this research has been made available from the Economic Social Research Council (ESRC) to support the doctoral research of Kyriaki Myrissa in this area.

#### Who has reviewed this study?

All research is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the South Yorkshire NHS Research Ethics Committee

#### Who do I contact for further information?

If you want further information about this study or information regarding this research or if you need extra advice please contact one of the following researchers:

Kyriaki Myrissa (k.myrissa@leeds.ac.uk; 0113 343 5753)

Dr Joanne Quinn (Joanne.Quinn@midyorks.nhs.uk; 01924 816032)

Dr Chinnadorai Rajeswaran (Chinnadorai.Rajeswaran@midyorks.nhs.uk; 01924816144)

Dr Clare Lawton (c.l.lawton@leeds.ac.uk; 0113 3435741)

Professor Louise Dye (I.dye@leeds.ac.uk; 0113 3435707)

Finally, thank you for taking the time to read this information.

#### INFORMED CONSENT FORM

# Factors associated with weight loss and/or weight loss maintenance following an NHS weight management programme Please

Initial

- 1 I confirm that I have read and understood the Participant Information Sheet dated 14<sup>th</sup> October 2014 (version 3) for the above study. I have had the opportunity to consider the information, ask questions about the study and have had these answered satisfactorily.
- 2 I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. In addition, should I not wish to answer any particular question or questions, I am free to decline.
- 3 I understand that relevant sections of my medical notes and data collected during the study, may be looked at by the research team from the University of Leeds, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- 4 I agree to take part in the above study.

Participant's name

Date

Signature

10/10/2015

Researcher's name

Kyriaki Myrissa

Date

Signature

# Appendix 5.2 EAT WELL plate



## Appendix 5.3 Hospital Anxiety and Depression Scale (HADS)

Instructions: Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he or she will be able to help you more. This questionnaire is designed to help your doctor know how you feel. Read each item and circle the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

I feel tense or 'wound up':	Α
Most of the time	3
A lot of the time	2
Time to time, occasionally	1
Not at all	0
I still enjoy the things I used to enjoy:	D
Definitely as much	0
Not quite so much	1
Only a little	2

I feel as if I am slowed down:	D
Nearly all of the time	3
Very often	2
Sometimes	1
Not at all	0
I get a sort of frightened feeling like	Α
'butterflies in the stomach':	
Not at all	0
Occasionally	1
Quite often	2

I get a sort of frightened feeling like something awful is about to happen:	Α
Very definitely and quite badly	3
Yes, but not too badly	2
A little, but it doesn't worry me	1
Not at all	0

I can laugh and see the funny side of things:	D
As much as I always could	0
Not quite so much now	1
Definitely not so much now	2
Not at all	3

I have lost interest in my appearance:	D
Definitely	3
I don't take as much care as I should	2
I may not take quite as much care	1
I take just as much care as ever	0
I feel restless as if I have to be on the move:	A
Very much indeed	3
Quite a lot	2
Not very much	1
Not at all	0

Worrying thoughts go through my mind: Α I look forward with enjoyment to D things:

A great deal of the time	3	A much as I ever did	0
A lot of the time	2	Rather less than I used to	1
From time to time but not too often	1	Definitely less than I used to	3
Only occasionally	0	Hardly at all	2
I feel cheerful:	D	I get sudden feelings of panic:	Α
Not at all	3	Very often indeed	3
Not often	2	Quite often	2
Sometimes	1	Not very often	1
Most of the time	0	Not at all	0
I can sit at ease and feel relaxed:	Α	I can enjoy a good book or radio or TV programme:	D
Definitely	0	Often	0
Usually	1	Sometimes	1
Not often	2	Not often	2
Not at all	3	Very seldom	3

Questions relating to anxiety are indicated by an 'A' while those relating to depression are shown by a 'D'. Scores of 0-7 in respective subscales are considered normal, with 8-10 borderline and 11 or over indicating clinical 'caseness'

# Appendix 5.4 Dichotomous Thinking in Eating Disorders Scale

Please read each of the following statements and decide how true it is of your thinking over the past month

Not at all true of me | Slightly true of me | Fairly true of me | Very true of me

- 1. I think of food as either 'good' or 'bad'
- 2. I think of things in 'black' and 'white' terms
- 3. I think of myself as either good or bad
- 4. I view my attempts to diet as either successes or failures
- 5. I think of myself as either in control or out of control
- 6. When dieting, if I eat something that I had planned not to, I think that I have failed
- 7. I think of myself as either clever or stupid
- 8. When dieting, I view my eating as having been either good or bad
- 9. I either get on very well with people or not at all
- 10. I think of myself as either ugly or good-looking
- 11. I think of myself as doing things either very well or very badly

# Appendix 5.5 Diet Readiness Scale (DRS)

For each question, circle the answer that best describes your approach towards the weight loss programme.

- 1. Compared to previous attempts, how motivated to lose weight are you this time?
  - 1. Not at all motivated
  - 2. Slightly motivated
  - 3. Somewhat motivated
  - 4. Quite motivated
  - 5. Extremely motivated
- 2. How certain are you that you will stay committed to a weight loss program for the time it will take you to reach your goal?
  - 1. Not at all certain
  - 2. Slightly certain
  - 3. Somewhat certain
  - 4. Quite certain
  - 5. Extremely certain
- 3. Consider all outside factors at this time in your life (the stress you're feeling at work, your family obligations, etc.). To what extent can you tolerate the effort required to stick to a diet?
  - 1. Cannot tolerate
  - 2. Can tolerate somewhat
  - 3. Uncertain
  - 4. Can tolerate well
  - 5. Can tolerate easily
- 4. Think honestly about how much weight you hope to lose and how quickly you hope to lose it. Figuring a weight loss of 1 to 2 pounds per week, how realistic is your expectation?
  - 1. Very unrealistic
  - 2. Somewhat unrealistic
  - 3. Moderately unrealistic
  - 4. Somewhat realistic
  - 5. Very realistic
- 5. While dieting, do you fantasize about eating a lot of your favourite foods?
  - 1. Always
  - 2. Frequently
  - 3. Occasionally
  - 4. Rarely
  - 5. Never
- 6. While dieting, do you feel deprived, angry and/or upset?
  - 1. Always
  - 2. Frequently
  - 3. Occasionally
  - 4. Rarely
  - 5. Never

# Appendix 5.6 Binge eating scale (BES)

Instructions. Below are groups of numbered statements. Read all of the statements in

each group and circle the one that best describes the way you feel.

#1

- 1. I don't feel self-conscious about my weight or body size when I'm with others.
- 2. I feel concerned about how I look to others, but it normally does not make me feel disappointed with myself.
- 3. I do get self-conscious about my appearance and weight which makes me feel disappointed in myself.
- 4. I feel very self-conscious about my weight and frequently, I feel intense shame and disgust for myself. I try to avoid social contacts because of my self consciousness.

#2

- 1. I don't have any difficulty eating slowly in the proper manner.
- 2. Although I seem to "gobble down" foods, I don't end up feeling stuffed because of eating too much.
- 3. At times, I tend to eat quickly and then, I feel uncomfortably full afterwards.
- 4. I have the habit of bolting down my food, without really chewing it. When this happens I usually feel uncomfortably stuffed because I've eaten too much.

#3

- 1. I feel capable to control my eating urges when I want to.
- 2. I feel like I have failed to control my eating more than the average person.
- 3. I feel utterly helpless when it comes to feeling in control of my eating urges.
- 4. Because I feel so helpless about controlling my eating I have become very desperate about trying to get in control.

#4

- 1. I don't have the habit of eating when I'm bored.
- 2. I sometimes eat when I'm bored, but often I'm able to "get busy" and get my mind off food.
- 3. I have a regular habit of eating when I'm bored, but occasionally, I can use some other activity to get my mind off eating.
- 4. I have a strong habit of eating when I'm bored. Nothing seems to help me break the habit.

#5

- 1. I'm usually physically hungry when I eat something.
- 2. Occasionally, I eat something on impulse even though I really am not hungry.
- 3. I have the regular habit of eating foods, that I might not really enjoy, to satisfy a hungry feeling even though physically, I don't need the food.
- 4. Even though I'm not physically hungry, 1 get a hungry feeling in my mouth that only seems to be satisfied when I eat a food, like a sandwich, that fills my mouth. Sometimes, when I eat the food to satisfy my mouth hunger, I then spit the food out so I won't gain weight.

1. I don't feel any guilt or self-hate after I overeat.

2. After I overeat, occasionally I feel guilt or self-hate.

3. Almost all the time I experience strong guilt or self-hate after I overeat.

#7

1. I don't lose total control of my eating when dieting even after periods when I overeat.

2. Sometimes when I eat a "forbidden food" on a diet, I feel like I "blew it" and eat even more.

 Frequently, I have the habit of saying to myself, "I've blown it now, why not go all the way" when I overeat on a diet. When that happens I eat even more.
 I have a regular habit of starting strict diets for myself, but I break the diets by going on an eating binge. My life seems to be either a "feast" or "famine."

#### #8

1. I rarely eat so much food that I feel uncomfortably stuffed afterwards.

2. Usually about once a month, I eat such a quantity of food, I end up feeling very stuffed.

3. I have regular periods during the month when I eat large amounts of food, either at mealtime or at snacks.

4. I eat so much food that I regularly feel quite uncomfortable after eating and sometimes a bit nauseous.

#### #9

1. My level of calorie intake does not go up very high or go down very low on a regular basis.

2. Sometimes after I overeat, I will try to reduce my caloric intake to almost nothing to compensate for the excess calories I've eaten.

3. I have a regular habit of overeating during the night. It seems that my routine is not to be hungry in the morning but overeat in the evening.

4. In my adult years, I have had week-long periods where I practically starve

myself. This follows periods when I overeat. It seems I live a life of either "feast or famine."

#10

1. I usually am able to stop eating when I want to. I know when "enough is enough."

2. Every so often, I experience a compulsion to eat which I can't seem to control.

3. Frequently, I experience strong urges to eat which I seem unable to control, but at other times I can control my eating urges.

4. I feel incapable of controlling urges to eat. I have a fear of not being able to stop eating voluntarily.

#11

1. I don't have any problem stopping eating when I feel full.

2. I usually can stop eating when I feel full but occasionally overeat leaving me feeling uncomfortably stuffed.

Binge eating assessment 55

3. I have a problem stopping eating once I start and usually I feel uncomfortably stuffed after I eat a meal.

4. Because I have a problem not being able to stop eating when I want, I

sometimes have to induce vomiting to relieve my stuffed feeling.

#12

1. I seem to eat just as much when I'm with others (family, social gatherings) as when I'm by myself.

2. Sometimes, when I'm with other persons, I don't eat as much as I want to eat because I'm self-conscious about my eating.

3. Frequently, I eat only a small amount of food when others are present,

because I'm very embarrassed about my eating.

4. I feel so ashamed about overeating that I pick times to overeat when I know no one will see me. I feel like a "closet eater."

1. I eat three meals a day with only an occasional between meal snack.

2. I eat 3 meals a day, but I also normally snack between meals.

3. When I am snacking heavily, I get in the habit of skipping regular meals.

4. There are regular periods when I seem to be continually eating, with no planned meals.

#### #14

1. I don't think much about trying to control unwanted eating urges.

2. At least some of the time, I feel my thoughts are pre-occupied with trying to control my eating urges.

3. I feel that frequently I spend much time thinking about how much I ate or about trying not to eat anymore.

4. It seems to me that most of my waking hours are pre-occupied by thoughts about eating or not eating. I feel like I'm constantly struggling not to eat.

#### #15

1. I don't think about food a great deal.

2. I have strong cravings for food but they last only for brief periods of time.

3. I have days when I can't seem to think about anything else but food.

4. Most of my days seem to be pre-occupied with thoughts about food. I feel like I live to eat.

#### #16

1. I usually know whether or not I'm physically hungry. I take the right portion of food to satisfy me.

2. Occasionally, I feel uncertain about knowing whether or not I'm physically hungry. At these times it's hard to know how much food I should take to satisfy me.

3. Even though I might know how many calories I should eat, I don't have any idea what is a "normal" amount of food for me.