

**Randomised Controlled Trial of a Novel Dietetic
Treatment for Childhood Obesity and a
Qualitative Study of Parents' Perceptions of
Dietetic Treatment**

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TABLE OF CONTENTS

TABLES AND FIGURES.....	7
DECLARATION	10
LIST OF PUBLICATIONS	13
LIST OF ABBREVIATIONS	14
SUMMARY	16
CHAPTER 1.....	19
Childhood Obesity	19
1.0 Introduction	19
1.1 Diagnosis	20
1.1.1 Body Mass Index.....	20
1.1.2 Fat distribution and waist measurements	24
1.2 Prevalence of childhood obesity	26
1.2.1 Groups at high risk of obesity	28
1.3 Possible causes of childhood obesity	29
1.3.1 Diet.....	30
1.3.2 Physical activity and sedentary behaviours	32
1.3.3 Genetics	33
1.3.4 Endocrine causes of obesity	35
1.3.5 Sleep deprivation	36
1.4 Clinical assessment of childhood obesity	36
1.5 Consequences.....	39
1.5.1 Cardiovascular risk factors	39
1.5.2 The metabolic syndrome	40
1.5.3 Insulin resistance	43
1.5.4 Type 2 diabetes.....	44
1.5.5 Non alcoholic fatty liver disease	45
1.5.6 Polycystic ovarian syndrome	46
1.5.7 Respiratory problems	46
1.5.8 Orthopaedic.....	47
1.5.9 Psychological consequences and self-esteem.....	47
1.6 Prevention.....	47

1.7 Radical treatments for paediatric obesity	48
1.7.1 Drugs.....	48
1.7.2 Surgery.....	49
1.7.3 Very low energy diets	49
1.8 Evidence for treatment strategies	50
1.8.1 Recent relevant studies.....	53
1.8.2 SCOTT study in context	56
CHAPTER 2.....	57
Randomised Controlled Trial of a Novel Dietetic Treatment for Childhood Obesity: Quantitative study design and methodology.....	57
2.0 Introduction	57
2.1 Research question.....	58
2.2 Ethical approval	58
2.3 Study design	59
2.3.1 Power	59
2.3.2 Delivery of treatments	59
2.3.3 Inclusion and exclusion criteria	59
2.3.4 Blinding	62
2.3.5 Consent.....	63
2.3.6 Randomisation and concealment	63
2.3.7 Statistical analysis	64
2.4 Outcome measurements	65
2.4.1 Height, weight and BMI	66
2.4.2 Waist circumference.....	68
2.4.3 Measurements of activity.....	68
2.4.4 Quality of life questionnaire	69
2.4.5 Socioeconomic status	71
2.4.6 Six and 12 month measurements.....	72
2.5 Payments.....	72
2.6 Monitoring completers and non completers	72
CHAPTER 3.....	74
Novel and standard dietetic treatments	74
3.0 Development of the novel treatment programme.....	74
3.1 Influence of Epstein	75

3.1.1 Diet.....	76
3.1.2 Sedentary behaviours	76
3.1.3 Physical activity.....	77
3.1.4 Behavioural changes – family involvement	77
3.2 SIGN 69.....	77
3.3 Behavioural change interviewing techniques.....	78
3.3.1 Behavioural change techniques	79
3.3.2 Motivational interviewing	81
3.3.3 Training and assessment	83
3.4 Pilot study	84
3.5 Peer review of printed materials	85
3.6 The novel treatment protocol	86
3.6.1 Structure of programme	86
3.6.2 Dietary advice in the novel treatment programme.....	88
3.6.3 Activity levels and sedentary behaviour	90
3.6.4 Behavioural change interviewing techniques in the novel treatment programme.....	91
3.7 Standard dietetic treatment.....	95
3.7.1 Structure of appointments in standard care.....	96
3.7.2 Lifestyle advice in standard dietetic care.....	96
3.8 Comparison between novel and standard dietetic treatment.....	97
3.8.1 Intensity of treatment.....	98
3.8.2 Interviewing techniques.....	98
3.8.3 Lifestyle advice.....	101
CHAPTER 4.....	102
Results – Quantitative study.....	102
4.0 Statistical analysis and power.....	102
4.0.1 Data analysis.....	102
4.0.2 Treatment compliance and per protocol analysis	104
4.1 Characteristics of participants at baseline	105
4.1.1 Parental weight and family social status.....	105
4.2 Primary outcome – Change in Body Mass Index	106
4.3 Secondary outcomes	108
4.3.1 Changes in BMI centiles.....	108

4.3.1.1 Clinical significance of changes in BMI centiles	110
4.3.2 Changes in weight.....	112
4.3.3 Changes in waist measurements and SD score.....	114
4.3.4 Changes in habitual physical activity and sedentary behaviour.....	116
4.4 Possible adverse effects of treatment.....	118
4.4.1 Changes in height	118
4.4.2 Changes in Quality of Life	119
4.5 Per-protocol analysis	120
4.6 Discussion	121
4.6.1 Study power and quality	121
4.6.2 Study limitations	122
4.6.3 Study implications	126
4.6.4 Comparison with other studies	130
Chapter 5	134
Background: Qualitative research principles	134
5.0 Introduction	134
5.1 Qualitative research.....	136
5.1.1 Background/history	138
5.2 In-depth interviews.....	139
5.3 Sampling in qualitative research	140
5.4 Analysis in qualitative research.....	141
5.4.1 Framework analysis	142
5.4.2 Nvivo software package	144
5.5 Quality in qualitative studies	145
5.5.1 Reflexivity.....	145
5.5.2 Triangulation	146
5.5.3 Audit trail	146
5.5.4 Authenticity.....	146
5.5.5 Relevance	147
5.6 Training in qualitative methodology	147
5.7 Suggested further reading	148
CHAPTER 6.....	149

Parental perspectives of a novel, dietetic-led behavioural programme and standard dietetic care for the treatment of childhood obesity: Qualitative study design, methodology and results	149
6.0 Introduction	149
6.1 Study design and methodology.....	150
6.1.1 Ethical approval.....	150
6.1.2 Study sampling and recruitment.....	150
6.1.3 Interviews	153
6.1.4 Data handling	155
6.1.5 Payments	159
6.2 Characteristics of participants.....	159
6.3 Results.....	160
6.3.1 Results 1 - Qualitative evaluation of dietetic treatments.....	161
6.3.1.1 Parental expectations of treatment.....	161
6.3.1.2 Appointments	162
6.3.1.3 Behavioural change techniques	165
6.3.1.3.1 Exploring motivation to make lifestyle changes.....	165
6.3.1.3.2 Goal setting and rewards	166
6.3.1.3.3 Self-monitoring of lifestyle changes.....	167
6.3.1.4 Responsibility for lifestyle changes.....	168
6.3.1.5 Dietary changes during and after treatment	168
6.3.1.6 Changes in physical activity and sedentary behaviour.....	169
6.3.1.7 Parental suggestions for improvement in treatment experience	170
6.3.1.8 Barriers to lifestyle changes reported by parents	172
6.3.2 Results 2 - The parents' journey to and through treatment – Crying out for help.....	173
6.3.2.1 Beginning the journey – why enter treatment?	174
6.3.2.2 During the treatment – the need for support.....	178
6.3.2.2.1 Support from family	179
6.3.2.3 Post treatment – was it all worth it?.....	182
6.4 Discussion and interpretation.....	186
6.4.1 Discussion and interpretation results 1 - qualitative evaluation	187
6.4.2 Discussion and interpretation results 2 - The parents' journey.	191

6.4.3 Study limitations	194
6.4.4 Qualitative study implications with reference to other studies ..	196
CHAPTER 7	201
Discussion and interpretation of results.....	201
7.0 Introduction	201
7.1 The novel treatment programme.....	202
7.1.1 Length and intensity of treatment	202
7.1.2 Use of behavioural change techniques	204
7.1.3 Use of the traffic light healthy eating plan.....	207
7.1.4 Training issues for health professionals	208
7.2 Comparisons with other work.....	211
7.2.1 Epstein	212
7.2.2 Studies within the UK NHS.....	217
7.2.3 Studies from outside the UK.....	221
7.3 Main strengths of the present study.....	224
7.4 Main weaknesses of the present study	226
7.5 Suggested changes to studies for future research.....	227
7.5.1 The pilot study	228
7.5.2 Structure of the novel treatment protocol	228
7.5.3 Content of the novel treatment programme.....	229
7.5.4 Motivation to change	230
7.5.5 Outcome measurements	232
7.5.6 The qualitative study	233
7.6 Possible future research	233
7.7 Conclusions	235
REFERENCES	237
APPENDICES	

TABLES AND FIGURES

Table 1.1: Prevalence of overweight and obesity in Scotland (47)	27
Table 1.2: Suggested investigation plan for an initial visit to an obesity clinic(91)	38
Table 1.3: Comparison of criteria used by different investigators for diagnosis of the metabolic syndrome taken from Jones 2006 (100)	41
Table 1.4: Definition of metabolic syndrome used by Viner et al 2005 (105) .	43
Table 2.1: List of sources of referrals to the study	60
Table 2.2: Outline of measurements taken and information collect at each measurement clinic.....	67
Table 3.1: Summary of the client-centred approach and behavioural change techniques(156).....	83
Table 3.2: Quick reference table for novel treatment protocol	87
Table 3.3: Outline of the modified traffic light diet (156).....	89
Table 3.4: Typical answers given by children to the decisional balance charts (156)	92
Table 3.5: Typical goals set by child and agreed reward (171).....	93
Table 3.6: Comparison of standard and novel dietetic treatments	100
Figure 4.1. Flow of participants through the trial	103
Table 4.1: Baseline characteristics of the study participants.....	105
Table 4.2: BMI SD score by group over time	106
Table 4.3: Change in BMI SD score from baseline to follow-up (Mann Whitney test).....	107
Table 4.4: Changes in <i>within</i> group BMI SD score over time (Wilcoxon signed rank test).....	108
Table 4.5: BMI centiles by group over time.....	108
Table 4.6: Change in BMI centiles from baseline to follow-up (Mann Whitney test).....	109
Table 4.7: Changes in within group BMI centiles over time (Wilcoxon signed rank test).....	110
Table 4.8: Obesity gradings through time	111
Table 4.9: Movement in obesity gradings from baseline to 12 months	112

Table 4.10: Weight by group over time	113
Table 4.11: Change in weight from baseline to follow-up (Mann Whitney test)	113
Table 4.12: Changes in weight within group over time (Wilcoxon signed rank test).....	114
Table 4.13: Waist circumference and waist SD score by group over time ...	115
Table 4.14: Changes in waist circumference and waist SD score within group over time (Wilcoxon signed rank test).....	116
Table 4.15: Physical activity levels by group baseline and six months	117
Table 4.16: Median change (IQ range) in habitual physical activity and sedentary behaviour from baseline to six months by group.....	118
Table 4.17: Changes in height within group over time (Wilcoxon signed rank test).....	119
Table 4.18: Child self reporting and parent proxy Total Scale Scores for quality of life from baseline to follow-up	120
Table 4.19: BMI SD score and weight by group over time for completers ...	121
Table 4.20: Comparison of the present SCOTT results with four other.....	133
studies.	133
Table 5.1: Outlining the principles of qualitative research Spencer et al 2003 (184)	137
Table 5.2: Summary of the 'Framework' process.....	143
Table 6.1: Table showing main characteristics of sample population	151
Table 6.2: Topic guide used for interviews in the present study	154
Table 6.3: Chart headings used for mapping and interpretation of themes	158
Table 6.4: Characteristics of participants in the qualitative study n=17.....	160
Table 6.5: Standard care parental suggestions for improvement in treatment experience	171
Table 6.6: Parents' views on barriers to achieving lifestyle changes	172
Table 6.7: Parents emotions through the journey	173
Figure 6.1: Diagram representing parents' typologies at beginning of the journey.....	176
Table 6.8: Quotes from parents on needing an outside influence	179
Table 6.9: Quotes from parents on lack of support from the nucleus and extended family.....	180

Table 6.10: Quotes from parents on lack of support from grandparents	182
Table 6.11: People perceived by parents as being unsupportive.....	182
Table 6.12: Quotes from parents on positive feeling about the dietetic treatment	183
Table 6.13: Quotes from parents on negative feeling about the dietetic treatment	184
Table 6.14: Quotes from parents on weight outcomes.....	185
Table 6.15: Quotes from parents on their child's future weight perception ..	186
Table 6.16: Summary of common and distinctive themes.....	190
Table 7.1: Common answers given by children to the decisional balance charts(156)	206

DECLARATION

Contribution of the Author of the Thesis

I declare that all the work within this thesis is my own work. The scale and nature of the work described in this thesis was that of a research team and went beyond what could be carried out by any single researcher. During the studies described in the present thesis I was employed as part-time research assistant on two grants funded by the Scottish Executive Health Department Chief Scientist's Office (CSO): the quantitative study (Scottish Childhood Obesity Trial or "SCOTT") and the qualitative study. In both of these projects more than one member of staff was necessary because of the workload involved and it is appropriate to describe what I did in some detail in the thesis declaration.

Quantitative Study (SCOTT)

Literature Searching, Design, Method Development

I was originally involved in this area as an author of the systematic review/critical appraisal of the evidence based childhood obesity management guideline (SIGN 69 www.sign.ac.uk) which directly led to SCOTT project. I was fully involved in the design of SCOTT from the outset as a study collaborator.

I took the lead in designing and developing the novel treatment programme (see chapter 3 and appendix 1) with input from Prof Reilly, the other research dietitian employed on the project (J Chapple, née Houghton) and the postdoctoral fellow employed on the project (Dr Adrienne Hughes). In the early stages of development of the programme we took advice on it from Prof Bryan Lask, (St Georges' Hospital, London) Prof Jane Wardle and Helen Croker (UCL, London), and Prof Lori Stark (University of Cincinnati, USA). I had also been the

lead person in the development of treatment materials for the standard care (control group) patients.

Data Collection

Since SCOTT was an assessor – blinded RCT, the outcome measures were all made by Dr A. Hughes who was blinded to group allocation of patients. I could not make outcome measurements as a result of my involvement in the delivery of treatment to participants in the novel treatment arm of the trial in Edinburgh.

Data Analysis, Interpretation, and Write-up

I carried out all of the data analysis and interpretation described in the thesis, and all of the writing is my own. I took advice on analysis and interpretation of the data from the quantitative study from Prof John H McColl, a statistician and one of the SCOTT grant holders.

Qualitative Studies

A qualitative study was carried out based on in-depth interview of parents who had participated in the SCOTT project (see chapters 5 and 6).

Literature Searching, Study Design, Methods

I carried out the literature searches for the qualitative studies described in this thesis. I took the lead in the design of the qualitative studies and chose the methods of data collection and analysis. In making decisions over study design, I took the views of the other researchers and grant holders into account (particularly Prof Reilly, Dr Hughes, Dr Vanessa Poustie, Jan Chapple), and took advice from other experts in Qualitative Study Design and Methodology (particularly Jane Ritchie, Founding Director of the National Centre for Social Research, London).

Data Collection

In order to avoid bias, as described above, we decided, that data collection (by in-depth interviews) would require two researchers. Jan Chapple and I collected data from parents with whom we had no previous clinical input.

Data Analysis, Interpretation, and Write-Up

I analysed, interpreted and wrote the qualitative studies described in this thesis. As qualitative studies require agreement on themes, concepts and descriptions I closely consulted on with other members of the team, in particular Jan Chapple and Vanessa Poustie.

LIST OF PUBLICATIONS

Published

Stewart, L., Houghton, J., Hughes, A.R., Pearson, D., Reilly J.J. 2005 Dietetic Management of Pediatric Overweight: Development and description of a practical and evidence-based behavioural approach. Journal of the American Dietetic Association.105:1810-1815 – see appendix 18

Stewart L., Chapple J., Hughes A.R., Poustie V., Reilly J.J. Parents' perspectives of the journey to and through treatment for their child's obesity: qualitative study. Archives of Diseases in Childhood. 2008;93;35-39 doi:10.1136/ad.2007.125146 – see appendix 18

Hughes A.R., Stewart L., Chapple J., McColl J. H., Donaldson M. D. C., Kelnar C. J. H., Zabihallah M., Ahmed F., Reilly J.J. Randomized, controlled trial of a best-practice individualized behavioral program for treatment of childhood overweight: Scottish Childhood Overweight Treatment Trial (SCOTT). Pediatrics 2008;121;e539-e546 DOI: 10.1542/peds.2007-1786 – see appendix 18

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Stewart L., Chapple J., Hughes A.R., Poustie V., Reilly J.J. The use of behavioural change techniques in treatment of paediatric obesity: qualitative evaluation of parental perspectives on treatment.

LIST OF ABBREVIATIONS

ALT	Aminotransferase
BMA	British Medical Association
BMI	Body Mass Index
CAQDAS	Computer Assisted Data Analysis Software
CONSORT	Consolidated standards of reporting trials
COREC	Central Office of Research Ethics Committees
CPM	Counts per minute
CSA	Computer Science and Applications
CSO	Chief Scientist Office
CT	Computer tomography
CVD	Cardiovascular disease
Depcat	Deprivation category
DEXA	Dual energy X-ray absorptiometry
DNA	Deoxyribonucleic acid
DNA	Did not attend
GOOS	Genetics of obesity study
GP	General Practitioner
HDL	High density lipoprotein
HOMA	Homeostatic model
IDF	International Diabetes Federation
IGT	Impaired glucose tolerance
IOTF	International Obesity Task Force
IQ	Interquartile
ISD	Information Statistics Division
LDL	Low density lipoprotein
LEAP	Live, Eat and Play
MC4R	Melanocortin 4 receptor
MRI	Magnetic resonance imaging
MTI	Manufacturing Technology Inc
MVPA	Moderate-vigorous physical activity

NAFLD	Non alcoholic fatty liver disease
NASH	Non alcoholic steatohepatitis
NHANES	National Health and Nutrition Examination Survey
NHES	National Health Examination Survey
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NT	Novel Treatment
OGTT	Oral glucose tolerance test
PCOS	Polycystic ovarian syndrome
PedsQL	Pediatric Quality of Life Inventory
POMC	Propeptide proopiomelanocortin
PSW	Physical self worth
RCPCH	Royal College of Paediatrics and Child Health
RCT	Randomised Controlled Trial
RHSC	Royal Hospital for Sick Children
SC	Standard Care
SCOTT	Scottish Childhood Treatment Trial
SD	Standard deviation
SHOT	Sheffield Obesity Trial
SIGN	Scottish Intercollegiate Guideline Network
SNDRi	Scottish Nutrition and Diet Resource Initiative
T4	Thyroxine
TSH	Thyroid-stimulating hormone
TV	Television
UCL	University College London
UK	United Kingdom
USA	United States of America
VLED	Very Low Energy Diet

SUMMARY

Introduction

Obesity is the most common nutritional disorder in the world and is widely acknowledged as having become a global epidemic.(1) The prevalence of childhood obesity in the United Kingdom (UK) dramatically increased over a short number of years in the 1990s.(2-4) There are well-recognised health consequences of childhood obesity, both during childhood as well as those tracking into adulthood affecting health, psychological and economical welfare.(5;6) However, there is a surprising lack of well conducted published research into effective childhood obesity treatment strategies and few with relevance to the UK National Health Service (NHS).(5;7)

This thesis describes (a) the Scottish Childhood Obesity Treatment Trial (SCOTT), a randomised controlled trial (RCT) that compared standard NHS dietetic management of childhood obesity with a novel intensive dietetic approach in Scottish primary school aged (5 – 11 years old) children and (b) reports a complementary qualitative study that explored the parents' perceptions of the dietetic treatments their child received during the SCOTT project. The SCOTT project was conceived to be an easily reproducible treatment programme within the UK NHS system for primary school aged children.

Methodology

The SCOTT quantitative study was a single-blind RCT involving 134 obese children of primary school age (5 -11 years), 75 females and 59 males. Inclusion criteria were children with 'simple' obesity (body mass index (BMI) \geq 98th centile on the UK 1990 charts) and families that perceived the child's weight as a problem and were motivated to change. The intervention arm involved an evidence-based novel dietetic treatment over 6-months giving 5 hours of treatment and used client-centred behavioural change techniques to increase motivation for

changing diet (using a modified traffic light diet), increasing physical activity and reducing sedentary behaviour. The control arm received 1.5 hours of 'typical' dietetic weight management delivered in a traditional (educational) manner. Outcomes recorded at baseline, six and 12 months were BMI standard deviation (SD) score, objectively measured physical activity and sedentary behaviour (using accelerometers) and possible adverse effects of treatment (height growth and quality of life). The primary outcome was change in BMI SD score at six months.

The complementary qualitative study used in-depth interviews to explore the thoughts and feeling of parents of the children who had completed the dietetic intervention. All interviews took place after the SCOTT 12 month outcome measurements had been completed. Purposive sampling was used and out of the 79 eligible SCOTT parents 17 were interviewed. The interviews were taped and then transcribed by experienced secretaries. Analysis was carried out using the Framework methodology (8) and aided by Nvivo software.

Key Results

The novel treatment programme had no significant effect relative to the standard dietetic care on BMI SD score from baseline to six months (-0.10 vs -0.06; 95% CI -0.05 to 0.11) and 12 months (-0.07 vs -0.19; 95% CI -0.17 to 0.07). BMI SD score decreased significantly *within* both groups from baseline to six and 12 months. There were significant differences between the groups in favour of the novel treatment group for changes in total percentage of time spent in physical activity (95%CI 0.8 to 6.3) and light intensity physical activity (95%CI -4.8 to -0.5).

In the qualitative study we found themes and concepts both on our original evaluation and emergent data on the parents' thoughts and feelings on entering, continuing and leaving treatment. Those parents who had taken part in the behavioural change techniques applauded the process finding it child-friendly and talked of 'forming a partnership' with the child and dietitian. Developing a rapport with the dietitian was

significant for the parents in their perception of a positive experience. Parents appeared to be characterised as being unaware of their child's weight problem, in denial, or actively seeking treatment. Parents were consistently motivated to enter treatment due to perceived benefits to their child's self esteem or quality of life, and weight outcomes were considered less important. During treatment parents expressed a lack of support for lifestyle changes outside the clinic, and noted that members of the extended family often undermined changes. Parents generally felt that treatment should have continued beyond six months, and that it had provided benefits to their child's well-being, self-esteem, and quality of life, and this is what motivated many of them to remain engaged with treatment.

Conclusions

The modest magnitude of the benefits observed in the SCOTT study perhaps suggest that interventions should be longer term and more intense. The results of the qualitative study suggested that longer term interventions would be acceptable to parents.

The qualitative study was an informative addition to the SCOTT quantitative study as it allowed exploration of the subtle differences as perceived by the parents who took part in both arms of the study. It may help inform future treatments for childhood obesity by providing insights into the aspects of treatment and approaches applauded by parents. Future treatments may need to consider providing greater support to lifestyle changes within the extended family, and may need to focus more on psychosocial outcomes. This study highlighted skills and qualities required by dietitians and other health professionals to engage with families of obese children.

CHAPTER 1

Childhood Obesity

1.0 Introduction

Obesity is the most common nutritional disorder in the world and is widely acknowledged as having become a global epidemic.(1) The prevalence of childhood obesity has followed the increasing trend of the disease in adults and in the United Kingdom (UK) dramatically increased over a short number of years in the late 1980s to early 1990s.(2-4) There are well-recognised health consequences of childhood obesity, both during childhood as well as those tracking into adulthood affecting health, psychological and economical welfare.(5;6) In the UK the importance of finding effective strategies for the prevention and treatment of childhood obesity has gained national significance with the publication of various expert reports and evidence based guidelines (5;9;10) as well as government reviews and reports.(3;11;12) However there is a surprising lack of well conducted published research into effective childhood obesity treatment strategies and few with relevance to the UK National Health Service (NHS).(5;7)

The intention of this thesis is to describe (a) the Scottish Childhood Obesity Treatment Trial (SCOTT), a randomised controlled trial (RCT) that compared standard NHS dietetic management of childhood obesity with a novel intensive dietetic approach in Scottish primary school aged (5 – 11 years old) children and (b) report a complementary qualitative study that explored the parents' perceptions of the dietetic treatments their child received during the SCOTT project. The SCOTT project was conceived to be an easily reproducible treatment programme within the UK NHS system for primary school aged children. As one of the first reported RCTs on the treatment of childhood obesity in the UK it has added an important dimension to the body of UK evidence. Chapter one sets out to consider an overview of childhood obesity with

particular reference to the need for effective childhood obesity treatment strategies, principally within the context of the UK NHS.

1.1 Diagnosis

A definition of childhood obesity is important to ensure accurate clinical diagnosis as well as enabling the monitoring of trends in prevalence both within and between populations. Obesity can in simple terms be defined as an excess accumulation of body fat, however it has a clinical significance when this excess body fat leads to chronic health consequences.(13) Total body fat can be directly measured by methods such as computer tomography (CT), magnetic resonance imaging (MRI) or dual energy X-ray absorptiometry (DEXA) scan,(14) however these methods are expensive and not commonly accessible in routine practice. Therefore an 'easy to use' proxy measurement is necessary for general day-to-day clinical practice. Body mass index (BMI), calculated as $\text{weight (kg)} \div \text{height (m)}^2$, has been widely used to define and diagnosis obesity in adults (10;13;15) and its use in childhood obesity has gained wide acceptance.(5;10;16;17) However there is an important and continuing debate regarding the most appropriate cut off points for defining overweight and obesity,(18) these are explored in section 1.1.1 below.

A further key consideration is the actual distribution of fat around the body. There is a strong body of evidence that suggests that central fat distribution, in particular the level of visceral fat, in children and adolescents is associated with various health risk factors (19;20) and this is discussed in section 1.1.2.

1.1.1 Body Mass Index

For adult BMI there are well established internationally cut off points to categorise weight status-

- underweight <18.5
- ideal 18.6-24.9
- pre-obese (overweight) 25.0-29.9
- obese class I 30.0-34.9
- obese class II 35.0-39.9
- obese class III >40.(13)

Although these cut off points may be described as crude they have a clinical significance as they relate to increased risk of morbidity and mortality in adults.(13;15)

As in adulthood any definition of childhood overweight and obesity^a needs to be able to define not only body fatness but also the clinical relevance of this body fat i.e. at what level of BMI is there a significant increase in the adverse health consequences of childhood obesity.(21-23) Since BMI in childhood changes with age and varies between the sexes it requires to be plotted on sex appropriate centile charts. UK population based BMI centile charts, developed by Cole et al (1995) and produced by the Child Growth Foundation, have been available for children and adolescent since the early 1990s.(16) The data for these centile charts came from 11 different growth studies and consists of data from 15 636 boys and 14 899 girls aged from 33 week gestation to 23 years old. On these BMI centile charts there are nine centiles lines each two thirds of a standard deviation (SD) apart. Cole et al 1995 recommended that childhood BMI would be best expressed as SD scores.(16) For correct comparison and monitoring of trends it is important to ensure that UK 1990 BMI centile charts and data are used.(23;24)

^a There has been a consensus in the USA to use the terms overweight in place of obese and 'at risk of overweight' for overweight. However both overweight and obese are used through out this thesis meaning two distinct levels of excess body fat and associated health consequences.

BMI in children rises steadily in the early years after birth and then dramatically drops during the pre-school toddler years, after this low point BMI slowly increases again until adulthood. The timing when the BMI starts to rise again after this lowest point is known as adiposity rebound. Cole et al (1995) noted that the adiposity rebound was seen at a later age for those children who followed the lower centile than those following the higher centiles by around three years in boys and two years in girls; that is those children on the higher BMI centiles have adiposity rebound at an earlier age.(16) There is evidence to suggest that an early age of adiposity rebound is associated with an increased risk of later obesity in childhood.(25-27)

There has been a general consensus within the UK that the 1990 BMI centile charts should be used for both the epidemiological definition of overweight and obesity in the paediatric population and for clinical diagnosis.(5) However there is much debate over the most appropriate centile cut off points for this definition. There are essentially two schools of thought; those who use $\geq 95^{\text{th}}$ centile for defining obesity, with the $\geq 85^{\text{th}}$ centile for overweight (the SIGN 69 guidelines recommended for clinical practice $\geq 98^{\text{th}}$ centile for obese and $\geq 91^{\text{st}}$ centile for overweight);(5)^b and those who advocate the use of an international cut off point which on the UK 1990 charts is close to the 99^{th} centile for obesity and the 91^{st} centile for overweight.(28) The debate has focused around the need for a definition that allows meaningful international comparisons and the need for cut points that are both specific and sensitive as a diagnostic tool. A cut off with a high specificity has generally been regarded as more important for clinical applications than a high sensitivity to avoid unnecessarily classifying some children as obese.(24;29;30)

^b The difference between the definitions in the SIGN guidelines for epidemiological studies and clinical practice was a pragmatic one as there are no 85^{th} and 95^{th} centile on the UK BMI centile charts.

For some years the diagnosis of obesity has been based on the cut off point of the 95th centile, with the 85th centile taken as the cut off for overweight, first on the USA National Health and Nutrition Examination Surveys (NHANES) charts and then on other national BMI centile charts. It was considered that children with a BMI over the 95th centile had a higher risk of persistence of obesity in adulthood and of obesity related diseases.(22;31) This cut off point had been noted by Himes and Dietz (1994) as having a high specificity and a moderate to high sensitivity.(22)

At a meeting of the International Obesity Task Force (IOTF) a decision was taken to try and develop an acceptable international definition of childhood obesity and overweight to allow for monitoring of trends and prevalence across the world. International data were published in 2000 giving BMI centile cut of points with an internationally agreed definition of childhood overweight and obesity which were considered to have clinical significance.(28) This work had involved combining the data from six cross-sectional growth studies from the UK, Brazil, Hong Kong, USA, the Netherlands and Singapore. Giving a combined data set of 97 876 males and 94 851 females aged from birth to 25 years old. To offer clinically meaningful cut off points the authors extrapolated the adult definitions of BMI ≥ 25 for overweight and BMI ≥ 30 for obese in each of the national BMI datasets at age 18 years and then produced a curve which matched these cut off points down through the ages from 18 to 2 years. The centile lines corresponding to BMI ≥ 25 (overweight) and BMI ≥ 30 (obese) produced for each of the six countries were then statistically 'smoothed' to give one centile curve for each definition. This proved difficult with the Singapore data set as this had a substantially different curve from the other countries. However BMI cut off points were produced at six-month intervals for ages 2 to 18 years and then expressed as centiles. In the UK these international cut-offs points defining overweight and obesity have been superimposed on to the UK 1990 BMI centile charts.

Although many argue the usefulness of internationally agreed definitions for obesity and overweight for international comparisons (24;29) the debate continues mainly around the sensitivity and clinical significance of these international BMI cut off points. Some researchers have reported that the international cut off points have a high specificity but a particularly low sensitivity especially in adolescent girls.(30;32;33) There are concerns that the international cut off points exaggerate the differences between prevalence in boys and girls, that there are no associated SD scores and they cannot be used for children under two years of age.(29;34) The most recent review of obesity in the UK carried out by the National Institute for Clinical Excellence (NICE) recommended 'pragmatic' cut of points of the 91st centile for overweight and the 98th centile for obesity.(10) Without a doubt these arguments and this debate will continue for some time to come and a further discussion would go beyond the scope of this thesis.

1.1.2 Fat distribution and waist measurements

As discussed above it is important that any clinical definition of obesity relates the accumulation of excess body fat with increased risk of disease and ill health. In adults there is much evidence to support the concept that the distribution of fat, particularly central obesity, can influence health risks. Measurement of waist as an indicator of risk of particularly cardiovascular disease have been recommended in adults for some time.(13) In children there is also growing evidence that central or abdominal fat distribution is related to health risk factors in particular to dyslipidaemia and insulin resistance, both of which in turn are considered precursors to the metabolic syndrome, type 2 diabetes and cardiovascular vascular disease (19;35;36) (see section 1.5 for discussion on consequences of obesity). There is also evidence that it is not merely a central fat distribution but the accumulation of visceral fat which is the more significant component in causing the increased risks of disease.(14;20;36)

Visceral fat is a type of fat that is found within the abdominal cavity around visceral organs. The exact mechanisms for why visceral fat accumulation is important in the development of disease complications remain unclear and much of the work has been carried out on animal models. It would appear that visceral fat has both high lipogenic and lipolytic activity.(20) What is not clear is if increased triglyceride production leads to hyperlipidaemia and insulin resistance or whether high levels of insulin and glucose intolerance lead to hyperlipidaemia.(14;20;35) Insulin resistance and the metabolic syndrome are discussed further in section 1.5. Interesting recent work, mainly from Goran et al in the US has shown that there is a difference in the accumulation of visceral fat by ethnic groups. African Americans, particularly females, appear to have significantly lower levels of visceral fat than white Americans but at the same time they have a higher risk of developing insulin resistance.(14;36;37) This is obviously an area of continuing research.

Although total body fat can be measured using DEXA scans this technique cannot measure visceral fat accurately, which can only be accurately measured using CT or MRI scans.(14) However as discussed above, these methods are specialised, expensive and not available for routine clinical practice, thus there has been the need for proxy measurements of fat distribution. There has been good agreement amongst studies that the waist circumference measurement is a useful tool in children and adolescents for measuring fat distribution and particularly for identifying central fatness.(19;38) Whereas waist to hip ratio, sometimes advocated in adults, has not been found to be such a good indicator of central fatness in children and adolescents.(39;40)

McCarthy et al (2001) published data on waist circumference centiles for British children.(41) These centiles were based on cross-sectional data originally collected in 1988 from 3585 males and 4770 females in the UK from across geographical urban and rural settings and socio-

economic classes. Trained researchers using non-elastic measuring tapes took the measurements; the waist was measured at the mid point between the tenth rib and the iliac crest to the nearest millimetre. Smoothed centile curves were produced for both sexes at age intervals. Although measurements were taken from birth to 17 years the published data were for ages 5 to 16.9 years. McCarthy et al noted that training in the correct measuring techniques would be required and that precise clinically relevant cut offs were not possible to state.(41) These waist circumference centiles are now available on the reverse side of the Child Growth Foundation's BMI centile charts for use in routine clinical practice in the UK. At this point in time there remains no agreement on the relevant clinical cut off points for the UK waist centile charts.(10;39;42)

1.2 Prevalence of childhood obesity

Reporting on prevalence and trends in the paediatric population is, as discussed above, dependent on the definition used.(34) However regardless of the definition used there is overwhelming evidence that the prevalence of childhood and adolescent obesity has increased dramatically across the world in both developed and developing countries over a relatively short period of time.(1)

In the UK the BMI centile charts developed by Cole et al (1995) were the first such reference data for the UK.(16) Taking a definition of $\geq 85^{\text{th}}$ centile for overweight and $\geq 95^{\text{th}}$ centile for obesity gave a prevalence rate in 1990 of 15% overweight and 5% obese at any given age. To obtain a true picture of changing prevalence and trends in UK childhood obesity it is important to compare studies to the UK 1990 BMI age and sex-specific population data.(23;24) Dramatic increases in the prevalence of childhood obesity in the UK were noted in the mid to late 1990s.(2;43-45) Indeed a British Medical Association (BMA) 2005 reporting on childhood obesity (definition of obesity used not cited)

estimated that there were approximately one million obese children and adolescents under the age of 16 in the UK.(4)

The most up to date prevalence data for Scotland available from the ISD (Information Statistics Division) Scotland website and based on routinely collected data are given by age groups in table 1.1 (accessed 04.04.07). The 2003 Scottish Health Survey reported the overall prevalence of overweight and obesity combined as 43.6% of boys and 30.0% of girls. In both boys and girls BMI increased with age and a greater proportion of boys than girls were classified as overweight or obese. There was no clear association with the level of overweight and obesity in boys with socioeconomic status, while there was a trend for higher prevalence in lower socioeconomic groups for girls. There was a higher prevalence of both overweight and obesity in boys from Scotland than in England but this was not seen in girls.(46)

Table 1.1: Prevalence of overweight and obesity in Scotland (47)

Age	Overweight ($\geq 85^{\text{th}}$ centile)	Obese ($\geq 95^{\text{th}}$ centile)	Severely obese ($\geq 98^{\text{th}}$ centile)
Pre-school ^a	20.7%	8.6%	4.1%
P1 ^b	21.8%	9.1%	4.4%
P7 ^c	34.1%	19.4%	11.2%
S3 ^c	31.3%	16.5%	9.6%

Reported figures for ^a2001, ^b2005/06, ^c2004/05

Jotangia et al 2005 report for the Department of Health on obesity amongst under 11 years old in England reported a prevalence of overweight ($>85^{\text{th}}$ centile) increasing from 22.7% in 1995 to 27.7% in 2003. While obesity ($>95^{\text{th}}$ centile) increased from 9.9% in 1995 to 15.5% in 2002 and was 13.7% in 2003.(48)

This UK trend in an increasing prevalence would appear to be mirroring a similar dramatic increase in the prevalence of childhood obesity that has occurred in the USA. Troiano et al (1998) compared the prevalence of childhood obesity (>95th centile) in the USA from the NHES^c II/III (1963 – 70) through subsequent NHANES^d to NHANES III (1988 – 94).(49) This showed no general increase between the NHES II/III (1963 – 70) and the NHANES II (1976 – 80); however there was a significant increase from the NHANES II (1976 – 80) to the NHANES III (1988 – 94). They also noted that the biggest increase in prevalence had been among black girls, from around 5% in the NHES II/III to approximately 15% in the NHANES III surveys.(49)

Troiano et al (1998) interestingly also looked at the pattern of BMI distribution and found that there was little change at the lower centile range of the BMI centiles however there was a trend with increasing age for an upward shift in the entire distribution of the BMI and a disproportionate increase in the higher centiles.(49) A number of studies have reported that waist circumferences in British children have also increased over this time period.(50;51) McCarthy et al (2003) reported that mean increase in waist circumference for boys (aged 11-16 years old) from 1977 to 1997 was 6.9cm while the increase for girls (aged 11-16 years old) from 1987 to 1997 was 6.2cm. Interestingly these authors noted that over the same period the increase in BMI had been smaller than those seen in the waist circumference and that the BMI increase was similar between both sexes while increase in waist circumference was more marked in girls than boys.(52)

1.2.1 Groups at high risk of obesity

Within the UK there are certain groups that have been reported to have a higher prevalence of childhood and adolescent obesity than the general population. Children from families in the lower socio-economic

^c National Health Examination Survey (NHES)

^d National Health and Nutrition Examination Surveys (NHANES)

groups (V and IV) (53;54) and certain ethnic groups in particular Asians, Africans and Afro-Caribbeans (54;55) have been reported at risk of higher prevalence. Jebb et al (2003) reported there to be a higher prevalence in lower socioeconomic groups in Scotland and Wales than in England.(55) There is also some evidence to suggest that children and adolescents with special needs may have a significantly higher prevalence of obesity and severe obesity than the mainstream population.(56-58)

1.3 Possible causes of childhood obesity

At its most simplistic weight gain leading to an accumulation of excess fat can only occur when there is chronic energy imbalance; that is more energy from food is taken in than is being used up by physical activity and energy expended for maintenance. However, it has been recognised for some time that there are genetic factors which predispose certain people to being overweight and obese. Börjeson (1976) showed that monozygotic twins had similar fat distributions while dizygotic twins were three times more likely to have different levels of body fat.(59) A study of adoptive children carried out by Stunkard et al (1986) showed that the weights of those children who had been adopted were more closely associated to those of their birth parents, in all weight categories, than to their adoptive parents.(60) A further study by Stunkard et al (1990) on twins who grew up apart reported that the adult weight of identical twins was closely associated even though their childhood environment had been different.(61)

All these studies concluded that genetic factors were the more dominant factor in causing obesity than childhood environment (genetics is briefly discussed further in 1.3.3). It is well recognised that children and adolescents are at a higher risk of obesity if one parent is obese and at an even higher risk if both are obese.(5;10;27;62) However it is difficult to say whether this is due to genetics or familial environmental factors and many consider that it is more likely to be a

combination of both.(42) The argument for environmental influences on obesity has gained credence as genetic factors alone cannot explain the rapid increase in the prevalence of childhood obesity seen in the UK and across the world since the early 1990s.(63;64) There is a strong belief that the modern environment and lifestyle that includes 'fast foods', high car usage, low physical activity, television watching, use of computers and playing video games has led to populations in chronic positive energy imbalance.(42) The term the 'obesogenic environment' has been used to describe this environment, which encourages both foods high in energy density but low in nutrients and decreased physical activity levels.(65-68) However the causes of childhood obesity and the current epidemic are without a doubt complex and multifactorial, some of these issues are explored further below but a detailed discussion of aetiology of obesity would be beyond the scope of this thesis.

1.3.1 Diet

There is evidence to show that the overall proportion of fat in the modern diet has increased over the last 50 years.(67;69) There have been trends for increased consumption of foods which are particularly high in fat and energy density such as more convenience foods used in the home and increased consumption of 'take away' meals.(67) High fat foods influence the overall energy intake as these foods are more energy dense, that is more energy per gram of food is eaten than if lower fat foods were consumed. There is also evidence to suggest that a diet high in fat can lead to an over-riding of the body's satiety mechanisms which in turn encourages overeating.

There appears to be a trend of increasing food portion sizes over the last few decades, this has been particularly reported in foods eaten outside the house.(67;68) French et al (2001) report in the US for example that a 12oz soft drink portion is now sold as a 'child' size while in the 1950s this same size was considered an adult 'king' size. Bagels

and muffins which were once sold at a standard portion size of 2-3oz are now sold as 4-7oz size.(67) These authors have suggested that such increases in portion sizes outside the home could have influenced portion control within the home by affecting the concept of 'normal' healthy family portion sizes.(67)

The increased consumption of sugary soft drinks with their ubiquitous availability in vending machines, particularly in schools, has also been associated with childhood obesity and the obesogenic environment.(67;68;70) Ludwig et al (2001) reported on an observational prospective study in school-aged children that the odds ratio of becoming obese increased by 1.6 for each can or glass of sugary juice drunk. They concluded that both the baseline intake of sugary juice and an increase in the amount of sugary juice consumed are both independent predictors of increase in BMI.(65;69;71) In addition intervention studies that have focused on reduction in consumption of sugary sweetened drinks have begun to suggest that reduced consumption of these drinks might be helpful in prevention of obesity.(72)

There have been a number of studies that have shown that infants who were breastfed or had a late introduction of formula feeds had a lower risk of developing childhood or adolescent obesity.(73;74) The exact mechanism of why breast feeding would be protective is unclear and may be related to controls on satiety.(70) However at least one recent follow up cohort study did not find an association with breast feeding and a reduced risk of later obesity.(27) This remains an area where further research may elucidate the appropriate health message.

Part of the complexity of the issue around the contribution of diet to the obesity epidemic is the fact that the National Food Survey has shown that there has been a decrease in the total energy consumed by the British public. This in turn has led authors such as Prentice and Jebb

(1995) to suggest that a decrease in total energy expenditure is a more important factor in the development of obesity.(69)

1.3.2 Physical activity and sedentary behaviours

There is a general consensus that our environment, town planning and modern life encourages a less physically active lifestyle, such as increased car use with corresponding less walking and cycling.(42;66;68;69)

The rise of television viewing has been strongly suggested as a contributing factor to the obesogenic environment.(75-77) Dietz and Gortmaker (1985) reported on two cross sectional surveys and one prospective survey in the US on the association of time watching television and obesity levels (defined using tricep skinfold thickness measurements). They reported significant strong associations between the time spent watching television and prevalence of obesity, this association was particularly strong for teenagers.(75) Whereas, Robinson et al (1993) reported a weak association between television viewing and adiposity in a cross sectional and longitudinal study in adolescent teenage girls.(78) However there is substantial support in the literature that there is an association with the amount of time spent viewing television and the prevalence of obesity.(79)

There are a number of suggestions proposed as to why television viewing may encourage weight gain and obesity in children. The first and perhaps the most obvious is that time spent viewing television displaces the amount of daily time available to take part in physical activity. Sport England (1999) reported that children and adolescents living in England on average in one week spent 11.4 hours watching television/videos, 4.4 hours playing computer games while only 7.5 hours on sport or exercise.(80)

There are also suggestions that the process of television viewing encourages an increased intake of high sugar/high fat energy dense snacks by a behavioural association with eating while watching TV. There is a wide ranging debate on the influence of television advertising of high fat, high energy snack/fast foods on children's choices of foods.(75;77;81-83)

1.3.3 Genetics

Progress has been made in the last 10 years into the identification of possible genes that could influence human obesity phenotypes.(63;64;84) Much of the work on the genes which predispose to obesity have been carried out in animals mainly mice. However work into polygenetics and human obesity taken across different human populations and the replication of these finding between human populations suggest that there are a number of genes or their variants, which could influence the development of human obesity.(85;86) For polygenetic obesity it has been suggested that the most common genetic cause will be found to involve a number of genes which could 'predispose' a person to gaining excess fat leading to obesity if they were exposed to an environment which encourages the necessary behaviours i.e. high fat diet, low levels of activity. However, at this point in time it remains unclear whether there is a large number of genes each with a small influence or a smaller number of genes which each exert a larger influence.(63;64) The recent discovery of variation in the FTO gene (where variants are common and have small but important effects) suggests that a good deal of future research will focus on the 'gene with small influence' hypothesis.(87) It has been suggested that by identifying common gene variants that predispose individuals to obesity subgroups of obese people could be targeted for particular interventions such as specific diets, behavioural approaches or drugs.(85)

Many genes have been investigated for their possible influence on the development of obesity these include those implicated in food and energy expenditure regulation, and lipid and carbohydrate metabolism. Research has also been undertaken looking for 'candidate' genes by investigating certain obese phenotypes such as early onset obesity, known biological function, a role in causation of monogenetic obesity in humans or animals.(85;86) For example Trp64Arg variant in the Beta-3 adrenergic gene has been shown to have some affects particularly in Asians people but not other populations. The Val103Ile variant in the MRC4 has been found to reduce the risk of obesity. A single nucleotide polymorphism in ENPP1 has been found to associate with childhood obesity and insulin resistance. Multiple linkage studies looking at various chromosomal regions, such as chromosome 2p, 3q, 10p, 20q have been undertaken with some positive results. These are listed on the 'Human Obesity Gene Map'.(85) Research in to polygenetics and obesity is still exceedingly complex and it may be some years before these research findings can be of use in day to day clinical practice.(63) Interestingly the role of monogenetics and obesity is perhaps clearer and this is discussed next.

Although described as rare, monogenetic causes of obesity in humans have been found.(64;88;89) O'Rahilly and Farooqi et al from Cambridge, UK have carried out much of this work, particularly from the Genetics of Obesity Study (GOOS). The GOOS project has recruited children from across the world who have severe obesity (>3.0 SD), a strong family history of obesity and from consanguineous families. The GOOS study has led to the identification of seven monogenetic causes of obesity.(84) Most of these have involved mutations in leptin production, leptin receptors, propeptide proopiomelanocortin (POMC) and the melanocortin 4 receptor (MC4R).(64;84)

Within the hypothalamus the hormone leptin, POMC and MC4R are all known to be involved in appetite regulation and energy balance. Mutations in MC4R are believed to be found in approximately 3-5% of

people with a BMI above 40. Mutations in MC4R appear to result in a range of phenotypes from those showing no signs of obesity to individuals with severe obesity (particularly at an early age), hyperphagia, increased lean body mass as well as linear growth and hyperinsulinaemia.(64;88) Deficiencies in the hormone leptin have been reported to produce morbid obesity (usually from a young age), increased appetite, hyperphagia and hypogonadotropic hypogonadism. Injections of leptin in these individuals have been shown to reverse the hyperphagia and morbid obesity.(64) POMC is an important propeptide involved in skin pigmentation, adrenal function as well as appetite control and energy balance. Individuals with POMC mutations are reported as having severe obesity (from an early age), hyperphagia, altered pigmentation, usually red hair, and adrenal insufficiency.(64;89) Although fascinating further discussion on polygenetic and monogenetic influences on the development of human obesity are out with the remit of this thesis.

There are a number of known inheritable disorders in which obesity is a clinical feature of the syndrome. Lobstein et al (2004) suggested that there are around 30 such inherited disorders; most of these are associated with learning disabilities and dysmorphic features. The most common inherited disorders associated with childhood obesity seen in routine clinical practice are –

- Down's Syndrome
- Prader-Willi syndrome
- Duchennes muscular dystrophy
- Fragile X (42)

1.3.4 Endocrine causes of obesity

The endocrine glands produce hormones that are important in the regulation and maintenance of a stable body environment. In children they are particularly important in ensuring normal growth and the timing of puberty. There are a number of endocrine disorders caused by

dysfunction in the production of hormones or their utilisation that are associated with childhood obesity. These include hypothyroidism, growth hormone insufficiency, hypopituitarism, hypogonadotrophic hypogonadism, hypogonadism, excessive corticosteroid administration, pseudohypoparathyroidism and craniopharyngioma.(90)

Many of these endocrine disorders and the inheritable syndromes discussed above manifest short stature as a clinical feature.(90;91) There is strong agreement that in clinical practice obese children who present with short stature for their age should be referred to a tertiary paediatric centre for further investigation for possible underlying medical causes of their obesity.(5;10;42)

1.3.5 Sleep deprivation

There is evidence to suggest that partial sleep deprivation can effect energy balance and thus influence weight gain. Taheri (2006) in a review of the literature on partial sleep restriction and childhood obesity noted that a number of large population studies have identified a relationship between short sleep duration, weight gain and metabolic disturbances. The exact mechanisms for this effect are as yet unclear but research suggests that reduced sleep levels may influence hormone production and sympathetovagal balance, as well as reducing physical activity due to tiredness during the day and increasing the opportunity to overeat at night. At least eight hours of uninterrupted sleep per night would appear to be the optimal for children and adolescents.(92)

1.4 Clinical assessment of childhood obesity

The vast majority of children and adolescents seen in an NHS obesity clinic have what is generally termed 'simple' obesity. Simple obesity implies that there is no reason to assume monogenetic obesity, an inherited disorder or an endocrine cause of their obesity. However at

initial assessment possible underlying medical causes as well as co-morbidities should be considered.(5;91;93) Current weight and height with BMI calculated and correctly plotted on sex and age appropriate UK 1990 BMI centile charts are essential. A history of weight gain, growth, pubertal onset and normal eating habits should also be taken. Early onset of severe obesity (i.e. under 5) and poor height growth should be cause for concerns and suggest further tests (see table 1.2 below). A physical examination for signs of pubertal development, acanthosis nigricans (dark, velvety hyperpigmented thickened skin seen particularly the neck and in skin creases (94)), goitre, skin colour, dry skin and hair should be carried out. A family history of possible co-morbidities should be taken, particularly important are a family history of type 2 diabetes, morbid obesity, hypertension, dyslipidaemia, polycystic ovarian syndrome and early cardiovascular disease.(91)

Viner and Nicholls (2005) gave a useful summary of possible clinical investigations for childhood obesity and these are summarised in table 1.2 below. The NICE 2006 guidelines concur with most of the assessment outlined in table 1.2, however they recommend that fasting lipids are only measured in those who have a particular family history of cardiovascular heart disease and that fasting insulin and glucose is only carried out in those with a family history of type 2 diabetes, signs of acanthosis nigricans and those from certain ethnic backgrounds.(10)

Table 1.2: Suggested investigation plan for an initial visit to an obesity clinic(91)

Definition	Investigations
A. Obese but with no signs of symptoms suggestive of secondary obesity or obesity complications	<p>Baseline bloods -</p> <p>Fasting glucose</p> <p>Fasting insulin</p> <p>Fasting lipids (total and HDL cholesterol, triglycerides)</p> <p>Liver function (bilirubin and ALT)</p> <p>Thyroid function (T4, TSH)</p> <p>Full blood count</p> <p>Urea and electrolytes</p> <p>Blood pressure using an adequate large cuff, comparison to BP centiles for age and sex.</p>
B. Obesity with acanthosis or family history of metabolic syndrome	<p>Baseline bloods and test as above</p> <p>Oral glucose tolerance test</p>
Morbid abdominal obesity with or without family history of metabolic syndrome	
C. BMI SD score ≥ 3.0	<p>Baseline bloods and test as B plus DNA screening for monogenetic forms of obesity (if onset < 5 years)</p> <p>Sleep study for obstructive sleep apnoea if significant symptoms (snoring, difficult to wake, nightmares, daytime somnolence)</p>
D. Signs or symptoms suggestive of secondary obesity	<p>Baseline bloods and tests as B</p> <p>Karotypes</p> <p>Midnight and 8 am cortisol</p> <p>Referral to an endocrinologist or geneticist as appropriate.</p>

1.5 Consequences

The medical significance of childhood and adolescent obesity are the interrelated health consequences of chronic excess weight and body fat. Dietz and Nelson (1999) stated that 65% of obese 5 – 10 years old had at least one cardiovascular disease risk factor and that 25% of the same age group had at least two or more.(95) Dietz (1998) noted that for men and women who were obese as adolescents there was an increased rate of cardiovascular disease and diabetes. For women, but not men, there were adverse psychosocial effects relating to fewer years in education, higher rates of poverty and lower rates of marriage and household income.(96) Freedman et al (2001) reported that the most significant association between childhood obesity and cardiovascular risk factors in adulthood were from the tracking of childhood obesity into adulthood.(97) There is also a growing body of evidence on other co-morbidities of adult obesity such as cancer. There is overwhelming evidence to suggest that obese children and in particular obese adolescents become obese adults.(62;98) Dietz (1998) noted that approximately 50% of obese adolescents become obese adults.(96)

1.5.1 Cardiovascular risk factors

In their review of the health consequences of childhood obesity Reilly et al (2003) cited 31 high quality studies that reported an association between childhood obesity and cardiovascular risk factors. The major cardiovascular risk factors were high blood pressure (hypertension), dyslipidaemia, abnormalities in the left ventricular mass and/or function, hyperinsulinaemia and/or insulin resistance.(6) Freedman et al (2007) reporting on the Bogalusa Heart Study noted that of the children and adolescents with a BMI \geq 99th centile 59% had at least two cardiovascular risk factors.(98)

The metabolic syndrome (also know as syndrome X or the insulin resistance syndrome) is the name that has been given to a variety of

clinical abnormalities that are known to be risk factors for cardiovascular disease in adults and this is discussed further in the next section.(99;100)

1.5.2 The metabolic syndrome

There is disagreement about the definition of the metabolic syndrome in adults and this has led to a certain amount of confusion over the most appropriate diagnostic criteria in children and adolescents. There is however agreement that it should include a combination of the following

- Insulin resistance/hyperinsulinaemia
- Obesity – particularly central visceral fat distribution
- Dyslipidaemia – high triglycerides, high low density lipoprotein (LDL) cholesterol, low high density lipoprotein (HDL) cholesterol
- Impaired glucose tolerance or type 2 diabetes mellitus
- Essential hypertension – increased systolic and diastolic blood pressure
- Polycystic ovary syndrome

There are a number of papers which state that there may also be increased prothrombotic and anti-fibrinolytic factors associated with the metabolic syndrome.(99) Jones (2006) summarised the varying diagnostic criteria for the metabolic syndrome that have been used in children and adolescents and this is reproduced in table 1.3.

Table 1.3: Comparison of criteria used by different investigators for diagnosis of the metabolic syndrome taken from Jones 2006 (100)

Risk factor	Cook et al (101)	De Ferranti et al (102)	Cruz et al	Weiss et al (103)
Abdominal obesity	≥ 90 centile	>75 centile	≥ 90 centile	BMI SD score ≥ 2.0 for age and sex
Triglycerides	≥ 110mg/dl	≥ 100mg/dl	≥ 90 centile	≥ 95 centile
HDL cholesterol	≤ 40mg/dl	< 45mg.dl*	≥ 10 centile	< 5 centile
males	≤ 40mg/dl	< 50mg/dl	≥ 10 centile	< 5 centile
females				
Blood pressure	≥ 90 centile	>90 centile	≥ 90 centile	> 95 centile
Fasting glucose	≥ 110mg/dl	≥ 110mg/dl	IGT	IGT

*Males 15 –19 years

All of these diagnostic criteria have been based on the differing criteria used in adult diagnosis. It will probably be some time before there is an international consensus on appropriate diagnostic criteria for metabolic syndrome for children and adolescents. However an attempt has been made to come to an international agreement on the childhood and adolescent diagnosis of the metabolic syndrome with the publication by the International Diabetes Federation (IDF) of their recommended criteria for different age groups.(104) The IDF's definition of 'at risk' groups are

- under 6 years of age no definition
- 6 to less than 10 years > 90th centile for waist
Not possible to firmly diagnosis the

metabolic syndrome but further tests should be carried out in children with a family history of the metabolic syndrome, type 2 diabetes, dyslipidaemia, CVD, hypertension or obesity

10 to less than 16 years	<p>> 90th centile for waist</p> <p>Triglycerides $\geq 1.7\text{mmol/L}$</p> <p>HDL cholesterol $< 1.03\text{mmol/L}$</p> <p>Blood pressure $\geq 130\text{mm Hg}$ systolic or $\geq 85\text{mm Hg}$ diastolic</p> <p>Glucose $\geq 5.6\text{mmol/L}$ (recommended) or known type 2 diabetes</p>
>16 years	Use adult IDF criteria.(104)

Viner et al (2005) assessing the prevalence of insulin resistance syndrome (metabolic syndrome) in a UK paediatric obesity clinic population used a diagnostic definition based on the WHO criteria and this is outlined in table 1.4. As circulating insulin increases during puberty hyperinsulinaemia in this study was defined based on pubertal staging; prepubertal $\geq 15\text{ mU/L}$, mid-puberty (stages 2-4) $\geq 30\text{ mU/L}$, post-puberty defined as per WHO criteria for adults $\geq 20\text{mU/L}$.(105) Using these criteria Viner et al (2005) reported that in 103 obese children aged 2-18 years 40% had hyperinsulinism, 11% impaired fasting glucose, 30% dyslipidaemia and 32% hypertension. Thirty-six percent of this study population had two components, 28% had three and 5% had all four components. They concluded that 30% of children in this clinical sample aged under 12 years of age had metabolic syndrome.(105)

Table 1.4: Definition of metabolic syndrome used by Viner et al 2005
(105)

Syndrome component	Definition
Obesity	BMI \geq 95 th centile for age and sex
Abnormal glucose homoeostasis	Any of the following <ul style="list-style-type: none"> a. Fasting hyperinsulinaemia b. Impaired fasting glucose (\geq 6.1mM/L) c. Impaired glucose tolerance; glucose at 120 min \geq 7.8mM/L
Hypertension	Systolic blood pressure \geq 95 th centile for age and sex
Dyslipidaemia	Any of the following <ul style="list-style-type: none"> a. High triglyceride (>1.75mM/L) b. Low HDL (<0.9mM/L) c. High total cholesterol ($>95^{\text{th}}$ centile)

1.5.3 Insulin resistance

An important precursor, although not the only causative factor, to the development of the metabolic syndrome would appear to be insulin resistance. Insulin is the hormone required by the body for the cellular up take of circulating blood glucose. Steinberger and Daniels (2003) noted that the understanding of the mechanisms of insulin resistance in children and adolescents remains unclear.(106) There appears to be a complex relationship between the hyperinsulinaemia and the development of both hypertension and dyslipidaemia. It is believed that excess body fat and in particular centrally distributed visceral fat causes a depressed sensitivity to the function of insulin in certain cells. The body produces sufficient insulin but various cells and organs are unable to utilise the insulin effectively thereby causing an increased circulation of glucose. The increased blood glucose level in turn stimulates the production of further insulin, which can lead to both elevated levels of glucose and insulin. It is believed that these elevated glucose and insulin levels can cause a disturbance in a number of cycles, which can

in some individuals ultimately lead to dyslipidaemia and hypertension. The exact mechanism of how hyperinsulinaemia causes hypertension remains unclear however it has been shown in adolescents to be reversible with weight loss and exercise.(106)

The measurement of insulin resistance is complicated and not easily carried out in clinical practice. The gold standard method of euglycaemic insulin clamp is used in research but not in clinical practice. The euglycaemic insulin clamp technique involves continuous administration of both insulin and glucose intravenously over 3 hours. The insulin sensitivity (inverse of insulin resistance) is measured by the amount of glucose required to maintain normal glucose levels (euglycaemia).(99;106) Although less accurate other methods used in clinical practice include the homeostatic model (HOMA) which is calculated as fasting plasma insulin multiplied by the fasting plasma glucose then divided by 22.5. Scores range from 0 to 15, the higher the score the greater the insulin resistance.(99;103;107) C-peptide is produced in the body in equal amounts to insulin and fasting C-peptide levels can be used as a proxy measure for insulin.(106;108) Viner et al (2005) in the study described above found that fasting levels of glucose and insulin were both sensitive and specific for the diagnosis of metabolic syndrome.(105)

1.5.4 Type 2 diabetes

Type 2 diabetes was previously described as a disease of adults but has now been reported in adolescents.(42;94) Obesity is reported as the single most important risk factor for the development of adolescent type 2 diabetes. The American Diabetes Association (2000) noted that around 85% of children diagnosed with type 2 diabetes are overweight or obese.(94) Other risk factors include a family history of type 2 diabetes, ethnicity and presence of acanthosis nigricans.(42;94;109) There are well reported higher incidences of type 2 diabetes in non-white populations in particular African American, Hispanics, Asians and

American Indians.(42;94;110;111) The onset of puberty seems to play a role in the development of type 2 diabetes with diagnosis typically seen over the age of 10 years in middle to late puberty. (94)

The following outlines the clinical diagnostic criteria for type 2 diabetes

- Random blood glucose $\geq 11\text{mmol/l}$
- Fasting blood glucose $\geq 7.0\text{mmol/l}$ (fasting no calorie intake for 8 hours)
- Oral glucose tolerance test (OGTT) at 2 hours $\geq 11.0\text{mmol/l}$ (glucose load equivalent to 75g of anhydrous glucose dissolved in water)(94)

The early onset of type 2 diabetes in adolescence is of concern as it is believed that it increases the risks of disease complications such as cardiovascular disease, kidney failure, visual impairment and limb amputation at a younger age in adulthood.(42) Although the numbers of children with clinical type 2 diabetes is low at present most experts suggest that the numbers will increase with the increasing obesity prevalence in this age group.(42;94)

1.5.5 Non alcoholic fatty liver disease

The term non-alcoholic fatty liver disease (NAFLD) ranges from fatty infiltration of the liver (steatosis) through non-alcoholic steatohepatitis (NASH) to cirrhosis.(112;113) Patton et al (2006) suggest that NAFLD seen in children and adolescents is significantly different from that seen in adults.(113) The exact pathways and mechanisms involved in the development of NAFLD still remain unclear, however there does appear to be a strong association with the development of NAFLD and visceral obesity, insulin resistance and race/ethnicity.(112-114) Many people with NAFLD may be asymptomatic and the progression of the disease appears to be slow and can be slowed down by controlling weight and lifestyle.(42;93) A conclusive diagnosis of NAFLD can only be made at

present by liver biopsy. As a proxy measurement levels of aminotransferase (ALT) are often used in studies, sometimes in conjunction with an ultrasounds or MRI scan of the liver.(42;112;113)

1.5.6 Polycystic ovarian syndrome

Polycystic ovarian syndrome (PCOS) is a condition that affects the female menstrual cycle and fertility. It is characterised by of combination of –

- High levels of male hormones
- Irregular or no menstrual cycle
- Hirsutism (excessive hair growth)
- Acne
- Small cysts on the ovaries may or may not be present.(42;93)

PCOS has been associated with excess weight and insulin resistance in both adolescents and adults. Lobstein et al (2004) note that PCOS is often undiagnosed in adolescents and that the prevalence in this group is unknown.

1.5.7 Respiratory problems

Sleep associated sleeping disorders are well recognised in obese individuals, especially in severe obesity.(42) These include heavy snoring, resistance to airflow and apnoea. Speiser et al (2005) suggest that obese children are 4-6 times more likely to have an obstructive sleep apnoea compared to similarly aged lean subjects.(93) There has also be a suggestion of an association between the reduction in oxygen flow in the body and the development of insulin resistance.(42)

A number of studies have shown an association between childhood obesity and asthma.(6) However in their reviews of childhood obesity both Lobstein et al (2004) and Speiser et al (2005) suggest that a

causative biological link between asthma and excessive weight should not be assumed.(42;93)

1.5.8 Orthopaedic

Obese and overweight children and adolescents have been reported to have a higher risk of developing certain orthopaedic problems such as Blount's disease, flat feet, ankle sprains, slipped epiphysis, osteoarthritis and fractures.(42;93)

1.5.9 Psychological consequences and self-esteem

A number of studies have reported an association with obesity and low self esteem as well as lower social and economic attainment in children and adolescents.(5;6;42) Latner and Stunkard (2003) report that stigmatisation of obese children is worse in a 2001 study compared to a similar study in the 1960s. Viner and Cole (2005) reporting on a 1970 British birth cohort, noted that when childhood obesity persists in to adulthood there is an association with poorer employment and relationship outcomes for women.(115) Schwimmer et al (2003) using the Pediatric Quality of Life inventory (PedsQL) questionnaire reported obese children as having a worse quality of life than children suffering from cancer.(116)

1.6 Prevention

As with all chronic diseases, prevention of childhood obesity is without a doubt the best course, surprisingly there are few reported successful childhood obesity prevention interventions. The most recent Cochrane review (2005) on interventions for preventing childhood obesity found a limited number of well conducted studies and recommended that future interventions consider sustainability and environmental changes along with individual and family lifestyle.(117) It is suggested that prevention strategies require to focus on the complex issues around childhood obesity involving diet, physical activity, sedentary behaviour, family

lifestyle and environment.(117;118) These interventions must therefore engage complex behavioural changes such as in the school based 'Planet Health' project.(119) As this thesis is concerned about the treatment of childhood obesity further discussions on prevention interventions are outside the scope of both this chapter and thesis.

1.7 Radical treatments for paediatric obesity

Obese adults, usually those with morbid obesity, are often offered what are described as 'radical' treatments. The term radical treatments encompass use of drug therapy, liquid meal replacements and surgery. Some of these treatments have now been recommended for adolescents with extreme obesity.(10) Most of these treatments would still be considered as too radical for use in the primary school age population discussed in this thesis, however a brief overview of these alternative treatments seems appropriate at this point.

1.7.1 Drugs

Drug therapy is always recommended to be taken in combination with diet, lifestyle intervention and behavioural modifications.(10;93)

Orlistat is a drug that inhibits pancreatic lipase thereby inducing malabsorption of fat, particularly of triglyceride, and causing increased faecal fat.(93) Orlistat requires to be taken in combination with a low fat diet. There have been a few studies most notably by Chanoine et al (2005) which have shown that the use of Orlistat can be effective in the treatment of adolescent obesity.(120) Orlistat is currently available in the US for children over 12 years of age.(93)

Sibutramine is an anorexic agent that inhibits the neural uptake of serotonin, norepinephrine and dopamine. Although shown to effectively reduce BMI it has a number of serious side effects such as mild hypertension and tachycardia, to date it has only been used for

treatment of obesity in adolescents and young adults, aged 16 and above.(93).

The NICE (2006) guidelines have recommended that Orlistat and Subutramine can be used in the UK for children aged 12 years or older only if there are co morbidities such as sleep apnoea present. The guidelines underline the importance of treatment only being commenced in a specialist paediatric setting within a multidisciplinary team experienced in prescribing in this age group.(10)

1.7.2 Surgery

In adults with severe morbid obesity bariatric surgery has been successfully used for weight reduction. There have been a number of surgical procedures used for weight loss, most have involved a reduction in the size of the digestive system or have induced a degree of malabsorption. At present the two most commonly used surgical procedures are laparoscopic gastric banding and the Roux-en-Y gastric bypass.(93) The NICE (2006) guidelines recommended bariatric surgery in children and young people only in 'exceptional circumstances' and only if they were close to physiological maturity.(10)

1.7.3 Very low energy diets

Very low energy diets (VLED) have been used in adolescent obesity treatment, these have tended to be protein sparing modified fasts mainly based on foods although liquid diets have also been used. These VLED have been reported to use 1.5 – 2.5g protein per kilo of body weight and have included additional vitamin and minerals. These diets usually induce a rapid weight loss and the National Health and Medical Research Council for Australia (2003) recommended the use of very low energy diets in adolescents only if the clinical circumstances required such rapid weight loss. (121)

1.8 Evidence for treatment strategies

Systematic reviews of childhood obesity treatment interventions have consistently reported a lack of high quality and well conducted studies.(5;7;10) The Cochrane review (2003) on the treatment of childhood obesity noted many studies had poor study power, lack of description of interventions and/or analysis.(7)

The work of Epstein and colleagues from the US has influenced many other research teams and are frequently cited in systematic reviews on this subject. Although Epstein has repeatedly reported success in treating childhood obesity including long term follow up (122) systematic reviews have found flaws in his published work.(5;7) It has not been possible to replicate his treatment programmes, as they are not adequately described in published papers. What is clear is that his programmes include a traffic light diet scheme, generally increase in physical activity and decrease in sedentary behaviours. A family approach is taken, with at least one parent usually part of the treatment programme and behavioural change techniques involving goal setting, self monitoring and contracting used.(123) Even with the problems described above Epstein's work influenced the SCOTT treatment programme described in the present thesis. A fuller discussion on Epstein's treatment programmes is given in chapter 3.

In 2002 the Royal College of Paediatrics and Child Health (RCPCH) published a short best practice approach to managing childhood and adolescent obesity in primary care.(9) The paper gave a brief description of diagnosis, assessment and recommended that treatment should include increasing physical activity, decreasing sedentary behaviours and reducing the overall energy content of the diet. It discussed the importance of negotiating goals, involving the family, addressing positive parenting and offering regular follow up.(9) It did not however give details on the manner of implementing these recommendations.

The 2003 Scottish Intercollegiate Guideline Network (SIGN) clinical guideline 'Management of Obesity in Children and Young People' (SIGN 69) recommended that treatment strategies should be family based, involve at least one parent, target changes in diet, increased physical activity and decreased sedentary behaviours.(5) They did not however describe how these treatment strategies should be implemented in clinical practice. Both the author of this thesis and thesis supervisor (Prof. J.J. Reilly) were members of this SIGN 69 working group. The SCOTT research project was a direct response to the SIGN 69 guidelines recommendation that research into treatment of childhood obesity should be undertaken in a UK NHS context.

More recent British reviews and guidelines on the treatment of childhood and adolescent obesity have similarly recommended changes to lifestyle behaviours. However most have also recommended the use of behavioural change and motivational approaches such as goal setting, self-monitoring, contracting and consideration of 'risky' situations.(10;11)

In view of the limited quantity and moderate-poor quality of the evidence on treatment of childhood obesity it is not surprising that similar approaches to treatment have been recommended in recent international guidelines and reports, notably from Australia in 2003 (119), Canada 2004 (118) and the most up to date report from the American Academy of Pediatrics published in 2007.(124) These reports and guidelines also noted a lack of good quality evidence in the treatment of childhood and adolescent obesity, with the Australian guidelines in particular calling for on-going good quality research.(119)

A summary of the consensus from systematic reviews and guidelines would appear to be that the 'best bets' for treating childhood and adolescent obesity are as follows

- that treatment should be directed at motivated families only

(where the child and/or parents perceive obesity as a problem and appear willing to make lifestyle changes);

- treatment is directed at the entire family rather than just the obese child;
- weight maintenance (rather than weight loss) is a desirable treatment outcome for most obese children;
- treatment should be more intensive than has been the norm (more frequent and longer appointments);
- treatment should combine changes in diet *plus* changes in physical activity and/or reduction in sedentary behaviour (e.g. TV viewing);
- that behavioural change and motivational techniques should be incorporated into the treatment programme.(5;10;31;121)

All international guidelines agree that treatment should be family based and only undertaken when the family, in particular at least one parent, is willing to engage in treatment. Treatment programmes should be integrated and be multi component, i.e. equally target diet, physical activity and sedentary behaviour. The use of behavioural changes methods is consistently recommended and these should be family-based, tailored to individual needs and age appropriate.(10;121;124)

All of the guidelines recommend positive, healthy changes in dietary habits, incorporating a nutritionally balanced diet in conjunction with a decrease in energy intake.(10;118;121;124) Due to the prevalence of papers from Epstein's group the traffic light diet scheme is summarised in many of these reviews and guidelines.(10;121;125) Manipulation of dietary fat and carbohydrate intake is discussed by some guidelines and it is noted that there is little or no evidence to recommend either approach for childhood weight management.(10;121;124) The USA expert committee report particular emphasis the need to decrease sugary drinks, high fat foods, snacks and meals eaten outside the

house while encouraging five fruit or vegetables per day and more family meal times.(124)

Changes in physical activity levels and sedentary behaviour are recommended by all international guidelines. There is a current agreement that this should be a target to increase physical activity to at least one hour per day and to decrease sedentary behaviour (often called screen time) to no more than 2 hours per day.(10;121;124) The Australian guidelines noted that there is no evidence to suggest the actual amount, intensity or type of physical activity that should be undertaken by children and adolescents for weight management.(121)

There is international consensus that on a population and societal level there should be a commitment to healthier school meals, development of public spaces which promote increased family physical activity levels and a regulation on advertising of certain 'unhealthy foods' to young children and adolescents.(10;118;121)

1.8.1 Recent relevant studies

At the time of starting the SCOTT project no RCT on a childhood obesity treatment programme had been carried out within the UK NHS that included all the components discussed above. Since the start of the SCOTT project there has been one UK RCT on treatment of adolescent obesity published called the Sheffield Obesity Trial (SHOT).(126) This study was a physical activity intervention which looked at the effect of exercise therapy sessions in obese adolescents, the study's primary outcomes were changes in physical self worth (PSW) and in psychological conditions. Participants were randomised to either an exercise therapy group, an exercise placebo group or usual care. At 28 weeks there was a statistically significant positive change in PSW as well as self-esteem and physical activity in favour of the exercise therapy group. There was no significant change between groups in BMI SD scores.

Internationally there have been three relevant childhood obesity treatment RCTs published in the last two years. The LEAP (Live, Eat and Play) trial was an RCT comparing an intervention involving 4 GP sessions over 12 weeks using solution-focused therapy with a control group who received no intervention in Melbourne, Australia.(127) The primary outcome measure was BMI, measurements were reported for nine and 15 months. There was no significant difference for the change in BMI SD score between the two groups at either measurement point.

The PEACH (Parenting, Eating and Activity for Child Health) trial 2007 involved a parent-based intervention with parents randomised to either a parenting-skill training group, a parenting-skill training group with lifestyle education or a 12-month waiting list control group in Adelaide, Australia.(128) The primary outcome measure was BMI SD score, measurements were taken at six and 12 months. For all three groups there was a significant decrease in mean BMI SD score from baseline to 12 months but no significant difference *between* groups at 12 months.

Perhaps the most interesting recent randomised controlled trial is the Bright Bodies study undertaken at Yale Pediatric Obesity Clinic, New Haven, USA. (129) Participants were randomised in a ratio of 2:1 into either the Bright Bodies programme or a control group seen every six months. The Bright Bodies programme is highly intensive with participants attending twice weekly sessions of exercise and nutrition/behaviour modification for six months and then fortnightly sessions for six months. The primary outcome measurement was change in BMI and was measured at baseline, six and 12 months. The intervention group had a statistical significant change in mean BMI at 12 months as well as in insulin resistance (measured by HOMA) compared to the control group.

Within the UK there have also been reported the results of two pilot studies, the UCL project and WATCH IT (130;131) and preliminary

results from the intervention arm of an RCT (MEND).(132) All of these recent studies in the UK were group based and involved the child and their parents being seen in parallel but separate sessions and aimed to change diet, physical activity time and to decrease sedentary behaviour. Two of the studies, WATCH IT and MEND also involved separate exercise sessions run by the treatment organisers.

The UCL study was the closest in design to the SCOTT project. It was closely based on Epstein's work, used the traffic light diet scheme, self-monitoring goal setting, positive reinforcing, stimulus control and relapse prevention.(130) Twenty seven families completed the programme of 12 sessions each lasting 1½ hours over 4 months. The primary outcomes were changes in BMI SD score and percentage BMI. BMI SD score reduced in the 7 months and weight decreased slightly, all changes were statistically significant. Self-esteem as measured by the Piers-Harris test showed a statistically significant improvement at follow up measurement.

WATCH IT is a community based programme delivered by WATCH IT trained, non-health professional staff.(131) The treatment was delivered away from clinical settings in local sports and community centres. The programme used motivational and solution focused approaches and included one-hour group physical activity sessions at a local sports centre led by a sports coach. BMI data were available for 48 children at six months (three months after the end of the intensive treatment phase). There was a significant change in mean BMI SD score from baseline to six months.

The MEND programme was a 9 week community based programme that involved twice weekly sessions, one exercised based and the other involving behavioural therapy and nutritional education. Dietitians, nutritionist and physical activity professionals delivered the programme and the available results were from a variety of sites in England. The preliminary results of 45 children who had completed the 9-week

programme were reported.(132) At the end of the 9-week programme mean BMI SD score had reduced as had mean waist circumference SD score.

In chapter 7 there is presented a full comparison of the SCOTT study results with these international and UK studies. While in chapter 4 a briefer comparison to Epstein studies and the above noted UK studies is given.

1.8.2 SCOTT study in context

The quantitative and qualitative research projects reported in this thesis were conceived to implement, compare and evaluate the above recommended treatment 'best bets' (see section 1.8) within the workings and cost restraints of the UK NHS. The original study fund holders and collaborators (including this author) felt that within the UK NHS dietitians were the single most obvious professional group to deliver such a treatment programme. The SCOTT RCT set out to compare a more intensive, behavioural-based dietetic led treatment programme (known as the novel treatment) with the then standard dietetic treatment delivered in the two main paediatric centres in Scotland. The treatment programme and its development are discussed in detail in chapter three and the full treatment programme is given in appendix 1 and all patient written materials are given in appendix 2. The qualitative research project was carried out to evaluate both the novel and standard dietetic treatments and to analysis the parents' perspective of the treatments their child had received. This thesis and the work it describes have therefore added to the understanding of the treatment of childhood obesity within the UK NHS.

CHAPTER 2

Randomised Controlled Trial of a Novel Dietetic Treatment for Childhood Obesity: Quantitative study design and methodology

2.0 Introduction

The SCOTT project was a single blinded randomised controlled trial of dietetic intervention in primary school aged children (5-11 year olds) with 'simple obesity'. The trial compared a study group (known throughout this thesis as the novel treatment group) and a control group (known throughout this thesis as the standard care group). A full description of both the novel and standard dietetic treatments, including a comparison of their differences and similarities is given in chapter 3 and the novel treatment protocol is described in detail in appendix 1. The dietetic interventions were delivered for between six to ten months and outcome measurements were taken at baseline, six months and twelve months. The trial used an 'intention to treat' analysis and followed the CONSORT guidelines on the conduct and reporting of RCTs.(133)

The study was funded by a Scottish Chief Scientist Office's (CSO) health service research full grant (grant number CZH460) and Prof. J.J. Reilly of Glasgow University was the principal grant holder. The study was funded from February 2003 to January 2006. The SCOTT research team consisted of two part time research dietitians - one based at the Royal Hospital for Sick Children (RHSC), Edinburgh (the author of this thesis) and the other at Yorkhill Hospitals, Glasgow as well as a full time post doctoral research fellow who was also based at Yorkhill Hospitals, Glasgow.

The remainder of this chapter outlines the study design and methodology.

2.1 Research question

As described in chapter 1 the SIGN 69 guidelines (5) revealed a number of promising strategies for the successful management of childhood obesity mainly from work by Epstein(122;134-136). These strategies adopted a more intensive approach than 'typical' NHS dietetic care in the UK and particularly targeted changes in physical activity, sedentary behaviour and diet with self-monitoring of behaviour changes within a defined protocol. The SCOTT team developed an intensive novel dietetic programme based on Epstein's strategies and included the use of behavioural change interviewing techniques (see chapter 3 and appendices 1 and 2). The null hypothesis for this study was that there would be no difference in the Body Mass Index (BMI) standard deviation score (SD score) between the novel treatment and the 'typical' NHS standard care groups. The study's primary outcome measure was change in BMI SD score at six and 12 months - see 2.4 below.

The study also aimed to investigate a number of secondary outcomes (see 2.4 below) namely changes in estimated body fat, self-esteem, physical activity and sedentary behaviour, as well as looking at possible adverse effects of the interventions and a comparative economic costing of both dietetic treatments was carried out. It should be noted that the results of the estimation of body fat are not reported within this thesis and the comparative economic costing is briefly returned to in chapter 4.

2.2 Ethical approval

The study received ethical approval (under the pre-COREC ethics procedure) from the local ethics committees of Lothian Health, Greater Glasgow Health Board, Lanarkshire Health Board and Forth Valley Health Board.

2.3 Study design

2.3.1 Power

The study was powered using the data about changes in BMI SD scores (over six months) from the Avon Longitudinal Study of Parents and Children (137) and variation in children (SD of <0.4), with a target effect size of -0.25 SD score over six months. With power 0.9, 5% significance level and a 1-sided test, this gave a requirement of 44 children in each group. There was a drop out allowance to six months of 36%. Although a previous audit of the patients attending the RHSC, Edinburgh obesity clinic had shown a drop out rate of 50% (138) we believed that this estimated drop out rate of 36% was justifiable, as this present study would endeavour to enrol only motivated families and parents. The study aimed to enter 120 participants over 12 months i.e. June 2003 to May 2004.

2.3.2 Delivery of treatments

The research dietitians delivered the novel treatment in the Edinburgh and Glasgow centres. The dietitians who normally carried out the dietetic clinics in Edinburgh and Glasgow continued to deliver the standard care treatment in those centres. Care was taken to avoid 'contamination' between the two treatment groups. Both research dietitians worked from different offices in their base than the dietitians delivering standard care. The research dietitians were also aware of the necessity not to discuss any aspects of the novel treatment, their training on behavioural interviewing techniques (see chapter 3) or to show the standard care dietitians the written materials used for the novel treatment.

2.3.3 Inclusion and exclusion criteria

Referrals to the SCOTT project were accepted from a number of sources and these are outlined in table 2.1.

The study enrolled children of primary school age, 5 - 11 years old, who were clinically obese (BMI $\geq 98^{\text{th}}$ centile) (5) and whose parents were willing to take part in the study, at least one parent was required to attend all the clinic appointments. The inclusion and exclusion criteria for the study are noted below and the remainder of this section discusses some of these criteria in depth.

Table 2.1: List of sources of referrals to the study^e

Hospitals/Trust	Referrals accepted from
RHSC, Edinburgh	Paediatric Endocrinologists
Yorkhill Hospital, Glasgow	Hospital Paediatricians
	Community Paediatricians
	GPs
	School nurses
	Dietetic department's waiting list
	Primary Care Community Dietitians
Glasgow Primary Care	GPs
St. John's Hospital, Livingston	Hospital Paediatricians
	Community Paediatricians

Children were considered eligible for inclusion if they;

- were aged 5 –11 years old and attending primary school,
- had a BMI $\geq 98^{\text{th}}$ centile (UK 1990 charts),
- had at least one parent willing to take part in the study,
- had no obvious underlying medical cause of obesity e.g.

^e No referrals for the study were received for the present study from either Lanarkshire or Forth Valley Health Board.

metabolic, endocrine, genetic,

- had no serious co-morbidity requiring urgent medical or surgical attention e.g. sleep apnoea,
- had no registered special needs and were attending mainstream school,
- had not attended any dietetic clinic in the past 12 months.

Primary school aged children (5 – 11 year olds) are a significant group of those referred to dietetic departments for weight management and it was felt appropriate to test the novel treatment with this age group. It was believed that this age group would be appropriate for the behavioural aspects of the novel treatment and the pilot study, undertaken before the main SCOTT trial (see chapter 3), supported this view. Discussions did take place over raising the upper age cut off but it was felt that once children were at senior school their parents had less control over certain aspects of their lifestyle and this would add an unnecessary confounding factor to the trial.

The SIGN 69 guideline clinical definition for obesity of a BMI $\geq 98^{\text{th}}$ centile, (5) was used as a referral criteria to this study. In the initial study participation request letter the parents were asked to obtain an estimated weight (e.g. using bathroom scales or scales at Boots the chemist) and height (using household measuring tape) of the child. This helped to ensure that when the postdoctoral research fellow subsequently telephoned the family any child obviously below the 98th centile for BMI could be ruled out at this point. At the first measurement clinic the postdoctoral research fellow accurately took the child's weight and height then calculated and plotted the BMI on UK 1990 BMI centile charts to ensure they were 'obese' using our working definition.

The family being ready and willing to make lifestyle changes was also an important criterion for treatment in the SIGN 69 guidelines(5) and has been suggested by other authors, notably the Barlow and Dietz US

expert committee,(31) the RCPCH guidelines(9) and Epstein.(122) Discussions took place within the SCOTT research team over using set questions to formally grade the parents 'readiness to change'(139;140) however it was felt that motivation and readiness to change were continuously changing and thus formal questions to assess readiness to change were not appropriate.(141;142) It was felt that the parent's willingness to take part in a study that involved the possibility of attending eight outpatient appointments and three measurement clinics over twelve months was an indication of willingness and readiness to change and so this was used as our willingness to change criterion.

The present study intended only to involve children with 'simple obesity' and therefore any child who had a possible underlying endocrine or metabolic cause of their obesity was excluded. Referring doctors were expected to have used their clinical expertise to exclude children with a likely underlying cause, but referrals were also expected from non-medical staff (see table 2.1). Smallness in stature for weight is considered a good indication of possible underlying endocrine problems (see chapter 1 section 1.3.4),(5) therefore the initial letter to the parents asked if an estimate of the heights of the child's natural parents could be taken. The postdoctoral research fellow then calculated mid parental height centile and ensured that the child was within the expected target centile range.

2.3.4 Blinding

All the outcome measurements (see 2.4) taken at baseline, six and 12 months were measured by the postdoctoral research fellow who remained blinded to group allocation throughout the study and until after the twelve month statistical analysis. The research dietitians, the standard care dietitians, the children and families were for obvious reasons not blinded to group allocation.

Care was taken to avoid unblinding of the postdoctoral research fellow. Although the research fellow was based in Yorkhill Hospitals, Glasgow she did not share an office with the Glasgow research dietitian. The measurement clinics for subjects in both centres were held in a separate area from the outpatient clinics. At their first measurement clinic and in all subsequent correspondence the child and family were asked not to tell the research fellow which dietitian they saw, the number of appointments they had or the day of the week they attended clinic. The postdoctoral research fellow recorded any incidents of unblinding.

2.3.5 Consent

Once referrals for the study were received the parents and children were sent an information pack (see appendix 3). Two weeks after sending the information the postdoctoral research fellow then telephoned the families to inquire if they were interested in taking part in the study. The research fellow ensured as far as possible that the child was eligible for the study (see 2.3.3 for inclusion criteria). If the child was eligible and the family willing to take part in the study then a measurement clinic appointment was arranged. At this appointment the study was explained in full to the parent and child, informed consent obtained from both to take part in the study and consent forms signed (see appendix 4).

2.3.6 Randomisation and concealment

Once consent had been obtained the postdoctoral research fellow allocated the children a participant number, these numbers were in strict consecutive order of attendance at the measurement clinic i.e. the third child to attend the measurement clinic in Edinburgh had a study code of E03. The children were then randomly allocated between the two groups remotely by a statistician (Prof. J McColl) at Glasgow University. The group randomisation was stratified for sex and was computer generated in blocks of 10. Prof. McColl worked in a different

site of the University than the other members of the SCOTT team thereby ensuring the process of recruitment and randomisation were completely separate.

The research fellow sent by email to the statistician only the participants study code and sex while sending by email to the appropriate research dietitian the participants names and study codes. After randomisation the statistician sent by email to the respective dietitian the study code and group allocation. The research dietitians then telephoned the families to inform them of the group allocation and to arrange the first dietetic out patient appointment. For participants allocated to the standard care group the research dietitian placed a note in front of the patients' record card to ensure that the standard dietitians were aware that the patient was taking part in the SCOTT project. For both groups the child's subject code was noted on front of their dietetic record cards.

2.3.7 Statistical analysis

All statistical analysis presented in this thesis were carried out by the author. Data were analysed using Minitab 14^f, a full description of the statistical analysis is given in chapter 4. We have called our data analysis an intention to treat by which we mean that all study participants were retained in the groups to which they were originally allocated and no participants were removed from the analyses by the researchers. After taking advice from Prof. McColl, statistician for the project, it was agreed that for those participants who did not attend for their follow up measurement no previous measurement would be carried forward nor a substituted measurement inputted. Therefore at the six and 12 months follow up measurements only those participants who attended for measurement were analysed. Participants were strictly analysed in their allocated groups, regardless of whether they had attended or completed treatment.

^f MINITAB Release 14 Statistical Software produced by Minitab Inc. www.minitab.com

2.4 Outcome measurements

As discussed in section 2.1 the primary outcome measure for the study was change in BMI SD score. Secondary outcomes measures were estimated changes in fat free mass, estimated changes in physical activity, changes in height, quality of life and self-esteem of the child.

Measurements were taken by the postdoctoral research fellow at baseline (1-3 weeks prior to the first dietetic appointment), six months (actual times 26 to 38 weeks) after the first dietetic appointment and then twelve months (actual times 51 to 63 weeks) after the first dietetic appointment. Table 2.2 shows the measurements and information collected at each measurement clinic. The postdoctoral research fellow received training in all the necessary measurement techniques from experienced nutritional researchers and followed standard written protocols for the measurements. As previously discussed the research fellow remained blinded to group allocation throughout the study and until after the twelve-month study data were statistically analysed.

Measurements for all Lothian subjects were taken in non-clinical rooms at the RHSC, Edinburgh and for Greater Glasgow subjects at Yorkhill Hospitals, Glasgow.

In the letter confirming the measurement clinic appointments the child was asked to ensure the following points (these were mainly necessary for the impedance estimation of body fatness) –

- not to eat or drink 2 hours before the appointment,
- to empty their bladder before the appointment,
- to avoid vigorous exercise 12 hours before the appointment (e.g. jogging, running, swimming, playing sports etc).

The remainder of this section gives further details of the measurements discussed in this thesis. The results for arm circumference, estimation

of fat and fat free mass are not reported in this thesis and therefore these particular outcome measures are not discussed further in this thesis. The comparative economic costing is briefly discussed in chapter 4.

2.4.1 Height, weight and BMI

Height was measured for each child using the Leicester height measurement.^g The child was measured in light clothing with socks and shoes removed. The research fellow ensured that the child's feet were flat and together on the centre base plate, the head was in the horizontal Frankfurt plane position and that they were standing up straight. To ensure an accurate measurement was taken the height was measured 2-3 times for each subject and the mean recorded. Height was measured to the nearest 1mm.(143)

Weight was measured using a Tanita Body Fat Analyser model TBF 300,^h with the child in light indoor clothing. To ensure an accurate measurement weight was measured twice for each subject. Weight was measured to the nearest 0.1 kg. This same machine was use to estimate body fatness and fat free mass (as discussed above the results from these measurements are not discussed in this thesis).

At each measurement clinic the BMI was calculated and plotted on a UK 1990 BMI centile chart by the research fellow. This was particularly important at the first measurement clinic to ensure that the subject met the inclusion criteria of a BMI $\geq 98^{\text{th}}$ centile. BMI SD score and BMI centile were calculated from each measurement clinic using the Child Growth Foundation's computer programme.^g

^g Child Growth Foundation, London, UK

^h Cranley & Co, Birmingham, England, UK

Table 2.2: Outline of measurements taken and information collect at each measurement clinic

Measurement	Baseline	6 months	12 months
Height	√	√	√
Weight	√	√	√
BMI calculated and plotted on centile charts (UK 1990)	√	√	√
BMI SD score calculated	√	√	√
Height velocity calculated		√	√
Arm circumference	√	√	√
Waist circumference	√	√	√
Fat and Fat free mass estimated by impedance	√	√	√
Quality of life questionnaire completed (parent and child)	√	√	√
Child asked to wear CSA monitor for 7 days	√	√	√
Post code recorded for allocation of deprivation categories	√		
Parents occupation and employment status recorded	√		
Parents weight and height recorded (self reported)	√		
Child's past medical history and any current medication noted (parent reported)	√		

2.4.2 Waist circumference

Waist circumference is an index of central fat distribution in children as well as adults. The waist circumference is often described in papers as being taken at the midpoint between the tenth rib and the iliac crest.^(19;41) However in practice this can be difficult and the more pragmatic method as described on the Child Growth Foundation waist centile charts was employed for this study. Waist was measured 2 – 3 times, to the nearest 1mm, using a tension tape (Child Growth Foundation). The child's clothes were loosened at the waist and with the child standing with their head in the Frankfurt plane they were asked to bend to one side. The indent by the sideways bend made was marked with a pen and this point was measured as the waist.^(41;144) The waist centile and SD score calculated using the Child Growth Foundation computer programme.

2.4.3 Measurements of activity

Physical activity and sedentary behaviours were measured objectively over seven days using a CSA/MTI 7164 accelerometerⁱ. An activity belt is worn around the waist with the small, lightweight accelerometer attached and sitting at the side above the child's hip. The validity and reliability of this accelerometer to measure physical activity and sedentary behaviour in children has been repeatedly demonstrated.^(145;146)

At each measurement clinic the postdoctoral research fellow explained the purpose and importance of wearing the activity belt and keeping an activity diary for seven days. She then demonstrated how the belt should be fitted above the child's hip. A recorded delivery addressed envelope was given to the parents to ensure that the activity belt and diary were returned timeously to the research fellow in Glasgow. The parent and child were given the following instructions –

ⁱ Manufacturing Technology Inc. Fort Walton Beach, Florida, USA

- To place the elastic belt around the child's waist, so that the buckle is at the front and the activity monitor is on the right hip under the clothes.
- Make sure that the arrows on the activity monitor are pointing up towards the head.
- Record the time the child started to wear the activity belt in the 'Activity Belt Diary'.
- The activity belt should be worn all day, but it must be removed if taking a shower/bath or going swimming.
- Remove the activity belt at bed time.
- Record the time when the child stops wearing the belt in the 'Activity Belt Diary'.

The accelerometers were set to record activity in one minute epochs, these counts per minutes (cpm) were used as a measure of total physical activity.(147;148) The percentage of time spent in sedentary behaviour, light intensity activity and moderate to vigorous physical activity (MVPA) were determined from the accelerometer readings by use of agreed cut off points based on previous validated studies in which accelerometer output was compared to either direct observation of movement or to energy expenditure during movement.(147;149) The cut off points used in the present study were as follows –

<1100 cpm - sedentary behaviour

1100 – 3200 cpm – light intensity activity

>3200cpm – moderate to vigorous physical activity.(149)

2.4.4 Quality of life questionnaire

Low self-esteem and quality of life have been reported in obese children,(6) therefore to observe if there was a change in quality of life over the duration of the study both the child and parent were asked to complete a quality of life questionnaire. The PedsQL™ Pediatric Quality of Life Inventory (UK) version 4.0 questionnaires were used.(150)

These generic questionnaires have been validated for measuring the quality of life in children age 2-18 in both health and disease states (151) and are now being widely used in paediatric obesity studies such as the Watch IT study.(131)

The PedsQL™ questionnaires are described by the authors Varni et al (2001) as using multidimensional child self-reporting and parent proxy scales.(150) There are self-reporting questionnaires available for three age groups, 5-7 years of age, 8-12 years and 13–18 years, with parent proxy questionnaires available for age groups 2-4 years of age, 5-7 years, 8-12 years and 13-18 years. Similar questions are asked in the child and parents proxy questionnaires and only the language used is the main difference. For younger children (5-7 years) the questionnaire is administered verbally and the child answers each question by pointing to pictures of descriptive faces.

The questionnaires consist of four sub-sections; these cover physical health, emotional functioning, social functioning and school functioning. A score for psychosocial health is derived from the emotional, social and school functioning sub-scales. The scores of 0 - 4 are transformed in reverse to 0 -100 i.e. 0=100, 1=75, 2=50, 3=25, 4=0. These figures are the totalled and divided by the number of questions answered. There is an overall total score derived from all the questions answered with a high score indicating a higher quality of life.

Varni et al (2001) reported the internal reliability of the Total Scale Score in both the self-reported and proxy reports to be good and recommended them for use in health related quality of life outcomes in group comparisons and clinical trials. The mean total scale score reported by Varni et al (2001) for healthy children from the self-reported questionnaires was 83.0 (SD 14.8) and from the parent proxy as 87.6 (SD 12.3). For chronically ill children the mean self-reported total was 77.2 (SD 15.5) with the parent proxy 74.2 (SD 18.4). There was a

statistically significant difference between these scores, $p < 0.05$ for both child and parent.(150)

For the present study we used the self-reporting and parent proxy questionnaires for the 5-7 and 8-12 year olds. These four questionnaires are reproduced in appendix 5 with the kind permission of Prof. J. Varni (Professor of Research, Texas A&M University, Texas, USA). As recommended by Varni et al the questionnaires were completed before any other measurements were taken. The postdoctoral research fellow administered the questionnaire of the young children verbally and if it was felt appropriate the questionnaire for the older children was self-administered by the child.(150)

2.4.5 Socioeconomic status

Socio-economic status were derived from the family home postcodes using the Carstairs deprivation categories ('depcat') scores.(152) Carstairs scores are used in Scotland to define the socioeconomic status of populations living within a geographical area that is defined by the postcode with information taken from the 2001 census. The definitions of deprivation used in the 2001 census were overcrowding, male unemployment, low social class and no family car. There are 7 'depcat' scores with 1 being the least deprived and 7 the most deprived. Chalmers and Capewell (2001) showed that in Scotland those with the most deprived areas had a high risk of premature death in middle age.(153)

In the present study we defined those children and families as non-deprived as those in depcat scores 1-4 and those deprived in depcat scores 5-7. These cut offs for deprived and non-deprived socioeconomic status are arbitrary and may differ in other reports.

2.4.6 Six and 12 month measurements

Two weeks before both the six and twelve month points from their first dietetic appointment the postdoctoral research fellow sent a letter to the families to inform them that she would be contacting them by phone to arrange a measurement clinic appointment. This letter emphasised the requirement for the families not to tell the research fellow of which group they were in nor which dietitian they saw, the number of appointments they had and the day of the week they attended clinic. See table 2.2 for a list of outcome measurements taken at each stage.

2.5 Payments

There were no payments for taking part in the study, but participants were offered travelling expenses for all journeys from their home to hospital. All the children received a small toy at each measurement clinic. The children in the novel treatment group received a small activity toy e.g. swimming goggles, hula-hoops, a football when attending their sixth hospital clinic appointment.

2.6 Monitoring completers and non completers

During the study the research dietitians in Glasgow and Edinburgh kept information on a database on whether the subjects attended, failed to attend or cancelled their clinic appointments. Each next clinic appointment was recorded and the over all length of time they attended the dietetic clinic. Families in the standard care arm were expected to attend 3-4 appointments over 6-10 months while those in the novel treatment were expected to attend 8 appointments over 6 months (see chapter 3 for more details).

In both arms of the study if a child and family failed to attend a first appointment no further appointment was sent and they were considered a non completer. If they failed to attend a follow up appointment then a further appointment was sent out; if however a

family failed to attend two consecutive appointments no further appointments were sent and they were considered to be a non completer of treatment. As noted subjects were analysed within the groups to which they were randomly allocated i.e. an 'intention to treat analysis'.

CHAPTER 3

Novel and standard dietetic treatments

3.0 Development of the novel treatment programme

The novel treatment used in the SCOTT study was an intensive dietetic weight management programme. The core principles of the novel intervention were to target lifestyle changes in diet, physical activity and sedentary time by employing patient centred behavioural change interviewing techniques (see section 3.3).(154) The primary aim of the intervention was weight maintenance allowing the child to 'grow into their weight', ideally until their BMI was within normal centile ranges.(5;31) The programme was developed by the SCOTT research team to be delivered by experienced paediatric dietitians who have had training in behavioural change interviewing techniques.(141;155;156)

As discussed in chapter 1 the literature search and critical appraisal of papers for the SIGN 69 guideline (5;157) revealed that although Epstein's work in the USA (122;123;134-136) showed promising results no reproducible 'off the shelf' weight management programme existed.(7;125) The CSO funded the project before a firm novel treatment protocol was written therefore the first task for the author of this thesis was to produce a novel treatment programme and manual. The author developed the novel dietetic treatment in collaboration with other members of the SCOTT team over the five-month period February to June 2003. This included the writing of the treatment manual (given in full in appendix 1) and the production of new printed patient materials to support the programme (appendix 2). Near the end of the development of the novel protocol the SCOTT research team visited another research team in London who were also carrying out a similar intervention based on Epstein's work. Interestingly both research teams had developed similarly structured protocols and written materials independently, although the London team used group

sessions in their aim to replicate the Epstein's treatment programmes in a UK setting.(130)

The two research dietitians, who delivered the programme in the SCOTT study, underwent an intensive two-day training course in behavioural interviewing techniques that was specifically aimed at fulfilling the needs of this project. A condensed novel treatment programme and all the written materials were piloted in a small group of patients from April to the beginning of June 2003.

The novel treatment programme was developed to be a pragmatic, practical and reproducible dietetic programme, therefore the clinical expertise of the SCOTT research team and the experiences of the pilot greatly influenced the final treatment manual (appendix 1). The rationale for the structure of the novel protocol is discussed in depth in the following sections.

3.1 Influence of Epstein

The work carried out by Epstein's group (122;123;135;136) over a number of years has indicated that an intensive intervention which uses targeted lifestyle changes along with the setting of goals, monitoring of lifestyle and the use of rewards can be successful in paediatric obesity management. He has also been emphatic about the importance of the programme and all the lifestyle changes being family based with the support of the parents and family fundamental to any success.(122;123;136) The targeted lifestyle behaviours are changes in diet, decreasing sedentary behaviours and increasing physical activity.(123;135;136) However, although he has described his approach in numerous articles no treatment manual is generally available and to our knowledge no other groups were using the Epstein approach other than in small pilot studies.

3.1.1 Diet

In his programmes Epstein uses a 'traffic light diet', where in its simplest terms red foods are particularly high in energy and thus should be restricted/avoided, amber foods are to be taken with caution and green foods can be eaten freely.(123;136)

Epstein also employs within his traffic light diet strategy a 'calorie restriction' of 1200 kcal per day as well as a complicated method of ensuring that the subject takes the appropriate number of portions from the four main food groups.(123) Green foods are those that have energy value less than 20 kcal per average portion, thus most fruit would not be a green food. Amber foods are categorized in the four basic food groups and are calorie restricted. Red foods are those that have one of the following – an energy value greater than a yellow food, a low fat alternative e.g. low fat crisps, fat reduced lasagne; a food which has a red food component or is over 300 kcal per serving. The restriction on low fat alternatives is an attempt to change people's food preferences and the calorie restriction per portion is to try to teach the necessity of portion size reduction. Participants are allowed 4-7 red foods per week.(123)

3.1.2 Sedentary behaviours

Several of Epstein's studies have shown that targeting sedentary behaviours, in particularly television viewing, have been associated with a significant reduction in overweight. His work has shown that targeting sedentary behaviours can lead to an increase in physical activities and can be more effective in making long-term changes to activity behaviours than targeting an increase in physical activity.(134;135) The exact mechanism by which targeting sedentary behaviour is effective is unclear. Children may substitute sedentary behaviour for activity, with a higher energy cost, and/or they may show less of a tendency to 'snack' or 'graze' when not watching TV.(158)

3.1.3 Physical activity

Epstein has looked at increasing physical activities to help decrease overweight and obesity. He has compared encouraging an increase in lifestyle physical activity (walking, using stairs) to the encouragement of structured aerobic exercise. He found that an emphasis on lifestyle activity led to a better long-term increase in physical activity than emphasising increasing structured aerobic exercise.(134;136)

3.1.4 Behavioural changes – family involvement

Epstein has shown that the involvement of the family in helping the obese child to make the necessary lifestyle changes is fundamental to both short and long term success in weight management. In many of his studies he uses families where at least one parent is obese and both parent and child are seen for weight management advice.(123)

Over a number of studies Epstein has developed behavioural change strategies and has shown these to be effective in maintaining long-term weight management. These include keeping food and activity diaries for self monitoring by children and families, the use of goal setting, contracts and rewards for meeting goals, along with positive reinforcement of the changes made.(123;159)

3.2 SIGN 69

As the SIGN 69 guideline (5) was the first evidenced based guideline to be produced worldwide it was felt important to follow the guidelines recommendations when devising the novel treatment programme for the present study.

The targeting of diet, increasing physical activity and decreasing sedentary behaviours plus the need to incorporate behavioural approaches were all highlighted as being fundamental to treatment strategies in the guidelines.(5) The SIGN guideline and 1998 US expert

committee report (31) and RCPCH guideline (9) also emphasised the importance to the success of any intervention of the readiness and willingness of the parents and families to make lifestyle changes.

However SIGN 69 (5) gave no specific advice or guidance on how to implement the recommendations. After discussing the draft novel treatment programme with a number of colleagues, including Prof Brian Lask (Professor of Child and Adolescent Psychiatry, St. Georges Hospital Medical School, London) and Prof Lori Stark (Director of Pediatric Psychology, Cincinnati Children's Hospital Medical School, Cincinnati, Ohio, USA), it was decided that the use of behavioural change techniques and the exploration of motivation was the best approach for the novel treatment programme in the present study.(160)

3.3 Behavioural change interviewing techniques

The novel treatment employed a number of behavioural change techniques (10) and was delivered in a style based on motivational interviewing.(155;161) As the techniques and style of delivery did not fit neatly into a particular school/paradigm the approach taken in the novel treatment is referred to as 'behavioural change interviewing techniques'.

The behavioural change techniques deployed in the novel treatment are underpinned by two well recognised theories of behavioural change. Namely the transtheoretical model of health change and the social cognitive theory.

The transtheoretical model of health change was originally postulated by Prochaska and Di Clemente in the 1980s.(139) This model construes behavioural change not as a single event but as a fluid process with five main stages (the stages of change). These five changes which are briefly outlined below are often represented as in a circle, however it is acknowledged that an individual may follow the

change model in any given order or direction e.g. moving from action on dietary change back to precontemplation.

Precontemplation – not intending to take any action, often measured as in the next three to six months.

Contemplation – intending to change in the next three to six months.

Preparation – intending to take action in the immediate future i.e. within the next month.

Action – specific, intended changes in lifestyle have been undertaken.

Maintenance – working to prevent relapse of behaviour.

Social cognitive theory suggests that an individual's capability to change a specific behaviour is affected by the reinforcements they receive for a given behaviour, their outcome expectation and their self-efficacy (that is their own expectations of their ability to perform a given behaviour). Problem solving, goal setting, modelling and exploring past change attempts can all be used in a manner to help increase self-efficacy and positive reinforcement for change.(162;163) These tools of behavioural change are discussed more fully below.

3.3.1 Behavioural change techniques

A number of core behavioural change techniques have been shown by Epstein (123;159) and others to be successful in managing lifestyle changes in children.(154;160;164) Most of these techniques are employed within lifestyle change programmes to assist the client in raising their awareness of lifestyle, focus on the aspects of their lifestyles which require change, and develop strategies to implement and monitor those changes. The 2006 NICE 43 obesity guidelines suggested that these are essential techniques for use in behavioural

intervention programmes with children.(10) The behavioural change and motivational interviewing techniques incorporated into the novel treatment programme are briefly outlined below and fuller description of how these were built-in into the programme is given in section 3.6.

Goal setting

Goal setting involves allowing the client, (the child), to take responsibility for identifying the lifestyle changes they feel able to make.(155;164) It is important for the dietitian to ensure that the goals are SMART – Small, Measurable, Achievable, Recorded, and Timed.(156;165)

Contracting

The signing of a 'contract' between the child, parent and dietitian helps to establish a commitment to meeting the goals in the allotted time period.(123;154;164)

Rewards for reaching goals

The setting of a 'reward' for achieving the agreed lifestyle change goals has been found to be helpful as a positive reinforcement to both the setting and attainment of goals.(123;154;164)

Self monitoring

Recording targeted lifestyle is as a key component of behavioural change which enhances motivation by increasing self awareness.(123;164;166)

Environmental/stimulus control

This strategy promotes changes in the environment to 1) help reduce the cues encouraging the lifestyle requiring change and 2) promote the new necessary lifestyle changes. For example the parent avoids buying and bringing into the home red foods or the child avoids walking home from school past a local sweet shop.(154)

Problem solving

Helping the child and family to think through possible 'high risk' situations where sticking to goals could be difficult e.g. holidays, parties and wet weather. This may be carried out as a paper exercise or as simulation and role play. (154;164)

Preventing relapse

At the end of the programme it is important to give strategies to cope with preventing relapse. These would include planning ahead for difficult situations and continuing with or returning to goal setting and self-monitoring.(154)

3.3.2 Motivational interviewing

Motivational interviewing has been used in many areas of behavioural change such as smoking and alcohol cessation as well as in adult obesity for a number of years.(155) However it's use in paediatrics and childhood obesity is still at an early stage.(167;168) The fundamental principle of motivational interviewing is that the approach used by the health professional is client centred i.e. that the client (in the case of the SCOTT project the **child**) is given control over which of their behaviours to change, they set their own goals for change and all concerned accept that change is an on going process that occurs over a period of time.(155;160;164) Within this over-riding principle the dietitian guides the child to the necessary lifestyle changes.(141;155)

The underpinning skills for motivational interviewing are interpersonal skills, an ability to interact with different people and an understanding of the change process.(155) The dietitian requires to establish a helping relationship with the child and let them know they are in a safe environment where they will be heard and understood; importantly that they have an opportunity to tell their story as well as gain information. To do this the dietitian employs active listening skills such as verbal following (also know as mirroring), uses minimal encouragers,

paraphrasing and reflection.(141) Open questions of 'how', 'what', 'could you', 'can you' are used and 'why' questions are avoided. The dietitian should also use 'we', 'us' and 'together' instead of 'you'. At each stage of the interview the dietitian needs to summarise and clarify before proceeding.(141) Most exponents of this type of interviewing technique expect that the client should be speaking for approximately 50% of the interview,(155) however in reality with children this is not always possible.

The first interview is vital for establishing a rapport, within a non-confrontational and supportive environment. The dietitian needs to explore the child and parent's expectations (hopes, fears and anxieties) of this interview and whole programme, while eliciting the current scenario and developing a common agenda.(155) It is a key component to explore ambivalence to change by helping the child to look at both the benefits and costs of change. This is ideally done using a 'decisional balance chart' (also know as an ambivalence grid or pro and cons chart).(155) A decisional balance chart is used to discuss and then record the subject's 'good' reasons for making change; 'not so good' reasons for change; 'good' reasons for not making change and 'not so good' reasons for not making change. The concept being that the child will hopefully see that they have more 'good' reasons to change behaviour than to stay the same.(169) Importance of change should also be examined by asking the child to give a number from 1 to 10 on how important it is for them to make change. When employing motivational interviewing there is an acceptance by the health professional that there will be resistance to change. The health professional needs to 'roll with the resistance' by using reflective listening, shared decision making and agenda setting.(155;161)

In true client centred interviews the client is given control of their lifestyle changes and no goals are imposed on them, however their goals need to be realistic and achievable (see 3.3.1 above). Once their

goals are chosen the dietitian needs to review if they are realistic and achievable.(141;155)

Table 3.1 outlines and summaries the qualities and skills required by the dietitian for undertaking the novel treatment programme as well as the principles and strategies employed by the programme.

Table 3.1: Summary of the client-centred approach and behavioural change techniques(156)

<p>Qualities of interviewer</p> <ul style="list-style-type: none"> • Acceptance • Genuineness • Empathy <p>Skills required by interviewer</p> <ul style="list-style-type: none"> • Appropriate use of questions (open questions) • Active listening (mirroring, paraphrasing, reflecting back) • Affirmation • Summarising 	<p>Principles of approach</p> <ul style="list-style-type: none"> • Client responsibility • Social influence • Collaboration • Expressing empathy • Rolling with resistance • Supporting self efficacy • Deploying discrepancy <p>Strategies employed</p> <ul style="list-style-type: none"> • Exploring readiness to change • Importance of change • Exploring ambivalence to change • Understanding current behaviours • Exchanging information • Exploring options • Problem solving • Goal setting • Self monitoring • Preventing relapse • Use of contracts • Receiving of rewards
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3.3.3 Training and assessment

The SCOTT team underwent an intensive two-day training course in behavioural change interviewing techniques from Dymphna Pearson;(141) a state registered freelance dietitian and a qualified

trainer in this subject. As this course was only for the SCOTT team the second day in particular was aimed at the requirements of this research project and involved discussions on how to use particular behavioural change techniques with children. Section 3.6 describes the incorporation of behavioural change techniques in the novel treatment protocol in detail.

To facilitate assessment of the core interviewing skills and to ensure that the two research dietitians were correctly implementing behavioural techniques a number of interviews were taped during both the pilot (see 3.4 below) and the full study. The taped interviews were transcribed and assessed by 2 independent behaviour change counselling experts, who had not been involved in training the SCOTT research dietitians (see appendix 6 for the assessment form).

Assessments were scored out of 7. The dietitians scored; 5-6 for global rating (patient-centeredness); 6-7 core conditions (empathy, genuineness, acceptance); 5-6 guiding principles (client responsibility, social influence, collaboration); 5-7 affirmation; and 4-7 for pace of interviews. The assessment concluded that both dietitians in the SCOTT project were highly skilled in these techniques.

3.4 Pilot study

The two SCOTT research dietitians carried out a small pilot study of the novel protocol in Edinburgh and Glasgow between April and June 2003. Due to the time constraints on the project the pilot involved a condensed version of the novel protocol with the subjects attending 4 hospital appointments over an eight-week period. Appointments 1-3 were given in their entirety and the fourth appointment consisted of a 20-minute version of appointment 4 (parent only interview) followed by a 20 minutes version of appointment 8 (see appendix 1 for the details of the novel treatment protocol). All the new printed materials produced for the study were used in the pilot (see appendix 2).

Five children and families were enrolled into the pilot study, three families in Glasgow and two in Edinburgh. Prior to starting the pilot study all the children were screened for eligibility for the study and had all baseline measurements taken by the post doctorate research fellow (as described in chapter 2 section 2.4). Of the five patients who started the pilot three completed the programme, with two failing to complete by not attending two consecutive appointments (see chapter 2 section 2.6).

At the end of the fourth appointment these three children and their parents were asked to comment on the treatment and printed materials using structured questions (see appendix 7 for these questions and a summary of the answers). These comments were very positive and they served to reinforce the novel treatment strategies. A number of changes were made to the novel protocol after the pilot and these mainly revolved around the use of the behavioural change interviewing tools. In particular the wording of some the questions had to be made more 'child friendly' and the decisional balance questions had to be revised in appointment 1 to only include the 'pro and cons' of making change (i.e. the children were not asked the 'pros and cons' of not making changes). Otherwise the final treatment protocol as described in appendix 1a was very similar to that used in the pilot study.

3.5 Peer review of printed materials

All the printed materials used in the novel treatment arm of the study were specifically written for this project. It was considered important by the SCOTT research team that these materials should be peer reviewed by senior dietitians working with obese children. A number of dietitians throughout Scotland^j were asked to take part. They were given a brief background to the project, the intended use of the

^jDietitians from the following departments were approached - Borders General, Ninewells Hospital, Dundee, Falkirk Royal Infirmary, Inverclyde Royal and the Community Dietetic Department, Paisley.

materials and asked to comment on the content and their suitability for the target client group.

A number of comments were received mainly concerning the traffic light scheme and in particular the yellow food group. All of these comments were considered by the research dietitians and changes made to the written materials (the written materials used in the SCOTT study are shown in appendix 2).

3.6 The novel treatment protocol

This section describes in detail the novel treatment and how the behavioural change techniques were used throughout the programme. The treatment manual which gives a full descriptive account of each appointment and possible scenarios is reproduced in appendix 1.

3.6.1 Structure of programme

The novel treatment protocol was developed to be an intensive weight management intervention suitable for practical application in the UK NHS. The novel programme consisted of eight dietetic interviews over twenty-six weeks. Seven of these interviews took place in a hospital outpatient department and one was a domiciliary (home) visit. The most intensive of these appointments was appointment 1 which lasted up to one hour (see below). With the exception of the domiciliary visit all other appointments lasted up to half an hour. Appointments 1-4 took place at intervals of two to three weeks apart. The fifth appointment was the domiciliary visit and was scheduled for three to four weeks after appointment 4 (aiming for as close to week ten as possible). This appointment took up to one hour plus the dietitian's travel time. The subsequent two appointments were scheduled four to five weeks apart with the final appointment five to six weeks later. A quick reference table for the novel treatment is given below in table 3.2. The parent(s)

and child were expected to attend each session apart from appointment 4, the parent(s) only interview.

Table 3.2: Quick reference table for novel treatment protocol

Appointment	Length*	Place	Measurements	Sheets required	Next appt in
1	60	OPD		Energy balance Importance Making your mind up Typical day Healthy eating plan Be active! Don't just sit there! My lifestyle diary	2-3 weeks
2	30	OPD	Weight and height measured BMI calculated and plotted	Goals sheet My lifestyle diary	2-3 weeks
3	30	OPD		Goals sheet My lifestyle diary	2-3 weeks
4 Parent/s only	30	OPD			3-5 weeks
5	60 **	Home		Goals sheet My lifestyle diary	4-5 weeks
6	30	OPD	Weight and height measured BMI calculated and plotted	Importance Coping with tricky situations Goals Frequency recording sheets	4-5 weeks
7	30	OPD		Goals Frequency recording sheets	6-8 weeks
8	30	OPD	Weight and height measured BMI calculated and plotted	Long term goals sheet Frequency recording sheets	Last appointment

* In minutes ** Plus travel time

Although the primary goal of the intervention was weight maintenance it was decided that since the emphasis of the programme was on lifestyle

behavioural changes the child's weight was only measured three times over the twenty-six week treatment programme at appointments 2, 6 and 8.

3.6.2 Dietary advice in the novel treatment programme

When writing the original research proposal discussions took place on the incorporation of a traffic light diet scheme into the treatment programme and it was agreed at that stage to produce a modified version. The dietary advice given in the novel treatment was a fusion of the Epstein traffic light diet concept (123) and the healthy eating advice currently in use in the UK.(170) It was the author's clinical experience that there are huge differences in energy intake between individual obese children and therefore it was not felt appropriate to base the dietary information on a specific 'calorie controlled number' like the Epstein 1200 kcal per day rule. The modified traffic light diet was intended to be much easier for children and parents to follow by reducing the complexity and abandoning the need to 'calorie count' as described by Epstein.(123) The overall aim of the dietary changes were to reduce energy intake through restricting high-energy dense foods particularly those high in sugar and fat. The dietary advice was contained in the 'Healthy Eating Plan' given out in appointment 1 (see appendix 2), a simplified overview is given in table 3.3.

In the modified traffic light healthy eating plan red foods were those that are particularly high in sugar and fat and offer 'empty' calories to the child's diet such as crisps, chips, sweets and sugary drinks. Many of these foods are often taken as snacks, sometimes in large quantities by children. As well as reducing the number of red foods taken the children were encouraged to exchange them for green foods (see below). It was felt unrealistic to recommend complete avoidance of red foods and therefore the long-term aim of the programme was to restrict the child's intake to one red food per day.

Amber foods were foods that should be taken in moderation and are required as part of a healthy balanced diet for a growing child. Similar to Epstein's traffic light diet, the foods were grouped together in recognised food groups. Meats, fish and alternatives were recommended to be taken twice per day and to be kept to meal times. Emphasis was also made on the method of cooking and avoidance of frying. Starchy foods were recommended to be only taken at mealtimes and where possible to use wholemeal and high fibre alternatives. Milk and dairy products were recommended to be eaten daily and emphasis placed on using low fat options. The advice on the size and number of portions to be taken from each food group was not as rigid as in the Epstein traffic light diet.

Table 3.3: Outline of the modified traffic light diet (156)

Red foods	Amber foods	Green foods
<ul style="list-style-type: none"> • Fried foods • Crisps • Pies, pastries, bridies • Carry out meals • Chips and burgers • Sugar • Sweeties • Chocolate • Chocolate biscuits • Fancy biscuits • Cakes • Fizzy and diluting drinks containing sugar • Puddings • Sugar or honey coated breakfast cereals 	<ul style="list-style-type: none"> • Lamb, pork, beef • Sausages • Chicken & turkey • Fish • Eggs & cheese • Vegetarian meals • Bread/chapatti • Potatoes • Rice • Pasta • Low fat alternatives of • Milk • Butter/margarine • Yoghurts 	<ul style="list-style-type: none"> • Fresh /dried fruit • Tinned fruit in fruit juice • Vegetables/salad • Home made/tinned vegetable soup • Sugar free jelly • Plain breakfast cereals and low fat milk • Plain popcorn, breadsticks • Sugar free lollies and ice poles • Diet or sugar free drinks

Green foods were all low in fat and sugar but were not calorie controlled as in Epstein's green foods. They included a variety of options such as fruit and vegetables as well as sugar free jelly, plain breakfast cereals and plain popcorn. They could be taken freely and the children were encouraged to substitute green foods for red ones. The healthy eating plan gave some behavioural change advice in the 'handy hints' section. This encourages family support and reinforced the need to alter the circumstances where food was eaten. These handy hints were similar to those in the standard care leaflets (see below) and are based on the changing behaviour advice given in annex 2 of the SIGN 69 guidelines.(5)

3.6.3 Activity levels and sedentary behaviour

It was decided that in line with the SIGN 69 guidelines that a two pronged approach to physical activity should be taken with advice given to both increase physical activity and decrease sedentary behaviour.(5)

Children were encouraged to increase both lifestyle physical activities such as walking, using stairs and more structured physical activity such as football, swimming and club sports. Suggestions of possible activities were outlined in the leaflet 'Be Active!' given to the children in appointment 1 (see appendix 2). The recommendations were that the children increased their physical activity initially to 30 minutes of moderate-vigorous activity at least 5 times per week then rising to a longer term goal of 60 minutes at least 5 times per week.(5)

In line with Epstein(134;135) and the SIGN 69 guidelines(5) the child's sedentary time, i.e. time spent watching TV, playing on computers and video games was particularly targeted to be restricted to no more than 2 hours per day or the equivalent of 14 hours per week. The type of sedentary behaviour, described to the children as 'non-active time', that should be targeted and ideas for possible alternative use of time is

listed in the 'Don't Just Sit There!' leaflet (see appendix 2) that is given to the child in appointment 1.

3.6.4 Behavioural change interviewing techniques in the novel treatment programme

Appointment 1 was the key interview, as it set the scene for the whole of the intervention. The child and parent were made to feel welcome starting with a handshake in the waiting room and the use of 'small talk' to help relax them when first entering the clinic room. Space was given throughout the session to allow the child and parent to ask questions and to make comments on anything the dietitian discussed.

The child was first asked if they knew why they were attending the clinic. This was used to help establish that everyone had an initial agreed agenda. Once it was established that the reason for the visit was weight management the dietitian moved on to discuss the structure of the programme. Education on energy balance was explained using the 'Energy Balance' sheet (see appendix 2). The energy balance seesaw was used as a tool to help the child understand the importance of energy in (food and drink) as well as energy going out (increasing physical activity and decreasing sedentary behaviours) to weight. This helped to emphasise the need to target the three areas of diet, physical activity and sedentary time. The need for parental and family support was emphasised to the participants at this point and throughout the programme.

The child and then the parent were next asked to assess their importance for the *child* to make the necessary lifestyle changes on a scale of 1-10 by marking the 'Importance' sheet (see appendix 2). A discussion would ensue depending on the scores elicited from the child and parent. The child was then asked to complete a decisional balance chart using the 'pros and cons' sheet (see appendix 2). The child was asked to consider what was 'good' about making changes to their

present lifestyle to help them 'slim down' and aspects that are 'not so good' about making changes. The child did this verbally with the dietitian recording the answers on the sheet in the child's exact words. Some time was then taken to discuss and explore these pros and cons with assurances given that no changes would be imposed and that the child would be in control of any lifestyle goals for change. Table 3.4 shows typical answers given to by children to the pros and cons charts.

The child was asked to describe a typical day and where diet, physical activity and non-active time fitted into their daily routine, this was recorded by the dietitian on the 'typical day' sheet (see appendix 2). This method of a 'typical day' is less interrogative than a standard diet recall normally used in dietetic interviews and is used only to get a flavour of the lifestyle of the child and family. A fuller description was not required as the child and parent were asked to keep detailed recordings of the targeted lifestyle changes. This was a key element of the programme and initially they are asked to keep a lifestyle diary (see appendix 2), where diet, physical activity and non-active time were recorded.(123;154;155)

Table 3.4: Typical answers given by children to the decisional balance charts (156)

Pros of lifestyle change	Cons of lifestyle change
<ul style="list-style-type: none"> • Will not be bullied • Will not be called names • Will be able to run faster • Will be happy • Will be able to fit into nice/fashionable clothes 	<ul style="list-style-type: none"> • Will miss sweeties • Will miss crisps • Will miss watching TV • Will miss playing X box

One of the most important aspects of this first appointment was that the child left without having been asked to make any lifestyle changes. They were asked to complete the daily lifestyle over a week and the child was given the 'Energy balance', 'Healthy eating plan', 'Be active!' and 'Don't just sit there!' sheets to take home (see appendix 2).

At the beginning of every appointment the dietitian reviewed the lifestyle recordings, continuously reinforcing the importance of keeping them throughout the programme. This lifestyle diary was used up to appointment 6 when a longer-term lifestyle frequency recording tick sheets was introduced (see appendix 2).

Appointment 2 was the first time that goal setting was used, the child was asked to consider two to four possible goals for change. The goals were based on the information they had been given both verbally and written, in appointment 1 and on their lifestyle recordings. The dietitian tried to ensure that the goals were realistic and achievable.(155) Once the goals were set the child and parent(s) agreed a treat as a reward for the child meeting 100% of the agreed goals. Both goals and treats were recorded on the 'My goal' sheet (see appendix 2) and this was signed as a form of contract by the child, parent and dietitian. Table 3.5 gives an example of goals set and reward.

Table 3.5: Typical goals set by child and agreed reward (171)

Goal 1	1-2 chocolate biscuits per day
Goal 2	No crisps but can have 1 packet of 'Snack a jacks' per day
Goal 3	Sweets once per week
Goal 4	To go for a cycle during the school holiday week 2 - 4 times
Reward	A magazine

The parents were encouraged to give the child positive reinforcement for all lifestyle changes made as well as the rewards. These rewards were small, relatively inexpensive and non-food such as CDs, books, outing to an event. Much discussion took place within the SCOTT research team over when rewards should be given to the children. It was decided that this should only be for meeting 100% of their goals as giving a reward for less than this would be positively reinforcing failure. The remaining interviews followed a similar basic pattern. The lifestyle diary was reviewed and whether the child had met 100% of their goals was agreed (or otherwise) by the child, parent(s) and dietitian. If the child had met their goals 100% of the time then the child should have been given their agreed treat from the parent as soon as possible. New goals and rewards were set and further recording sheets were given. However if they had failed to meet their goals the possible reasons why and barriers to meeting them were explored. If necessary the goals were revised or completely new goals agreed. On occasion the pros and cons chart and importance to change were revisited.

The parent only interview (appointment 4) was a chance for the parents to discuss any aspects of the intervention or the child's progress that they felt unable to talk about in front of their child. It was also an opportunity for the dietitian to emphasise whole family involvement and ways in which parental support could be given to the child e.g. parents and other adult members of the family can;

- lead by example,
- be consistent in situations around food and activities,
- set boundaries,
- limit pocket money,
- find reasons to praise the child's behaviour and give them positive feedback, instead of rewarding with food use e.g. family outings, CDs
- establish family meals and snacks,

- decide when and what food is offered and let the child decide if they will eat it,
- remove temptation (5).

The domiciliary visit at appointment 5 followed the interview techniques and structure described above. The dietitian used the occasion to look through the family's food cupboards and reviewed with the child and parents their understanding of green, amber and red foods with the foods found in the family home (see 3.6.2).

At appointment 6 the 'Tricky situations' sheet (see appendix 2) was used to discuss potential difficult situations e.g. birthdays, Christmas, rainy days, when it might be difficult to keep to goals (see section 3.3). The child and parent were asked to reassess their score of the importance to change and the child was asked to start considering long-term lifestyle goals. From this appointment the method of lifestyle recording changed to the simpler frequency tick sheets (see appendix 2)

At the end of the intervention at appointment 8 the child set their long-term goals and these were recorded on a new sheet (see appendix 2). They were encouraged to continue with the process of setting goals and rewards on a monthly basis and to continue lifestyle recordings. They were given a three month supply of frequency recording sheets and asked to either photocopy the recording sheets or to make their own when these ran out.

3.7 Standard dietetic treatment

It was considered essential that the novel treatment was compared to standard dietetic treatment that was typical of that being delivered by dietitians in the centres taking part throughout Scotland. At the start of this project there was the potential for standard care to be delivered by the dietetic departments at RHSC, Edinburgh, Yorkhill Hospital and

Primary Care Trust, Glasgow, St. John's Hospital, Livingston, Falkirk Royal Infirmary, Falkirk and Lanarkshire Health Board. All of these departments held discussions with the SCOTT team on their typical standard childhood obesity treatment. In the end standard care was only delivered at RHSC, Edinburgh, Yorkhill Hospital and Primary Care Trust, Glasgow. Eight dietitians undertook the standard care and none of these had any formal training in childhood obesity, motivational or behavioural change techniques. At the end of the treatment phase all the standard care dietitians were asked to complete a questionnaire concerning the treatment they delivered (see appendices 8a). 88% (7/8) of the questionnaires were returned a summary of the answer are given in appendix 8b; none of the dietitians reported changing their usual care during this period. The following descriptions of the typical standard care are based on the team's initial discussions and on the answers to the questionnaire. The author is therefore confident that the description below is typical of the dietetic intervention delivered across Scotland at the time of the SCOTT project.

3.7.1 Structure of appointments in standard care

Typically standard care involved three to four appointments over six to ten months. All the centres aimed to give the first three appointments within six months. With the exception of the Edinburgh centre, where the fourth appointment was always given as part of the standard care, the fourth appointment was optional and was only to be given if requested by the child and parent(s). The fourth appointment was to be given between six to ten months. The first appointment was 30-45 minutes in length with the follow up appointments in all centres 15-20 minutes at most in length.

3.7.2 Lifestyle advice in standard dietetic care

Typical dietetic weight management advice involved family based lifestyle changes targeting diet and physical activity. This in general included an emphasis on healthy eating in combination with limiting

those foods particularly high in fat and sugar (e.g. crisps, chips, sweets and sugary juice), as well as giving advice on portion sizes and meal patterns. The children were also encouraged to increase physical activities such as walking more instead of the car, taking up enjoyable out of school activities such as football, cycling and swimming.(170)

The centres delivering standard care agreed to use the newly produced Scottish Nutrition and Diet Resource Initiative (SNDRI)^k weight management leaflets for primary school children, namely –

The Right Choice – Healthy lifestyle: primary school age

The Right Choice – Meal and snack suggestions

The Right Choice – A guide for you and your child on increasing activity

The Right Choice – Food labels

The Right Choice – Goal sheet

The Right Choice – Asian evening meal suggestions

The primary leaflet ‘Healthy Lifestyle: primary school age’ was intended to be given to all children while the other leaflets were used at the discretion of the standard care dietitian. Standard care dietitians also tended to set goals for lifestyle change after discussions with the child and parent and these are recorded on the ‘Goal’ sheet. All of these leaflets are reproduced with the kind permission of the SNDRI in appendix 9.

3.8 Comparison between novel and standard dietetic treatment

An overview of the main differences and similarities between the standard and novel dietetic treatments is given in table 3.6.

^k Available from John McCormack & Co Ltd, Glasgow, UK

3.8.1 Intensity of treatment

The most obvious difference between the typical and novel dietetic treatment is the number and length of appointments. In the standard care treatment a child could have seen a dietitian for weight management advice for one hour to one hour and forty-five minutes in three to four appointments over six to ten months. This compares with a more intensive intervention in the novel treatment of up to five hours (depending on length of the domiciliary visit) in eight appointments over six months.

3.8.2 Interviewing techniques

The interview techniques used by the standard care dietitians are those skills associated with many dietetic interventions and are best described as following a medical model.(165) The advice given and the structure of the intervention were usually based on the dietitian's own clinical experience with them using techniques which had worked with other clients and from discussions with colleagues. The interviews were not standardised and it would not be unusual for dietitians in the same department to give varying advice and different structure to their interviews and interventions. However the total time of standard care appointments were short and similar, the focus was on diet and the same written materials were used. The novel treatment was a structured intervention with the outline of each interview defined (see appendix 1) with the lifestyle advice is based on evidence based guidelines.(5)

One of the most fundamental differences between the two treatment methods used in the present study was that the novel treatment was client centred; although the dietitian guided the child to the necessary areas of lifestyle change the child and not the dietitian set the goals of lifestyle change. The novel treatment was intended to empower the child to identify the lifestyle changes they will attempt to make and to consider how they would make them. There was an expectation of

resistance and ambivalence to change and a theoretical basis for dealing with this.(141) In contrast the standard treatment interview was professional led and assumed that the dietitian was in charge, that the client wanted to change and simply required either more information or a 'good telling off'.(165) The dietitian effectively told the child and parents what to do about diet and lifestyle changes after some education and there was little individualism. Once obtaining a comprehensive diet history from the child and parent the dietitian advised and sets goals for lifestyle changes based on this diet history.(172) The diet history was not used in the novel treatment and a less forceful method of a 'typical day' was used to elicit information on lifestyle from the child. The use of treats for meeting goals and on going recording of daily lifestyle were also not common practice in standard care of childhood obesity.

The areas of motivation and readiness to make changes were touched upon by most dietitians in the standard care interviews but were explored in depth in the novel treatment, where the child and parent were asked to score their importance for change and then the child completed a decisional balance chart (pros and cons of change, see appendix 2).

Table 3.6: Comparison of standard and novel dietetic treatments

	Standard treatment	Novel Treatment
Number of Appointments and length of intervention	3 - 4 appointments over 6 - 10 months	8 appointments over 6 months
Length of consultations	1 hour to 1 hour 45 minutes	~ 5 hours
Aim of therapy	Weight maintenance	Weight maintenance
Interview style	Professional led	Directional but client centred
Family involvement	Strongly encouraged	Strongly encouraged
Assessing motivation	Dietitian usually asks the child - if they feel there is a problem with their weight. - if they are ready to make lifestyle changes	Child and parent asked to - discuss history behind referral to clinic - assess importance of change Child asked to consider 'pros and cons' of change
Basis for advice	Based on dietitian's own clinical experience, what has worked for other families and discussions with colleagues	Taken from evidence based guidelines and given within a structured protocol
Dietary advice	Decreasing high fatty and sugary foods within a healthy eating framework	Traffic light diet, aiming to limit red foods (high in sugar and fat) to one per day
Physical activity	Encouraged an increase in overall physical activity	Encouraged increasing lifestyle and structured physical activity long term to 60 minutes per day. Decreasing non-active time to less than 2 hours per day.
Goal setting	Goals set by dietitian after discussions with child and parent	Goals set by child with dietitian ensuring goals realistic and achievable. Set treats agreed with the child and parent/s for meeting 100% of goals.
Monitoring of behaviours	None	Lifestyle diary Longer term using frequency recording sheets

3.8.3 Lifestyle advice

In both novel treatment and standard dietetic care importance was placed on family involvement and on long term lifestyle changes. The goal of intervention in both treatments was weight maintenance.

The emphasis on dietary change in both treatments was for a reduction in energy intake by particularly targeting a decrease in foods high in sugar and fat. However there was a potentially important difference on how this advice was conveyed to the child and family. Current practice amongst British paediatric dietitians is to use an approach of encouraging this reduction in foods particularly high in sugar and fat while highlighting healthy eating.(170) The traffic light approach of the novel treatment had been popular in the UK in the 1970s but had gradually gone out of vogue in the early eighties. This method of weight management was much more prescriptive than the healthy eating advice of the typical care with foods categorised into good and bad (green and red foods) and the child actively encouraged to count and reduce the number of red foods they ate.

Both treatments in the present study encouraged an increase in lifestyle and structured physical activity. Whereas the novel treatment gave specific advice on the amount of time to be spent on physical activity, initially 30 minutes of moderate- vigorous activity at least 5 times per week then rising to a long-term goal of 60 minutes at least 5 times per week, the standard treatment simply encouraged an overall increase.

Targeting a decrease in sedentary behaviours, which was one of the three equally emphasised areas of lifestyle change in the novel treatment was discussed but not specifically targeted in standard care treatment.

CHAPTER 4

Results – Quantitative study

4.0 Statistical analysis and power

Data were analysed using Minitab 14.¹ The author independently carried out all the analysis presented in this thesis. The postdoctoral research fellow, Dr A. Hughes had performed an initial analysis used for publication. Statistical analysis was carried out with the advice of Prof J. McColl, Department of Statistics, University of Glasgow.

237 participants were assessed for eligibility for the present study; 134 consented and were recruited into the study; 65 participants were randomised to the standard care (SC) and 69 to the novel treatment (NT). Of the 134 children entered at baseline, 97 (72%) participants – 48 SC, 49 NT, attended the six-month follow-up and 86 (64%) – 41 SC, 45 NT, attended at 12 months. The expected drop out rate used in the original power calculations was 36% at six months; the actual dropout rate was 27% at six months, with a dropout of 36% at 12 months. Figure 4.1 shows a CONSORT (122) flow diagram of the participants through the study.

As discussed in chapter 2 section 2.1 the primary outcome for the study was change in BMI SD score from baseline to six months and the study had been powered for 44 subjects in each arm with a change in BMI SD score of -0.25 at six months giving 90% power and 5% significance (see chapter 2 section 2.3.1).

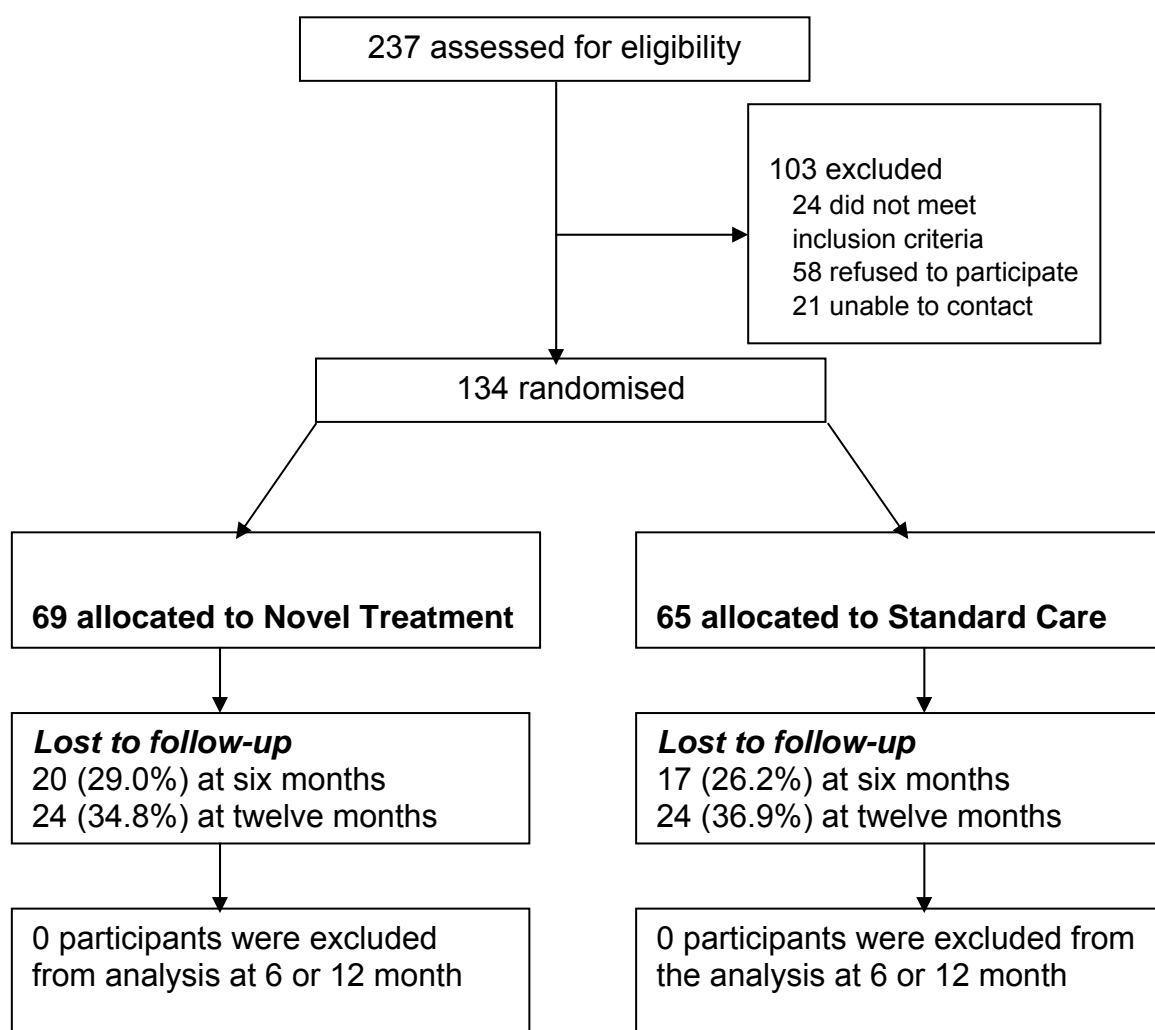
4.0.1 Data analysis

Outcome measures were tested for normal distribution by comparing the means and medians, reviewing box and dot plots, and using Ryan Joiner Normality Tests (a normal distribution was assumed if $p \geq 0.05$).

¹ MINITAB Release 14 Statistical Software produced by Minitab Inc. www.minitab.com

Tables 1-14 in appendix 10 show the results of these tests for each variable and figures 11.1 to 11.22 in appendix 11 display the boxplots for each outcome measurement over time. Most outcome measures were not normally distributed; indeed our sample had been taken from the extreme distribution of a population (BMI SD score above 3) and hence a normal distribution of the data should not be expected. Where a normal distribution had been found we believed this to be an unintentional anomaly of recruitment. Therefore all data within this chapter are reported as median and interquartile (IQ) range; the nonparametric tests Mann Whitney and Wilcoxon signed rank test were used throughout. It is worth noting however that the final results and conclusions would have been the same if parametric tests had been used. Categorical data were analysed using chi square tests.

Figure 4.1. Flow of participants through the trial



A p-value of less than 0.05 was taken to indicate statistical significance. All p values are reported as actual values, where Minitab noted $p=0.000$ this is reported as $p<0.001$. The primary analysis was performed on an intention to treat basis for each outcome measure. Where data was missing due to participants not attending for follow up measurements no substituted data were inputted. Analysis had been pre-planned to be carried out for changes in outcome measurements from 0-6 months and 0-12 months and for an analysis of completers (see below).

4.0.2 Treatment compliance and per protocol analysis

39 (56%) of the NT group and 41 (63%) of the SC group attended 100% of their arranged appointments; that is 8 appointments for the NT and 3-4 appointments for the SC (see chapter 3). These are referred to in this chapter as the 'completers', those who attended less than 100% of appointments are referred to as the 'non-completers'. A planned per protocol analysis for BMI SD score and weight was performed for the completers.

There were a number of notable 'protocol violators'. Three subjects from each arm failed to attend any of their arranged clinical appointments, none of these subjects attended for the six or 12 months measurements. Four of the NT group and 12 of the SC group attended their first appointment only, five of these children returned for the six-month measurements and none for the 12 month measurements. One of the NT children who attended only their first dietetic appointment was remarkable for having gained 16.5kg from baseline to the six months measurement. One SC child did not attend for their six-month measurement but did attend for the 12-month follow up. Three children from the SC group attended 5 appointments instead of the maximum per protocol of 4. One SC subject attended a Weight Watchers programme immediately after completing the standard care and returned for both follow up measurements.

4.1 Characteristics of participants at baseline

The baseline characteristics of the two study groups were similar and these are shown in table 4.1. The randomisation had been stratified for gender and there were 29 boys and 36 girls in the SC group with 30 boys and 39 girls in the NT group. The median age of the NT group was slightly older but not significantly at 9.3 years (IQ 8.0, 10.4) with the SC group 8.7 years (IQ 7.0, 10.1). BMI SD score and centiles were similar in both groups (table 4.1).

Table 4.1: Baseline characteristics of the study participants

Variable	SC Group (n=65)	NT Group (n=69)
Age in years	8.7 (7.0, 10.1)	9.3 (8.0, 10.4)
Male / Female	29 / 36	30 / 39
BMI SD score	3.3 (2.8, 3.6)	3.2 (2.7, 3.6)
BMI centile	99.95 (99.78, 99.99)	99.93 (99.62, 99.98)
Weight (kg)	49.0 (41.2, 61.7)	52.6 (43.8, 61.2)
Maternal BMI (kg/m ²)*	30.0 (25.2, 35.8)	28.0 (24.2, 32.8)
Maternal weight (kg)*	79.4 (63.3, 95.2)	73.0 (60.6, 88.9)
Paternal BMI (kg/m ²)*	27.1 (24.7, 31.7)	26.1 (23.7, 31.5)
Paternal weight (kg)*	82.6 (76.2, 98.0)	82.6 (73.0, 93.8)
Socio-economic status		
Non-deprived (1-4)	30 (46.2%)	28 (40.6%)
Deprived (5-7)	35 (53.8%)	41 (59.4%)

Data are median (IQ range) or number (%). *Parental weight and height were self-reported

4.1.1 Parental weight and family social status

The parent(s) attending the baseline measurements were asked to give their own height and weight and when applicable that of the child's

natural father/mother (see chapter 3). The median self reported maternal and paternal weights in both groups were similar with the mothers BMI's slightly higher than the fathers (see table 4.1). The median self reported BMI for both parents were in the adult overweight category (BMI >25 kg/m²). Family social status were categorised based on postcodes using the Carstairs scores (152) as described in chapter 3, with slightly more classified as deprived than non-deprived in both groups.

4.2 Primary outcome – Change in Body Mass Index

Table 4.2 shows the median (IQ range) of the BMI SD score over time. There was no statistically significant difference between both groups for mean SD score at any measurement point.

Table 4.2: BMI SD score by group over time

Measurement period	Group (number)	Median (IQ range)
Baseline	SC (n=65)	3.29 (2.85, 3.64)
	NT (n=69)	3.17 (2.68, 3.57)
Six months	SC (n=48)	3.17 (2.72, 3.52)
	NT (n=49)	2.95 (2.49, 3.40)
12 months	SC (n=41)	3.10 (2.70, 3.49)
	NT (n=45)	2.83 (2.41, 3.36)

The primary outcome for the study was change in BMI SD score from baseline to six months and the study had been powered on a change in BMI SD score of -0.25 at six months. Table 4.3 shows the changes in BMI SD score from baseline to six and 12 months (Mann Whitney test). The primary analysis was intention to treat and involved all participants who attended at 6 months (n=97) and 12 months (n=86); see study flow diagram, figure 4.1.

The median changes in BMI SD score at 6 months of NT group -0.10 (IQ $-0.24, -0.02$) and the SC group of -0.06 (IQ $-0.22, 0.05$) were smaller than the estimated change used in the original power calculation. For the primary outcome of change in BMI SD score there was no significant difference in the between group change in median BMI SD score at six months, difference 0.03 (95% CI $-0.05, 0.11$) $p = 0.41$.

Therefore, our hypothesis that the intensive novel dietetic treatment would be more successful in reducing BMI SD score than standard dietetic care was rejected.

There was also no significant difference in the group change in median BMI SD score from baseline to 12 months -0.04 (95% CI $-0.17, 0.07$) $p=0.49$.

Table 4.3: Change in BMI SD score from baseline to follow-up (Mann Whitney test)

Period	SC Group (number)	NT Group (number)	Between group difference in change † (95% CI)	p value
0 to 6 months	-0.06 ($-0.22, 0.05$) (n= 48)	-0.10 ($-0.24, -0.02$) (n= 49)	0.03 ($-0.05, 0.11$)	0.41
0 to 12 months	-0.19 ($-0.31, 0.02$) (n= 41)	-0.07 ($-0.32, 0.04$) (n= 45)	-0.04 ($-0.17, 0.07$)	0.49

Data are median (IQ range). †95%CI=95% confidence interval

Although the changes in BMI SD score were smaller than had originally been expected the Wilcoxon signed rank test showed that there was a statistically significant difference in the *within* group BMI changes between baseline to 6 months and baseline to 12 in both groups (see table 4.4).

Table 4.4: Changes in *within* group BMI SD score over time (Wilcoxon signed rank test)

Time period	Group (number)	Median † (95% CI)	P value
0 to 6 months	SC (n=48)	-0.06 (-0.16, -0.03)	0.003*
0 to 6 months	NT (n=49)	-0.10 (-0.18, -0.07)	<0.001*
0 to 12 months	SC (n=41)	-0.19 (-0.26, -0.08)	<0.001*
0 to 12 months	NT (n=45)	-0.07 (-0.22, -0.04)	0.005*

†95%CI=95% confidence interval * significant difference

4.3 Secondary outcomes

4.3.1 Changes in BMI centiles

As BMI centiles are used in the clinical setting to define overweight and obesity and to monitor progress it was considered important to look at the changes of the actual BMI centiles over time. Table 4.5 shows the median (IQ range) of the BMI centiles over time.

Table 4.5: BMI centiles by group over time

Measurement period	Group (number)	Median (IQ range)
Baseline	SC (n=65)	99.95 (99.78, 99.99)
	NT (n=69)	99.93 (99.62, 99.98)
Six months	SC (n=48)	99.92 (99.67, 99.98)
	NT (n=49)	99.84 (99.36, 99.97)
12 months	SC (n=41)	99.90 (99.66, 99.98)
	NT (n=45)	99.77 (99.20, 99.96)

As can be expected from the BMI SD score analysis above there was no significant difference between the two groups in change of BMI centile at six months difference 0.01 (CI -0.01, 0.04) $p=0.26$ as well as at 12 months, difference <0.001 (-0.06, 0.03) $p=0.69$. Table 4.6 demonstrates the differences in changes in BMI centiles from baseline to six and then 12 months using the Mann Whitney test.

Table 4.6: Change in BMI centiles from baseline to follow-up (Mann Whitney test)

Period	SC Group (number)	NT Group (number)	Between group difference in change † (95% CI)	p value
0 to 6 months	-0.01 (-0.06, 0.00) (n= 48)	-0.03 (-0.09, 0.00) (n= 49)	0.01 (-0.01, 0.04)	0.26
0 to 12 months	-0.02 (-0.13, 0.00) (n= 41)	-0.01 (-0.18, 0.01) (n= 45)	<0.001 (-0.06, 0.03)	0.69

Data are median (IQ range). †95%CI=95% confidence interval

The *within* group changes in BMI centiles were significant (Wilcoxon signed rank test) for both groups for the periods baseline to six months, SC $p=0.01$, NT $p=0.001$ and baseline to 12 months, SC $p=0.001$, NT $p=0.01$, see table 4.7.

Table 4.7: Changes in within group BMI centiles over time (Wilcoxon signed rank test)

Time period	Group (number)	Median † (95% CI)	P value
0 to 6 months	SC (n=48)	-0.01 (-0.07, -0.005)	0.01*
	NT (n=49)	-0.03 (-0.09, -0.02)	0.001*
0 to 12 months	SC (n=41)	-0.02 (-0.28, -0.02)	0.001*
	NT (n=45)	-0.01 (-0.30, -0.005)	0.01*

†95%CI=95% confidence interval *significant difference

4.3.1.1 Clinical significance of changes in BMI centiles

The inclusion criteria for the study used the SIGN 69 (5) clinical BMI cut off for defining obesity of BMI $\geq 98^{\text{th}}$ centile. It was considered relevant from a clinical point of view to look at the BMI centiles at the 3 measurement stages and assess how many children had actually changed their obesity grading level by passing through a BMI centile cut off point. The SIGN 69 BMI cut off point of 91^{st} - 97.9^{th} centile was used to define overweight. The SIGN obese category has been further divided in the present study into - obese (98^{th} - 99.5^{th} centile) and grossly obese ($\geq 99.6^{\text{th}}$ centile). Table 4.8 shows the BMI cut off points used for grading and the numbers in each obesity grading at baseline, six and 12 months.

Table 4.8 shows a small movement down through the centiles at six and 12 months, however at 12 months only six of the children were not clinically obese (BMI $\geq 98^{\text{th}}$ centile) with one being categorised as normal weight (BMI= 85.4^{th} centile) – SIGN (5) clinical definition of overweight $\geq 91^{\text{st}}$ centile. The majority of children still remained over the 99.6^{th} centile 12 months after the start of the treatment. Thus although the Wilcoxon signed rank test showed a significant difference

within groups over time the clinical significance of these changes is questionable.

Table 4.8: Obesity gradings through time

Period	Group (number)	Normal weight <91 st c	Overweight 91 st -97.9 th c	Obese 98 th -99.5 th c	Grossly obese ≥99.6 th c
Baseline	SC (n=65)	0	0	10 (15%)	55 (85%)
	NT (n=69)	0	0	17 (25%)	52 (75%)
6 months	SC (n=48)	0	1 (2%)	9 (19%)	38 (79%)
	NT (n=49)	0	3 (6%)	12 (24%)	34 (69%)
12 months	SC (n=41)	0	4 (10%)	5 (12%)	32 (78%)
	NT (n=45)	1 (2%)	1 (2%)	12 (27%)	31 (69%)

Shows number (percentage)

Of those that completed the 12-month measurement, the movement in gradings is shown in table 4.9. One child from the NT group went down 2 gradings from obese to normal weight and two in the SC group went from grossly obese to overweight. Five in the NT group and two in the SC went from obese (98th-99.5th centile) to grossly obese (≥99.6th centile).

Table 4.9: Movement in obesity gradings from baseline to 12 months

Movement	Group	Numbers
Down 2 gradings	NT	1 from obese to normal weight
	SC	2 from grossly obese to overweight
Down 1 grading	NT	1 from obese to overweight
		4 from grossly obese to obese
	SC	2 from obese to overweight
		3 from grossly obese to obese
Remained static	NT	8 obese
		26 grossly obese
	SC	2 obese
		30 grossly obese
Up 1 grading	NT	5 from obese to grossly obese
	SC	2 from obese to grossly obese

4.3.2 Changes in weight

Although looking at BMI SD score and centiles gives an indication of obesity level, in guideline recommendations and clinical practice the aim of intervention is weight maintenance.(5;31) It is therefore of potential clinical significance to review the changes in weight. Although there was a slight decrease in the BMI SD score, weight significantly increased over time for both groups, table 4.10 shows the median (IQ range) weights over time. Changes in weight SD score can be seen in appendix 10 table 3.

Table 4.10: Weight by group over time

Measurement period	Group (number)	Median (IQ range)
Baseline	SC (n=65)	49.0 (41.2, 61.7)
	NT (n=69)	52.6 (43.8, 61.2)
Six months	SC (n=48)	53.0 (43.2, 66.4)
	NT (n=49)	54.8 (46.8, 62.3)
12 months	SC (n=41)	53.9 (46.8, 66.0)
	NT (n=45)	58.1 (52.1, 64.5)

The changes in weight in both groups over time is very interesting, as can be seen from table 4.11 there were no significant differences in the weight changes between the groups at any measurement stage using a Mann Whitney test. However, table 4.12 demonstrates the highly significant weight increase over time *within* the two groups, $p < 0.001$ at all measurement stages using a Wilcoxon signed rank test with a median weight gain of 7.0kg in the NT group and 7.2kg in the SC group at 12 months.

Table 4.11: Change in weight from baseline to follow-up (Mann Whitney test)

Period	SC Group (number)	NT Group (number)	Between group difference in change † (95% CI)	p value
0 to 6 months	4.0 (2.6, 5.5) (n=48)	3.2 (1.3, 4.2) (n=49)	0.82 (-0.20, 1.80)	0.117
0 to 12 months	7.2 (4.5, 8.5) (n=41)	7.0 (3.9, 9.0) (n=45)	-0.10 (-1.55, 1.55)	0.931

Data are median (IQ range). †95%CI=95% confidence interval

The aim of both the clinical treatments in the present study was weight maintenance; it was therefore considered important to look at the number of children who had achieved weight maintenance or weight loss compared to those who had gained weight. In the NT group 6/49 (12%) had maintained or lost weight at six months, with 4/45 (9%) at 12 months. In the SC group 6/48 (12%) maintained or lost weight at six months and at 12 months 3 out of 41 (7%).

Table 4.12: Changes in weight within group over time (Wilcoxon signed rank test)

Time period	Group (number)	Median † (95% CI)	P value
0 to 6 months	SC (n=48)	4.0 (2.8, 4.4)	<0.001*
	NT (n=49)	3.2 (2.2, 3.6)	<0.001*
0 to 12 months	SC (n=41)	7.2 (5.5, 7.7)	<0.001*
	NT (n=45)	7.0 (5.4, 7.8)	<0.001*

†95%CI=95% confidence interval * significant difference

4.3.3 Changes in waist measurements and SD score

Waist circumference measurements as an indices of fat distribution were taken, as one of the study's secondary outcomes even though as discussed in chapter 1 the clinical meaning of this measurement is unclear in childhood and the appropriate cut off points remain debatable.(42) Therefore in this section the results are presented without any comment on their clinical significance. It is interesting to note that for both groups the median waist SD score was above 3 standard deviations at baseline,(41) see table 4.13.

Table 4.13: Waist circumference and waist SD score by group over time

Period	Group (number)	Measurement	Median (IQ range)
Baseline	SC (n= 64)	waist, cm	81.0 (73.3, 89.1)
	SC	SD score	3.30 (2.90, 3.69)
	NT (n= 67)	waist, cm	83.0 (77.2, 88.5)
	NT	SD score	3.32 (2.91, 3.56)
Six months	SC (n= 45)	waist, cm	80.9 (74.7, 90.9)
	SC	SD score	3.06 (2.75, 3.64)
	NT (n= 49)	waist, cm	82.5 (73.5, 86.8)
	NT	SD score	3.08 (2.62, 3.40)
12 months	SC (n= 41)	waist, cm	80.8 (75.0, 91.5)
	SC	SD score	3.25 (2.67, 3.62)
	NT (n= 45)	waist, cm	82.5 (75.8, 87.7)
	NT	SD score	3.05 (2.46, 3.40)

There were no significant differences between the groups for waist circumference or waist SD score at any of the measurement periods. There was a significant decrease in waist SD score for both groups between baseline and six months and baseline and 12 months, see table 4.14. However there was a significant increase of actual waist circumference measurements for the SC group in the period baseline to 12 months ($p=0.02$). For waist circumference centiles see appendix 10 table 7.

Table 4.14: Changes in waist circumference and waist SD score within group over time (Wilcoxon signed rank test)

Time period	Group Measurement (number)		Median † (95% CI)	P value
0 to 6 months	SC (n= 45)	waist, cm	0.5 (-1.2, 1.3)	0.75
	SC	SD score	-0.10 (-0.24, -0.06)	0.001*
	NT (n= 48)	waist, cm	-0.2 (-1.0, 0.6)	0.59
	NT	SD score	-0.18 (-0.25, -0.14)	<0.001*
0 to 12 months	SC (n= 41)	waist, cm	2.1 (0.5, 3.25)	0.02**
	SC	SD score	-0.16 (-0.28, -0.07)	0.002*
	NT (n= 44)	waist, cm	0.9 (-1.0, 2.4)	0.32
	NT	SD score	-0.20 (-0.34, -0.12)	<0.001*

†95%CI=95% confidence interval * significant decrease ** significant increase

4.3.4 Changes in habitual physical activity and sedentary behaviour

Levels of habitual physical activity and sedentary behaviour were measured at the three measurement stages using accelerometers (see chapter 2, section 2.4.3 for a fuller explanation and for the cut off points used for differing levels of activity). At the 12 months measurement more data were missing due to poor compliance with the accelerometry protocol and the raw data available were difficult to interpret, therefore only baseline and six month data are presented in this thesis. In table 4.15 the total physical activity time noted is defined as the accelerometer counts per minute (cpm), percentage of time in sedentary behaviour, light intensity activity and moderate to vigorous physical activity (MVPA) for both groups at baseline and six months. The CSA monitors were worn over 7 days for a mean of 11.4 (1.3)

hours per day at baseline and a mean of 11.3 (1.3) hours per day at six months. There was no significant difference between groups for the hours the CSA monitor was worn ($p=0.24$, 2 sample t-test).

Table 4.15: Physical activity levels by group baseline and six months

Measurement (group)	Baseline (number)	Six Months (number)
Total Activity (cpm)		
NT	649 (508, 749) (n=60)	626 (490, 716) (n=34)
SC	646 (526, 821) (n=57)	538 (458, 626) (n=33)
% of monitored time		
<i>Sedentary Behaviour</i>		
NT	81.2 (76.5, 86.4)	81.8 (78.4, 86.4)
SC	80.7 (75.4, 84.9)	84.4 (81.5, 86.9)
<i>Light Intensity Activity</i>		
NT	15.8 (11.4, 19.4)	14.5 (12.0, 17.5)
SC	16.5 (13.3, 20.3)	13.0 (11.1, 15.2)
<i>MVPA</i>		
NT	2.3 (1.8, 4.1)	3.0 (1.7, 4.2)
SC	2.6 (1.8, 4.5)	2.3 (1.3, 3.8)

MVPA = Moderate to vigorous intensity physical activity; Values are median (IQ range)

There was a significant difference in the changes in total physical activity (cpm) ($p=0.01$) sedentary time ($p=0.009$) and light intensity activity ($p=0.02$) between the two groups in favour of the NT group. Table 4.16 shows the results of a Mann Whitney test. These results suggest that although the NT group had no significant change in their overall habitual physical activity levels between baseline and six months, the SC group actually became significantly more sedentary over the six-month period.

Table 4.16: Median change (IQ range) in habitual physical activity and sedentary behaviour from baseline to six months by group

	NT Group (n= 33)	SC Group (n=33)	Mann Whitney (Control vs Intervention) (95% CI)	p value
Total Activity (cpm)	21 (-129, 157)	-115 (-194, 1.5)	-112 (-199, -31)	0.01*
% of monitored time				
Sedentary Behaviour	0.05 (-4.8, 3.8)	4.49 (0.02, 6.2)	3.6 (0.8, 6.3)	0.009*
Light Activity	-0.5 (-3.5, 2.6)	-3.8 (-5.2, -0.6)	-2.5 (-4.8, -0.5)	0.02*
MVPA	0.2 (-0.8, 1.4)	-0.7 (-1.8, 1.0)	-0.8 (-1.7, 0.1)	0.10

MVPA = Moderate to vigorous intensity physical activity * Significant difference

4.4 Possible adverse effects of treatment

Height and quality of life (see chapter 2 section 2.4.4 for description) were measured at each period to monitor if there were any adverse effects of following either dietetic treatment

4.4.1 Changes in height

Adverse height growth was tested by comparing the change in height over time between the two groups. Both groups showed *within* group significant increase in height from baseline to six and 12 months, $p < 0.001$ for all measurement periods, see table 4.17 for results from a Wilcoxon signed rank test. There was no significant difference between the groups for the changes in height over time (0-6 months $p=0.09$, 0-12 months $p=0.09$, Mann Whitney test). Children in both groups continued to grow in height at a similar and expected rate over the study period.

Table 4.17: Changes in height within group over time (Wilcoxon signed rank test)

Period	Group (number)	Median † (95% CI)	P value
0 to 6 months	SC (n=48)	3.6 (3.4, 3.9)	<0.001*
	NT (n=49)	3.2 (3.1, 3.6)	<0.001*
0 to 12 months	SC (n=41)	7.0 (6.4, 7.3)	<0.001*
	NT (n=45)	6.4 (6.1, 6.7)	<0.001*

†95%CI=95% confidence interval * significant difference

4.4.2 Changes in Quality of Life

Quality of life was assessed using the PedsQL™ 4.0 (UK) child self-reporting and parent proxy questionnaires. As described in chapter 2 the questionnaires had separate sub-sections on physical, emotions, social and school functioning. It was considered appropriate for this thesis to initially look at and present the overall Total Scale Scores for the quality of life for both the child self-reporting and parent proxy at each measurement stage. There was no statistically significant difference for either the child self-reported or parent proxy between the groups for any of the changes in the Total Scale Scores or sub-section scores (Mann Whitney test) at each measurement stage. Table 4.18 shows the actual Total Scale Scores for the child self-reported and parent proxy scores at each measurement stage. For the changes in Total Scale Scores for child self-reported and parent proxy total quality of life scores see appendix 10 tables 11 and 12.

Table 4.18: Child self reporting and parent proxy Total Scale Scores for quality of life from baseline to follow-up

Period	Group	Child (number)	Parents (number)
Baseline	SC	72.8 (60.9, 80.4) (n=57)	65.2 (54.9, 78.3) (n=61)
	NT	75.0 (63.6, 85.9) (n=69)	66.3 (58.7, 76.3) (n=67)
Six months	SC	78.3 (65.2, 85.2) (n=45)	69.6 (60.9, 81.7) (n=45)
	NT	81.5 (64.7, 87.5) (n=49)	70.6 (60.9, 83.7) (n=47)
12 months	SC	78.3 (67.4, 84.0) (n=38)	73.9 (55.2, 82.9) (n=38)
	NT	85.2 (69.6, 92.4) (n=45)	70.6 (57.6, 81.5) (n=43)

Data are median (IQ range).

There were statistically significant increases in the median *within* group change for both groups for the child self reported Total Scale Scores from baseline to 12 months (Wilcoxon signed rank test); NT 10.9 (-3.9,17.4) p=0.003; SC 8.7 (<0.001, 19.5) p=0.007. There were smaller but still statistically significant increases in the median *within* group change for both groups for the parent proxy Total Scale Scores from baseline to 12 months (Wilcoxon signed rank test); NT 3.1 (-3.3, 8.7) p=0.028; SC 4.3 (-3.3, 14.1) p=0.019.

4.5 Per-protocol analysis

It was considered relevant to look at the outcomes of those subjects who completed all (100%) of their intended treatment – known as the completers in a pre-planned analysis as noted in section 4.0.2. For the NT group this was 8 appointments and for the SC group 3-4 appointments. Thirty-nine (56%) of the NT group and 41 (63%) of the SC group completed their full treatment programme. Per protocol analysis was carried out for the primary outcome changes in BMI SD

score and for changes in weight only. There were no significant differences between the completers in the groups for the changes in BMI SD score and for weight at six and 12 months using a Mann Whitney test. Table 4.19 shows BMI SD scores and weights over time.

Table 4.19: BMI SD score and weight by group over time for completers

Period	Group Measurement (number)		Median (IQ range)
Baseline	SC (n= 41)	weight	48.1 (40.0, 60.4)
	SC	BMI SD score	3.2 (2.9, 3.6)
	NT (n= 39)	weight	52.6 (45.4, 60.6)
	NT	BMI SD score	3.1 (2.5, 3.6)
Six months	SC (n= 38)	weight	52.3 (42.7, 66.9)
	SC	BMI SD score	3.2 (2.6, 3.5)
	NT (n= 39)	weight	55.2 (48.0, 64.6)
	NT	BMI SD score	3.0 (2.5, 3.4)
12 months	SC (n= 35)	weight	53.9 (46.8, 67.8)
	SC	BMI SD score	3.1 (2.3, 3.4)
	NT (n= 36)	weight	59.2 (52.3, 68.6)
	NT	BMI SD score	2.8 (2.3, 3.4)

4.6 Discussion

4.6.1 Study power and quality

This was an adequately powered RCT which followed CONSORT guidelines.(122) Recruitment to the study was successful and sufficient

participants were entered into the study and subsequently returned for the six and 12 months measurements. The study had originally been powered for 44 subjects in each arm at six months, in reality 49 participants from the NT group and 48 from the SC arm attended at six months. The study was therefore adequately powered to show the expected changes. Indeed a post-hoc power calculation showed that the actual standard deviation in change in SD score was 0.21, which gives a delta value of 1.15 ($0.25/0.21$). Thus, with power 0.9, 0.05 significance level and a 2-sided test, the required sample size was 34 per group. With 97 participants included in the analysis of the primary outcome (BMI SD score) at 6 months, a significance level 0.05 and a 2-sided test, the actual achieved power to detect a difference in BMI SD score between the groups was 0.9999.

Concealment was ensured with allocation carried out remotely. All the children and parents were instructed not to discuss their group allocation with the postdoctoral research fellow who was blinded to group allocation. Although there were a number of protocol violators (see section 4.0.2 above) all the participants who returned for the follow up measurements were analysed in the groups they had been randomly allocated.

4.6.2 Study limitations

A number of the children, particularly from the younger age group, were not always keen to participate in the measurements in an appropriate manner. However all measurements were taken three times to ensure accuracy. Most difficulties were encountered with the habitual physical activity and sedentary behaviour measurements. The wearing and returning of the CSA monitor appeared to be a particular problem during the 12-month measurements and may account for this data being very incomplete and therefore not reported in this thesis. It is very interesting that in the interviews for the qualitative project (chapters 5 and 6) that without any prompting it was widely noted by the parents

that the children particularly disliked wearing the CSA monitors. The parents commented that this was due to the children feeling very self-conscious and that the monitor brought people's attention to their weight. The parents noted that they had more difficulty persuading the children to wear them at the 12 months than at the baseline or six month measurement.

The measuring of obese children's waist circumference in an accurate and consistent manner is not always simple. The postdoctoral fellow carried this out in as systematic a manner as possible and used the pragmatic method of having the child bend to one side to identify the waist.

No biochemical indices were used as outcome measurements in this study. In the original research proposal to the Scottish CSO it had been intended to measure appropriate CVD indices such as fasting glucose, insulin and lipids. The CSO had felt there would be too many outcome measurements and asked for these to be removed from the proposal. The removal of these as outcome measures is unfortunate, as these biochemical indices may have given a fuller picture of the possible overall health benefits of treatment.

There was also no attempt to objectively measure any changes in the child's and family dietary intakes. Again this had been part of the original research proposal but was removed at the request of the CSO research committee. Inclusion of such information may have provided interesting data on changes in dietary habits during and post interventions. Indeed the lack of information on dietary changes has been a criticism made in a systematic review of dietetic interventions in childhood obesity.(125)

There was no 'true' control group in the present study, that is one that had received no dietetic intervention. However Rudolf 2006 (131) reporting on the WATCH IT programme in Leeds, UK (see table 3.20)

did report a mean *increase* in BMI SD score of 0.2 SD over a 3 to 6 month in children on the waiting list for treatment, implying that in the absence of dietetic intervention BMI SD score may increase.

The majority of the participating children in the present study had a BMI over the 99.6th centile at baseline and therefore this study involved children with extreme obesity. A recent paper from Freedman et al (2007) reporting on the Bogalusa Heart study in the US confirmed evidence from systematic reviews that children at such extreme BMI centiles are very likely to have adverse cardiovascular risk factors and will be at high risk of adult obesity.(98) It may be that it was more difficult to show larger changes in BMI SD scores in this grossly obese group and that a study aimed at those with lower BMI gradings may have been more successful. In addition the use of BMI SD score as the primary outcome in this extreme obese group may reduce the apparent impact of treatment.(173)

The SIGN 69 guidelines (5) recommended that treatment should only be started where the parents are motivated to make appropriate lifestyle changes. We chose not to formally assess motivation of the parents believing that we would capture a motivated group due to their willingness to undertake a research project which could have entailed 11 visits to the hospital, for outcome measurements as well as clinic visits. Formal assessment of motivation to change may have provided a more motivated group than was recruited to the present study. Informally, all the participating parents did appear to perceive their child's obesity as a problem at baseline clinics in the present study and methods to enhance readiness to change were used in the NT arm.

The novel treatment in the present study was design to be delivered as a defined programme over six months. It was therefore important that both research dietitians followed the programme schedule and that they used the behavioural change techniques consistently. To try and ensure that this was carried out the two dietitians were trained together

in the behavioural change techniques, both participated in developing the treatment programme and observed each other during the pilot phase. Throughout the treatment phase they had peer review discussions on the progression of subjects through the programme. Interviews in the pilot and the treatment phase were tape-recorded and reviewed by independent assessors to ensure a consistent approach to the behavioural changes techniques. Both dietitians scored well in these independently assessed recorded interviews (see appendix 6). It is also possible that having only two dietitians carry out the NT was a constraint as their own level of motivation and enthusiasm could have been a limiting factor in the outcomes. However as this author was one of the novel treatment dietitians and worked closely with the other dietitian this is not considered a key factor in the present study. Indeed the rapport with the NT dietitians is discussed in very positive terms by the parents in the results of the qualitative study reported in chapter 6. Limitations of the novel treatment programme are fully discussed in chapter 7.

The same level of monitoring of the SC dietitians was not feasible. However prior to the project starting the SCOTT team discussed current protocols with the dietetic departments who potentially would carry out the standard care arm (see chapter 3). All the dietitians delivering standard care used the standardised diet sheets and material developed by the SNDRi project (see appendix 9). Once the treatment phase was completed an audit of all the dietitians who had undertaken standard care in the project was carried out (see chapter 3 section and appendices 8a and 8b). We are confident that the results of this audit show that standard care treatment as described in this thesis was consistently delivered through out the project.

The primary outcome measurement in the present study had been change in BMI SD score at 6 months. There was no significant difference in the BMI SD score between the two groups at six or 12 months. Therefore the study failed to show that the more intensive NT

could improve treatment outcome more than the present standard NHS dietetic care delivered in the two main paediatric centres in Scotland. Indeed all the outcome measurements, with the exception of the habitual physical activity, sedentary behaviour at six months, showed no significant differences between the groups in the present study.

4.6.3 Study implications

Our novel dietetic treatment had incorporated the evidence based recommendation of the SIGN 69 guidelines,(5) in particular that –

- treatment should be directed at motivated families only (where the child and/or parents perceive obesity as a problem and appear willing to make lifestyle changes);
- treatment should be directed at the entire family rather than just the obese child;
- weight maintenance (rather than weight loss) is a desirable treatment outcome for most obese children;
- treatment should be more intensive than has been the norm (more frequent and longer appointments);
- treatment should combine changes in diet as well as changes in physical activity and/or reduction in sedentary behaviour (e.g. TV viewing).

The NT programme also used behavioural change techniques that are recognised as being important in modifying lifestyle in chronic childhood conditions.(160) The failure to show statistically and clinically significant differences between SC and NT in the present study is disappointing particularly as the outcomes of standard care in the Edinburgh centre had previously been reported as unsuccessful over a five year period. The previous audit from Edinburgh showed that only 48% of families completed their dietetic treatment of 3-4 appointments.(138) The families undertaking this present study were perceived to be motivated but the numbers that attended all the appointments were lower than

expected. Fifty six percent of the NT group and 62% of the SC group attended 100% of their scheduled appointments. This may be an indication of the commitment required of families to complete such an intense programme.

Although there were no significant differences between the groups for changes in any of the measurements of body composition and fat distribution there were statistically significant changes over time *within* groups in BMI SD scores, BMI centiles, weight SD scores and waist SD scores. These significant decreases *within* both groups over the measurement time period could be seen as positive outcomes. However, great caution should be shown when interpreting the clinical significance of these decreases. There was very little movement through obesity grading with only four subjects graded as overweight at six months while at 12 months five subjects were overweight and one subject graded as normal weight. At 12 months the majority from both groups, 78% SC group and 69% NT group, remained graded as grossly obese (BMI \geq 99.6th centile) and therefore at a level likely to put these children at a high risk of the co morbidities of obesity.(6;98) Children and families are told that the goal of intervention is weight maintenance; at 12 months in both groups the median weight gain was approximately 7.0kg with only 9% of the NT group and 7% of the SC group actually maintaining or losing weight over the 12-month period. The weight increases for both groups at six and 12 months were highly statistically significant ($p < 0.001$).

An interesting aspect of the statistically significant weight increase *within* both groups over time is the decrease *within* groups over the same measurement times of all other indicators of body weight and overweight (i.e. BMI SD score, BMI centile, weight SD score and waist SD score). The present study may question the most appropriate clinical outcome for weight management in children. It may be more appropriate and positive for children and their families if the emphasis

in clinical practice and in clinical guidelines is changed from body weight to actual BMI centiles. Cole et al in 2005 also raised this issue of looking for the most appropriate measure of adiposity change in growing children.(173) Hunt et al (2007) have suggested that changes in BMI SD best reflect changes in body fat and should be used as the most appropriate outcome measure of childhood obesity interventions.(174)

At present the magnitude of the change in BMI SD score required to produce a clinically meaningful outcome for obese children is unclear due to lack of evidence. Reinehr and Andler (2004) (175) suggest that a decrease in BMI SD score of >0.5 is required to modify cardiovascular risk factors.

The only outcome where there was a statistically significant difference between the groups in the present study was in the measurements of habitual physical activity. In the overall measurement of habitual physical activity and in the light intensity activity there was a significant decrease in the SC group compared with the NT group at six months. There was also a significant increase in sedentary behaviours in the SC group compared to the NT group over the same period. These results appear to be showing that the NT group did not become more active but continued with virtually the same level of active and sedentary behaviour while the SC group became less active and more sedentary over the six-month period. With a body of evidence (5;9;31;134;135) recommending that treatment strategies for childhood obesity should incorporate an increase in physical activity and a decrease in sedentary time these results may help to emphasise the need for clinicians to give children and families detailed specific advice on these behaviours. Discussion on the different attitudes to physical activity levels and sedentary behaviour between the groups will be returned to in chapter 6 when discussing the results of the qualitative study.

Schwimmer et al (2003)(116) have shown that obese children have a lower quality of life score than children suffering from cancer and Rudolf et al (2006) (131) reported similar baseline Total Scale Scores for obese children in their weight management programme to this present study. Edwards et al (2006) (130) also showed that children undertaking a weight management programme had statistically significantly increased their self concept and self esteem, $p=0.01$ (using the Piers-Harris Self Concept Scale). The *within* group increase in quality of life scores for the children in the present study may be of clinical significance in the children's quality of life despite the modest change in BMI SD score.

The 12-month child self reported Total Scale Score for the NT group lies within Varni et al (2001) score for healthy children mean 83.0 (SD 14.8). For the SC group the 12-month child score is within Varni et al acutely ill child score mean 78.7 (SD 14.0). The 12-month parent proxy Total Scale Scores for both groups are still below Varni et al score for chronically sick children mean 74.2 (SD 18.4). (150) The parent proxy Total Scale Scores were lower at all measurements stages than the child self reported scores. This is in line with results reported by Schwimmer et al (2003) that showed that parents of obese children consistently reported lower quality of life scores using the same questionnaire.(116) It should be noted that Schwimmer et al noted actual scores in all categories for both children and parents lower than in this present study, as their study was based in the US one possible explanation for these lower scores could be cultural differences. Discussions on quality of life and self-esteem are returned to in chapter 6.

The children in both groups of the present study continued to grow in height at a median rate of 3cm per six months, indicating that there was no stunting in growth. These results indicate that the dietetic interventions used in this study appeared not to have any adverse affects on these children's growth.

There was no difference between the completers in both groups for BMI SD score and weight. This would indicate that attending the full number of appointments had no clinical benefit. It is worth noting that all of those who maintained or lost weight at 12 months were completers, this suggests that the completers contained the most motivated families and children in the present study.

Comparative economic costing were carried out by a health economist, Mehran Zabihollah, University of Liverpool Management School, UK. This showed per patient that the novel treatment, inclusive of training, cost £108 compared to £29 for the standard care treatment.(176) Although this economic comparison makes the novel treatment over three times more expensive per patient than the standard care it should be noted that those trained to undertake the NT would gain valuable, transferable behavioural change technique skills.

4.6.4 Comparison with other studies

Although discussed in detail in chapter 7 and with a more global/international focus, it is pertinent at this point to briefly compare the results from the present SCOTT project with those from other broadly similar studies – one from the Epstein group in the USA and three from UK childhood obesity treatment studies.

Table 4.20 shows a comparison of the SCOTT study with the results of these four other studies. The comparison is complex for a number of reasons – namely that there is little agreement between the studies on the primary outcome measure, on the method of reporting changes in BMI SD scores over time and on the length of the interventions.

In order to enable some comparison between studies in table 4.20 this author has -

- taken the mean BMI SD score reported in the Epstein,(159) and UCL (130) papers and then calculated the difference in mean BMI SD scores over time. [This particular Epstein et al (2000) paper was chosen for this comparison as it reported recent work from the Epstein research team and used a similar outcome measure to the present SCOTT study of BMI SD].

- shown the reduction in BMI SD score as stated in the MEND study paper,(132) however it is unclear whether this is a reduction in the mean BMI SD score or the mean of the change in BMI SD score. The SCOTT and WATCH IT (131) studies have reported respectively the median and mean changes in BMI SD scores over time. Interestingly the present SCOTT study is the only one to report the changes as median and not mean, therefore implying that the other studies found their results to have a normal distribution. As discussed at the beginning of this chapter this was not the finding of the present SCOTT study (see appendix 10 for tables showing summary of descriptive statistics).

Taking these caveats into consideration it can be seen from table 4.20 that the 'best' results in terms of difference in mean BMI SD score are those from Epstein et al (159) in North America. All three groups in this Epstein study show a difference in mean BMI SD score of over 1 SD at 12 months. A large part of the intervention in the present study was based on Epstein's work while attempting to make it simpler, less costly and appropriate to the UK NHS. Why there should be such a difference in treatment outcomes between those reported by Epstein et al and the SCOTT study is discussed in detail in chapter 7.

The three studies from the UK were either pilot studies and/or reports on preliminary results and were therefore not randomised. The results from the WATCH IT programme are similar to those of this study and are also the only other project to have clearly reported changes in BMI

SD score over time. The significance of the outcomes of these studies compared to this study are further discussed in chapter 7.

This present study has shown that an evidence based intensive, novel dietetic treatment using behavioural modification techniques proved not to be more effective than 'typical' standard dietetic care in Scotland.

Table 4.20: Comparison of the present SCOTT results with four other studies.

Study	Population	Outcome measure*	Outcome*
SCOTT	5-11 years old Scotland, UK SC 6 months n= 48 12 months n= 41 NT 6 months n= 49 12 months n= 45	Changes in BMI SD score at six months (end of treatment) Changes in BMI SD score at 12 months (6 month follow up after treatment)	SC -0.06 (-0.22, 0.05) NT -0.10 (-0.24, -0.02) SC -0.19 (-0.31, 0.02) NT -0.07 (-0.32, 0.04) Median (IQ range)
Epstein 2000 (150)	10.3 (1.1) years old New York State, USA Child & parent group n= 17 Child group n= 18 Standard group n= 17	Difference in mean BMI SD at 12 months (6 months follow up after treatment)	Child & parent group -1.1 Child group -1.3 Standard group -1.3 Difference in mean
WATCH IT - pilot study(131)0)	8 –16 years old England, UK n= 48	Change in BMI SD score at six months (3 months after end of intensive treatment sessions)	-0.07 (0.16) Mean (SD)
MEND – preliminary results(132)6)	10 (1.2) years old England, UK n= 45	Change in mean BMI SD at 9 weeks (end of treatment)	-0.16 Change in mean
UCL – Behavioural treatment programme. Pilot study (130)8)	8 –13 years old England, UK n= 27	Difference in mean BMI SD score at 7 months (3 months after end of treatment)	-0.15 Difference in mean

*All outcome measurements shown are taken from the published studies but are not necessarily the studies primary outcomes.

Chapter 5

Background: Qualitative research principles

5.0 Introduction

During the initial stages of the SCOTT project the team felt it was important to the overall understanding of the outcomes of the trial to examine the experiences of the parents/children regarding the dietetic interventions. The SCOTT team believed that a study that helped understand the parents' experiences and perceptions of their child's obesity and its treatment would assist in making changes to the design of the dietetic treatment and thus improve the efficacy of treatment and patient adherence to therapy. The "Expert Patient" white paper 2001 describes the need for families with children who are chronically sick to take greater responsibility for management of the chronic disease.(177) In order for this to happen, it suggests there must be greater concurrence between the perspectives of health professionals and patients and their families. The Health Development Agency report 2003 on childhood obesity calls for the collection of qualitative data on the thoughts and views of participants in interventions and consideration given to the barriers in translating effective strategies into the clinical settings.(11) Zeller et al (2004) in their report on drop out rates from a US paediatric obesity treatment programme called for qualitative research to be carried out which looked at the views of the patients to established which aspects of the programme did or did not work and why so many families failed to complete their treatment.(178) Patton (2002) describes qualitative research as a powerful tool for illuminating peoples' feelings and as valuable in programme evaluation as it captures participants' 'stories' and allows the participants to describe how the experience and programme felt from the inside.(179) For these reasons we chose to use qualitative research methodology, in particular in depth interviews, as we felt these best suited the aims of a programme evaluation. To our knowledge no other RCT on childhood

obesity, to date, has ever tried to evaluate their interventions using qualitative methods.

Due to the intense nature of qualitative research this work could not be carried out within the original grant or timetable for the SCOTT project. A separate study, the 'Qualitative study of parental perspectives of a novel, dietetic-led behavioural programme and standard dietetic care for the treatment of childhood obesity', was funded by a Scottish Chief Scientist Office small project grant (grant number CZG2166) and Prof. J.J. Reilly, University of Glasgow was principal grant holder. The project was funded from January 2005 to November 2005. The two research dietitians employed on the SCOTT project (this author and J. Chapple) carried out all the fieldwork and data analysis. The author of this thesis had the lead role in designing the qualitative study and as the principle person responsible for data analysis and interpretation. Data collection was shared with the other SCOTT research dietitian for reasons described below. Dr V. Poustie of the University of Liverpool provided supervision and support for the fieldwork and data analysis. Jane Ritchie, the founding Director of the National Centre for Social Research and a highly experienced qualitative researcher was a collaborator on the project and gave advice on the design, methodology and presentation of data.

The need to explore the children's thoughts and feelings about their dietetic treatment during the SCOTT project was also recognised as important. A separate qualitative study of the children conducted by Dr V. Poustie using focus groups was originally planned, however due to certain circumstances this unfortunately could not be carried out.

This chapter very briefly gives a background to the use of qualitative research and then the present study's design, methodology and results are discussed in chapter 6.

5.1 Qualitative research

The most common aim of qualitative research is to offer an understanding of an experience in the context of the participants own personal and social circumstances.(179-181) It is often concerned with exploring phenomena from the perspective of those being studied using unstructured methods, which 'capture' data (e.g. written, oral, film) that is incredibly detailed, complex and often contradictory; ubiquitously referred to as 'rich'.(181;182) The concepts of number counting, power calculations and statistical analysis are generally regarded as an antithesis to qualitative research.(183) An analytic process is often used which develops themes and explanations at an individual as well as at a broader social context.(179;180) These themes and explanations attempt to answer the 'what is', 'how' and 'why' questions.(180;184;185) When presenting results and data there is an avoidance of using quantitative language. It is the accepted approach in qualitative research that themes, descriptions and quotes are not reduced to simple numbers or percentages.(186;187) An excellent summary of the key features of qualitative research was produced by Spencer et al 2003 and is reproduced here in full in table 5.1.

Draper (2004) and Patton (2002) describe that qualitative work, with it's emphasis on meaning and understanding from the individuals perspective, can complement quantitative research and attempt to answer the questions that can be elusive in quantitative studies.(179;180) For example questions such as why do individuals with chronic conditions not comply with their prescribed treatment? As a nutritionist Draper summarises the application of qualitative research to health and nutrition as '*1) to understand patterns of behaviour and how these patterns may influence and interact with health and nutritional status and health-seeking behaviours, including patterns of food consumption; 2) on this basis, to identify priorities and needs relevant to particular social and cultural contexts and/or groups of individuals; 3) to design and implement interventions that are appropriate to these contexts and/or individuals.*'(180)

Table 5.1: Outlining the principles of qualitative research Spencer et al 2003 (184)

- A concern with meaning, especially the subjective meaning of participants.
- A commitment to viewing (and some times explaining) phenomena from the perspective of those being studied.
- An awareness and consideration of the researcher's role and perspective.
- Naturalistic inquiry in the 'real world' rather than in experimental or manipulated settings.
- Prolonged immersion in, or contact with, the research setting.
- The absence of methodological orthodoxy and the use of flexible (emergent) research strategy.
- The use of non-standard, semi-structured or unstructured methods that are sensitive to the social context of the study.
- The capture of data that are detailed, rich and complex (for example, the use of 'thick' description).
- The setting of data in context.
- The collection and analysis of data that are mainly in the form of words and images rather than numbers.
- A commitment to retaining diversity and complexity in the analysis.
- A respect for the uniqueness of each case as well as themes and patterns across cases.
- A mainly inductive rather than deductive analytical process.
- Attention paid to emergent categories and theories rather than sole reliance on a priori concepts and ideas.
- Development rather than testing of hypotheses.
- A concern with micro-social processes.
- Explanation offered at the level of meaning, or in terms of local 'causality' (why certain interactions do or do not take place) rather than 'surface workings' or context-free laws.

Patton meanwhile gives a more vivid and thought provoking description of the underlying concepts of qualitative research. *'Innovators are told: "Think outside the box". Qualitative scholars tell their students: "Study the box. Observe it. Inside. Outside. From inside to outside, and outside to inside. Where is it? How did it get there? What's around it? Who says it's a 'box'? What do they mean? Why does it matter? Or does it? What is not box? Ask the box a question. Question others about the box. Find documents related to the box. What does thinking have to do with the box anyway? Understand this box. Study another box. And another. Understand box. Understand. Then you can think inside and outside the box. Perhaps. For a while. Until it changes. Until you change. Until outside becomes inside – again. Then start over. Study the box.'*(179)

5.1.1 Background/history

Qualitative methodology has its history mainly in the area of social research however it has increasingly been used in medical/health care research.(188) A number of differing 'schools' exist that take diverse approaches to both the research methodology and data analysis.(179;180) There is great debate amongst qualitative researchers on how to define these schools and even on how many schools there may be, Creswell (1998) has suggested that there are five main 'schools' or traditions of qualitative research(185) –

- Biography – the story of one or more individuals
- Phenomenology – the study of phenomena from the perceptive of a person or groups of people
- Grounded theory – the study of phenomena from the perspective of a person or groups of people with the purpose of generating or discovering a theory
- Ethnography – the study of the culture within a group of people
- Case study – exploring a case or multiple cases over time and using a variety of methods e.g. observation, interviews, written documents.

A variety of methods can be employed in qualitative research including exploratory interviews, focus groups, observation (sometimes through participation), discourse and narrative analysis and documentary and video analysis.(179;185) Fuller discussion of these schools and methodologies are outwith the remit of this thesis, further information can be found in the recommended reading list at the end of this chapter.

As in-depth (exploratory) interviews were used in this research project to explore the parents' perspectives their use is discussed in the following section.

5.2 In-depth interviews

Properly and well-conducted in-depth interviews are very different from structured/semi structured interviews or questionnaires. A key feature of in-depth interviews is the interaction between the respondent and the interviewer.(179;189) There is no pre-determined script and the interviewer requires to use good listening skills and be highly responsive to the respondent's language and the concepts raised.(179;180) However the interviewer may work within an agreed/pre-defined agenda known as the topic guide (see chapter 6 table 6.2), as this ensures that the same broad questions or line of questioning is used with each participant.(179) Within the broadly defined agenda there is a need for the interviewer to remain flexible to enable them to get below the respondents initial answers and to explore the 'what is', 'why' and 'how' questions.(182) The interviewer needs to improvise questions throughout the interview and uses interviewing skills to explore in depth the respondent's answers.(179) To do this the interviewer employs mainly open questions that are focused but not leading. The questions should be short and simple with the respondent being given time to reflect and reply.(189) It is important for the interviewer to refer back to the respondents using their own

terms and language as well as asking them to define the words they use.(188)

5.3 Sampling in qualitative research

One of the major differences between qualitative and quantitative research are the methods used to determine study sample size. In qualitative research no power calculations are used and study numbers are estimations of how many participants may be required to answer the original research question.(179) The sampling is usually based on factors that have a bearing on the question/s being studied and those believed will give depth to the area being studied.(190) In qualitative studies these can range from random selection such as high street studies, where the numbers may be high, to a very selective single case study which is information rich due to being an out of the ordinary case.(179)

The aims and purpose of the study, as well as pre-existing knowledge of the subject matter or population, will influence the choice of sampling strategy in qualitative research.(185) It was clear that for our study's intended rationale we needed to interview a range of patients from both the novel and standard care treatment groups, we therefore chose to use purposeful sampling. Purposeful or purposive sampling can use criteria to ensure i) the inclusion of individuals who have the key characteristics that are relevant to the study (e.g. parents of children who took part in the SCOTT project) and ii) the need to optimise the diversity of the group ensuring a full range of features and as wide a spread as possible from all parts of the social world being studied (e.g. in the SCOTT project parents of children from both the younger and older age groups, two parent and single parent families).(191)

In some purposeful sampling designing a sampling matrix helps with deciding on the number of subjects required for the study. This matrix may be derived from demographic characteristics such as gender, age,

ethnic group, household composition, employment activity; and factors known or believed to have a bearing on the study area. There are a number of features that can influence the sample size and these are listed here.

- Objective of the study
- Heterogeneity or homogeneity of the study population
- Number of selection criteria
- 'Nesting' of criteria
- Groups of special interest
- Budget and resources

Sample sizes in qualitative studies tend to be much smaller than that expected in quantitative research and can typically be anything from around 15-30 subjects. However sample size in qualitative work requires to be flexible and can be increased or decreased depending on whether 'saturation'^m of the subject matter has been reached.(181;183) The depth, range and richness of the information collected is more important in qualitative research than the actual number of participants interviewed.(179)

5.4 Analysis in qualitative research

There are many ways to analyse qualitative data that will to some extent be dependent on the school of research being followed but will generally involve shifting through the data collected and developing layers of analysis.(185) Incredibly large amounts of data can be produced in qualitative work and the researchers needs to remain focused to their original research question while at the same time being flexible to ensure that unexpected issues and themes that emerge

^m Saturation in qualitative research is reached when different respondents repeat the same subject matter and further interviews are not revealing new material. Therefore interviews may be stopped before the project reaches the original estimated sampling size or indeed may be increased if the investigators feel that saturation has yet to be reached. (181)

during the analysis process are included.(192) When interviews are used these are often taped and then transcribed and the raw data (the transcribed data) used to develop themes, which in turn are used to explain and develop hypotheses.(179;185)

5.4.1 Framework analysis

In the present qualitative study we chose to use a method of analysis called 'Framework' that was developed by the National Centre for Social Research.(8) We chose this method as we felt it used a systematic process that was suitable to our original research purpose; it is also well recognised and accepted amongst qualitative researchers. Jane Ritchie, who trained both researchers in this method, was one of the principal developers of this methodology and agreed to be a collaborator on the initial stages of the project; Dr Poustie had also previously used this methodology. A brief summary of this process is outlined in table 5.2.

The first stage of 'Framework' analysis is to read a number of transcripts (raw data) and to identify broad themes and concepts from the words, sentences and paragraphs e.g. parents talking about their own cooking skills, difficulty in child taking time off school for appointments. Each researcher should develop the themes independently and then the team agrees the themes by consensus. Many of the themes will be related and these can be grouped together as themes and sub themes, these are given 'labels' and a thematic index is constructed (a list of the groupings of the themes and sub themes). The raw data (transcribed interviews) are then broadly labelled using the thematic index; due to the free flow of dialogue during the interviews a single sentence or paragraph can contain more than one theme and can be labelled under multiple themes.

The labelled data are then used to develop what are known as thematic charts or matrices to build up an ordered framework of the data. The

research question is broken into a number of smaller questions/themes and these in turn have subsection/sub themes. Each chart sets out to hold all the data that will answer a particular question e.g. to look at behavioural change techniques the chart had columns on goal setting, recording, etc. For an example of an edited ample of a chart used in this study see appendix 12. The subsections to be answered are along the top and the participants are named down the sides, the participants are always placed in the same order on each chart. The data are then pulled from the thematic index, for each participant in each column the data are summarised and placed on the chart ensuring that the summary can always be directly related to the text. Data and quotes are used if they are answering a particular question and if they are adding something important to the discussion. These charted data allow summaries for both each subsection and each participant, these are used to construct the analytic concepts, typologies and develop the descriptive and explanatory accounts/hypotheses.(8)

Table 5.2: Summary of the 'Framework' process

Familiarisation:	Tapes and transcriptions are reviewed to improve familiarity with the range and diversity of the data
Identification of themes:	Themes emerging from the data are categorised using headings. Sub-themes are allocated to relevant headings, allowing themes identified to remain grounded within the original data whilst linking common themes together.
Mapping and interpretation:	Characteristics of the data are drawn together to identify common and diverging themes. Theories grounded in the data are then developed.

Participants can be labelled/classified into groupings which explain their responses to the situation being studied these labels are often called typologies.(179;188) The researcher is required to make sense of the charts and to view them as a whole and to allow concepts and explanations to develop from both across and down the charted data. It is important when developing explanations that they remain grounded in the original transcribed text and all concepts, explanations or hypotheses should be supported by quotes from the texts. Rabiee (2004) offers criteria for helping the researcher explore for important concepts and patterns – words, context, internal consistency, frequency, intensity of comments, specificity of response, extensiveness (the number of people making similar comments) and the ‘big picture’.(192) It is essential that the richness and diversity of the data are fully used and all points of view especially contradictory ones should be quoted and used to develop explanations. It is important when developing the themes through to the final accounts that the process is transparent and that an audit trail of both paper and thought process is available for others to follow.(192)

5.4.2 Nvivo software package

Data analysis in qualitative research has traditionally been carried out manually however modern computer programmes known as Computer Assisted Qualitative Data Analysis Software (CAQDAS) that can help with the labelling of the raw data are available.(185;189) QSR NVivo is one such computer software package that can be used to code transcribed interviews and then store, sort and retrieve the coded data. In NVivo themes are known as ‘nodes’ and sub-themes as ‘trees’ and ‘child’. The transcribed interviews are saved into the computer programme and the researcher then reads through the transcripts on the computer screen, the text is coded by highlighting a section of text and then the clicking on the relevant node, tree or child. The data can be easily retrieved from the programme either as the whole transcript, a whole coded transcript or as the coded data for a single node. QSR

NVivo version 2.0 and QSR Merge for NVivo software programmesⁿ were used for the data coding and handling in this project.

5.5 Quality in qualitative studies

As the use of qualitative methods in health and social research and its impact on policy makers has increased, the need to ensure quality in study design and analysis has become an important topic.(182-184;193) There are a number of factors that should be taken into account by both qualitative researchers and those appraising their work. A quality 'framework' for both carrying out and assessing qualitative work was published by the Strategy Unit of the Cabinet Office in 2003.(184) The quality framework has four overriding principles – that the research should contribute to further understanding; should have a design that can answer the research question; is rigorously conducted in the collection, analysis and interpretation of the data; and that all claims should be credible. To help appraisal of research they have produced a set questions; these are reproduced in appendix 13. The remainder of this section describes the most important aspects for quality in qualitative research.

5.5.1 Reflexivity

All researchers bring a level of bias and personal perspectives to their analysis and interpretation of data. There are two suggested methods of dealing with these, either to acknowledge the bias and demonstrate how they have been taken into account (182;188;193) or to try to 'bracket them out'. Both can be acceptable but should be explicitly noted in the findings and it is important that authors of work show the process for dealing with bias. (183)

ⁿ Available from QSR International Pty Ltd. www.qsrinternational.com

5.5.2 Triangulation

This is a process for increasing the credibility of the work by using more than one method to collect data such as interviews and questionnaires and/or more than one analyst e.g. peers or participants.(182) Triangulation helps with the process of reducing bias in data analysis and in showing that the analysis and constructed themes are recognised by those interviewed and by other similar groups of people, thereby increasing the relevancy of the work (see 5.5.5). Member checking or respondent validation is a technique whereby the participants are given a copy of the findings and asked to review them to see if they sufficiently cover their experiences.(183;193) Another method of review is by peers meeting to discuss the thought process of the analysis and talking through the resultant findings and theory. (182;183)

5.5.3 Audit trail

Researchers should be explicit about their sampling and analytical methodology.(182;183) A clear audit trail should be noted for readers to examine the appropriateness and rigour of the analytical process.(180;192;194) The idea of transparency is also important and authors writing up qualitative research should be clear and open about their methods used.(188)

5.5.4 Authenticity

It is important to all qualitative work that it remains 'grounded in the data' and reflects the experiences of the participants. It is therefore important that there is judicious use of quotes from the original transcribed interviews. The quotes should support the development of theories and findings.(180) They should also display the diversity and richness of the data and contradictory views should be quoted.(182;183;193)

5.5.5 Relevance

As qualitative research is generally carried out on small numbers and within particular groups the researchers need to discuss whether the findings are relevant and generalisable to other circumstances and the wider population.(182) May and Pope suggest that this is done by making the report detailed enough for a reader to decide if the findings have relevance to other similar settings.(193)

5.6 Training in qualitative methodology

For the present study, both research dietitians had training in qualitative methodology during a two-day course run by the Social Research Association in Scotland in March 2004. Jane Ritchie an experienced qualitative researcher facilitated the course and later agreed to be a collaborator on this project. The course looked at the use of qualitative research, development of a study matrix, interviewing techniques, exploring and analysing themes as well as practice sessions. In addition the author also attended a further Social Research Association in Scotland training day on presenting qualitative data in March 2006 and a number of sessions on qualitative research as part of the postgraduate research-training programme run by the Faculty of Medicine, University of Glasgow.

Both dietitians had previously had training in interviewing and listening skills for the original SCOTT project. Dr V. Poustie provided further training on qualitative interviewing techniques and data analysis. During the fieldwork stage she gave constructive feedback on both the interviewers' techniques from the interview transcriptions and on the coding of a number of interviews. She also trained the research dietitians on the use of the analysis soft ware package NVivo (see section 5.4.2).

Throughout the fieldwork and analysis the two research dietitians gave each other peer support and assessment of techniques by reviewing a

number of each other's transcribed interviews and data analysis on NVivo.

5.7 Suggested further reading

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CHAPTER 6

Parental perspectives of a novel, dietetic-led behavioural programme and standard dietetic care for the treatment of childhood obesity: Qualitative study design, methodology and results

6.0 Introduction

The original purpose of the present study was to perform a qualitative evaluation of the two dietetic treatments used in the SCOTT study; by using in depth interviews to examine the thoughts and feelings of the parents on the dietetic treatments their children had received. We considered it important to try to identify and understand from the parents' perspective factors which may have influenced outcomes as well as their feelings regarding those outcomes. We were particularly interested in exploring the diversity, patterns and linkages in and between the standard care and novel treatment groups. The present qualitative study was designed to interview the parents once the SCOTT 12-month measurement phase had been completed.

This chapter describes the present study's design and methodology with reference to our efforts to ensure quality in our qualitative research methodology as discussed in chapter 5.(184) The analysis of the transcribed taped parents' interviews are presented in two parts. The first part of the results section, referred to as results 1 (section 6.3.1), reports the findings of the original research question evaluating the two dietetic treatments. This section highlights common and distinctive themes both across and between the two groups of parents (see table 6.16) and tentatively offers some interpretation.

However, although not part of our original research questions rich data emerged from the analysis that raised many complex issues around parents' attitudes, their struggles and coping mechanisms with their

child's weight problems (see section 6.1.4). Since there appeared to be several distinct phases and individual parents articulated differing emotions in each phase we felt this characterised a 'journey' and results 2 (section 6.3.2) was added in an attempt to understand this parents' journey. Results 2 therefore explores the themes that emerged during the data analysis on patterns of thoughts, behaviours and possible typologies across the groups at distinct phases of the parents' attempts to recognise and seek help for their child's weight, through the treatment and reflections on treatment outcomes.

6.1 Study design and methodology

6.1.1 Ethical approval

The study received ethical approval from the Multi-centre research ethics committee for Scotland and local management approval with Prof. J.J. Reilly as chief investigator in Glasgow and the author as principal investigator in Edinburgh.

6.1.2 Study sampling and recruitment

Purposive sampling was used and a sampling matrix was developed that took account of characteristics of the study population considered to be most important (points 1-3 in table 6.1). This gave a sample size of around 32. Points 4-6 in table 6.1 were monitored and a number of families who had failed to complete (dropped out of) the SCOTT intervention were approached. As the families had to have completed the SCOTT 12 month outcome measurements 79 parents were eligible for the present qualitative study.

The researchers who recruited and interviewed the parents were the dietitians who had carried out the novel treatment during the SCOTT project (this author and J. Chapple). To reduce any possible bias and to ensure frank and uninhibited comments from the parents the dietitians did not recruit or interview parents from their own intervention group.

Rather, they recruited and interviewed parents from the standard treatment group from their own base as well as recruited and interviewed the parents from each other's novel treatment group (i.e. this author as the SCOTT study Edinburgh dietitian recruited and interviewed parents from the Edinburgh standard care group and recruited and interviewed parents from the Glasgow novel treatment group). The interviewers introduced themselves as researchers from the SCOTT project and the parents remained unaware that they were dietitians.

Table 6.1: Table showing main characteristics of sample population

1. Treatment group i.e. novel treatment group or standard care treatment group
2. Successful outcome / unsuccessful outcome of treatment ^o
3. Age of child i.e. divided into 5-8 years and 9-11 years
4. Study location i.e. Edinburgh or Glasgow
5. Gender of child
6. Family situation e.g. two parents or single parent family, main carer not a parent

Each interviewer contacted their own subjects and although aware of the matrix were blind (at this point) to any other information concerning the child and family. On completing the 12-month outcome measurements for the SCOTT project the parents were contacted by letter (see appendix 14) and then contacted by the interviewer by telephone to ask if they wished to participate and arrange an interview. To ensure that the postdoctoral research fellow for the SCOTT project remained blinded to group allocation until after the 12 month data

^o As the primary outcome of the SCOTT project was change in BMI SD score at six months the definition of success used for the sampling was having either the same or lower BMI SD score at six months.

analysis she took no part in the selection, recruitment and interviewing of the participants.

Unfortunately we encountered difficulty in recruiting to the present qualitative study, of the 79 parents potentially available (i.e. had completed the 12 months measurements for the SCOTT project), all were approached, but 62 refused to take part or were unable to be contacted. A number of parents agreed to participate then failed to turn up for the arranged interview. Due to the time limits on the project (both research dietitians finished paid employment on the project at the end of July 2005) interviews had to stop by the end of May 2005 with 17 interviews completed.

In the time available numerous attempts were made to recruit as many parents to the study as possible. Telephone calls were made at differing times of the day and week including early morning, evenings and weekends. Telephone numbers were checked against updated hospital records and from telephone books. Further letters were sent to parents who had been unable to reach by telephone asking them to contact the interviewers. All arranged interviews were confirmed by letter and the parents were telephoned the day before the interview as a reminder, however a significant number still failed to attend for interview. Interviews at home were offered, only one parent accepted this offered and telephoned to cancel and drop out of the qualitative study on the day of the interview. For this reason we are unsure if full saturation of the subject matter was reached on every question and this is discussed in section 6.4.3.

We are unable to explain why so many parents did not wish to take part in the present study, a number stated changes in family/work circumstances. Some had not found the SCOTT project a positive experience and were not prepared to discuss it further even when reassured that these were in fact the types of opinions the study was trying to elicit. All of these negative comments came only from the

standard care group of parents. Interestingly one of the novel treatment parents, who did take part, stated that her child would have been very unhappy if she had known she was being discussed when she was not present. None of the parents who had dropped out of either arm of the SCOTT intervention agreed to take part in this qualitative study. The characteristics of the participating families are shown in section 6.2.

6.1.3 Interviews

As stated in chapter 5 in depth interviews were used and these took place in non-clinical rooms in the Royal Hospital for Sick Children, Edinburgh and Yorkhill Hospitals, Glasgow. Before the interview began written consent was obtained from the interviewee (see appendix 15). To ensure a consistent approach and to ensure the capture of rich, complex and detailed data by the interviewers a topic guide was used; there were no set questions. Table 6.2 shows the topic guide that was developed by the SCOTT team in consultation with Dr Poustie.

While following the topic guide the interviewers appreciated the need to remain open and flexible to the participants' responses. In some styles of qualitative interviewing the topic guide is changed when emergent themes come out of early interviews. Our topic guide was not changed but emergent themes were explored during interviews and discussed between the interviewers and Dr Poustie. The length of an interview was between 50 - 80 minutes. After each interview field notes were made e.g. on the place and length of interview, people present and any other information felt pertinent to data analysis.

Table 6.2: Topic guide used for interviews in the present study

<ul style="list-style-type: none"> - Introduction to the study (no right or wrong answers) - Introduction to the interviewer - Explain confidentiality & tape recording <ol style="list-style-type: none"> 1. aim – to provide an overview on the parents thoughts regarding the dietetic interventions <ul style="list-style-type: none"> - number of appointments - too many <ul style="list-style-type: none"> - too few - lengths of appointments – too long <ul style="list-style-type: none"> - too short - place appointments held – travel time/cost of travel - was information helpful - attitude of dietitian - was treatment completed 2. aim – to explore views on the printed materials used <ul style="list-style-type: none"> - informative/helpful - too little/too much information - age appropriate - easy to understand/follow 3. aim – to explore parents thoughts on child’s and families motivation and readiness to make changes both before and during intervention <ul style="list-style-type: none"> - was motivation of child/family explored by dietitian - were goals helpful <ul style="list-style-type: none"> - did the child like setting own goals (NT) - did the child like having their goals set (SC) - was encouragement given for family involvement <ul style="list-style-type: none"> - difficult/easy - how easy was it to follow goals - how easy was it to keep diary - was pro and cons useful (NT) 4. aim – to explore if the parents considered the intervention was successful for their child <ul style="list-style-type: none"> - expectations of treatment <ul style="list-style-type: none"> - were expectations met - did they consider their child’s weight outcome a success - was it a positive/negative experience for the child/parent/family <ul style="list-style-type: none"> - barriers to weight management - have they continued with changes - what could have been done to make the experience better/more positive <p>Thank respondent for their time & reassure about confidentiality</p>
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6.1.4 Data handling

All interviews were tape-recorded using standard Dictaphones and the tapes were fully transcribed for data analysis by experienced secretaries. All names and any details that could identify the child, family or health professionals were removed from the transcriptions.

For the development of themes and concepts the Ritchie and Spencer 'Framework' analysis method as described in chapter 5 section 5.4.1 was used.

The initial 4-6 transcripts were used to identify the raw themes emerging from the interviews. Both interviewers and Dr Poustie developed the themes independently on paper copies of the transcripts, and then came together to agree the principle themes and sub themes. Once the themes and sub themes and their definitions were agreed these were inputted into the computer-assisted qualitative analysis software programme Nvivo as 'nodes', 'trees', 'child' (see chapter 5 section 5.4.2). As the fieldwork progressed when agreed new themes emerged these were added into the Nvivo programme. The interviewers then coded the themes in the interviews using the Nvivo computer programme. Prior to coding the interviews the researchers listened in full to the tapes to help immerse themselves in the data and if necessary to correct the transcribing. To ensure consistency of coding the two interviewers separately coded a number of each other's interviews and Dr Poustie reviewed the coding of a number of randomly chosen interviews. When required disagreements over coding were discussed until agreement was reached and if necessary coding was modified. Appendix 16 shows the final list of themes used for analysis.

The authors agreed six main headings with subheadings to facilitate answering the original research question and to explore emergent themes (see table 6.3). At this stage there were two emergent themes from the data - the overall relationship with the dietitian and the parents' perception of what could possibly influence barriers to the children

making lifestyle changes in the future (emergent themes are highlighted in table 6.3 with an asterix). Each question with subheadings were placed on a separate chart to outline the matrix analysis. Each case was always placed on the same position on the charts and the novel and standard care subjects were grouped on separate charts (i.e. two charts for each heading). The coded data were then lifted from the Nvivo programme and placed on the appropriate chart and under the appropriate subheading. At this stage to help the researchers remain grounded in the data paper copies of the coded data and charts were used. The interviewers carried out the charting of data, the mapping and tracking of words, themes and stories and the interpretation of themes jointly. These were then reviewed and discussed by all the collaborators (V. Poustie, J. Reilly, A. Hughes) until agreement on the interpretation was reached. The mapping and interpretation of these original six questions was done prior to knowing the results of the SCOTT quantitative study. The themes, concepts and interpretations developed from these charts are discussed in results 1 below (section 6.3.1).

During the mapping and interpretation of these initial charts certain words and stories across and within both treatment groups began to emerge. It became apparent that this was rich data concerning the parents' feelings about support before, during and after treatment. Therefore two further charts were mapped under the heading of support (sub headings are outlined in table 6.3) to explore and further develop these themes, concepts and typologies. These are discussed in results 2 below (section 6.3.2). An edited sample of a matrix chart is given in appendix 12.

The comments from the families who took part in novel treatment pilot study on the NT programme (see chapter 3 and appendix 7) and those from the standard care dietitians post RCT audit on the SC clinical sessions (see chapter 3 and appendix 8b) were used to help

triangulation with the themes developed from the qualitative in-depth interviews.

Throughout the fieldwork and analysis the two interviewers gave each other peer support and assessment of techniques by reviewing a number of each other's transcribed interviews and data analysis on Nvivo. There was peer debriefing with discussions and agreement on coding of the transcripts, on charting and mapping the materials, and the interpretation with all team members. This peer reviewing was considered very important to help counter any bias from the interviewers that may have been emerging in their interpretation of the data.

To ensure a transparent audit trail all the audiotapes, paper transcripts, field notes, Nvivo coding, notes regarding the charting and mapping and all charts were retained and are available for review.

Table 6.3: Chart headings used for mapping and interpretation of themes

HEADINGS	SUBHEADINGS
Structure of programme	<ul style="list-style-type: none"> - number of appointments - frequency of appointments - length of appointments - written information given
Expectations	<ul style="list-style-type: none"> - expectations of treatment - expectations met - positive/negative experience - suggestions for future
Behavioural change techniques	<ul style="list-style-type: none"> - motivation discussed - goal setting/keeping - recording - monitoring
Outcomes	<ul style="list-style-type: none"> - changes child made - changes parents made - changes family made - changes in child's weight
Barriers to change	<ul style="list-style-type: none"> - during programme - after programme - possible influences on barriers in the future*
Dietitian*	<ul style="list-style-type: none"> - information given - rapport - support - encouragement
Support*	<ul style="list-style-type: none"> - pre treatment - during treatment - post treatment

*Emergent themes

6.1.5 Payments

There were no payments for taking part in the study, but as with the main SCOTT project subjects were offered travelling expenses from their home to hospital.

6.2 Characteristics of participants

The characteristics of participating families are shown in table 6.4, these were not significantly different from the overall SCOTT sample. Despite the smaller sample size than originally intended, we recruited a range of participants from diverse backgrounds and family circumstances as described in the original sampling matrix (see section 6.1.2). Seventeen parents were interviewed, 14 were mothers, two fathers and one grandmother^p. The parents interviewed for this present study reflected those who had attended the SCOTT treatment sessions.

The participants in the present study were therefore typical of the range of parents and families that took part in the SCOTT study. In turn the children, parents and families that attended the SCOTT project were characteristic of those referred to the two major paediatric centres in Scotland for childhood obesity management. Children in the SCOTT project were recruited from those already on dietetic waiting lists and those referred by paediatricians, GPs and school nurses, all standard routes for referral for dietetic interventions. The children all had a BMI above the 98th centile with the median BMI SD score above 3.0 for all the SCOTT participants.

^p In this family the grandparents were the main guardians/carers although both natural parents were alive and saw the children.

Table 6.4: Characteristics of participants in the qualitative study n=17

Characteristics	Novel treatment n= 8	Standard care n=9
Treatment goal met*	4	3
Treatment goal unmet*	4	6
Male (child)	5	3
Female (child)	3	6
5-8 years old	4	4
9-11 years old	4	5
Parent/s obese §	5	5
Depcat 1-4 ^ϕ	6	3
Depcat 5-7	2	6

* Goal met = BMI maintained/loss Goal unmet = BMI gain

§ Parental weight is self-reported

^ϕ Depcat scoring is described in chapter 2 section 2.

6.3 Results

Throughout this chapter verbatim quotes from the parents are used to illustrate and support the arguments, interpretations and tentative conclusions put forward. All quotes have been anonymised and the following notations have been used for identification; NT – novel treatment parent; SC – standard care parents; 1 – goal met; 2 – goal unmet (see table 6.4). As discussed in chapter 5 qualitative data should not be presented and categorised in a quantitative style therefore there are no indications of numbers or percentages presented in this chapter. However, there is a suggestion of strength of perception and feeling by the use of language such as ‘widespread’, ‘strongly’, ‘overwhelmingly’ and ‘less typical’.

Due to the limited number of parents interviewed we have attempted to avoid direct comparisons between the two treatments but where different opinions were voiced between the groups these have been signposted.

6.3.1 Results 1 - Qualitative evaluation of dietetic treatments

The aim of the present study was to explore parents' perceptions and experiences of the dietetic treatment their child received and to evaluate these treatments. Below are the five research questions as stated in the original research grant proposal:

- What expectations did parents have of their child's treatment and to what extent did the treatment meet their expectations?
- Parents views on the novel programme and standard care including: the number and duration of dietetic appointments, the duration of treatment, information contained in the printed materials, the effectiveness and ease of adopting the treatment strategies (e.g. setting goals).
- Parents views on the child and family's motivation to make lifestyle changes before and after treatment.
- Parents views on their child's outcome of treatment including; did they consider their child's weight outcome to be a success, was the treatment a positive experience for the child/parent/family, have the behavioural changes been maintained following completion of treatment and what could be done to make the experience more positive.
- Parents' views on what factors, if any, acted as a barrier to achieving weight maintenance.

6.3.1.1 Parental expectations of treatment

It was generally noted that parents had not known what to expect from the dietetic treatment and commonly expressed that they had been apprehensive about being given diet sheets, strict or prescriptive

diet/menus, *'to be honest I thought we would actually be handed a menu and told just to follow it. I thought it would be like a certain healthy foods we had to eat and told to do so much exercise I never thought there would been opportunity for C to decide what she wanted to do to change things and I never thought there would be a reward system'* (NT1).

Parents from both groups had realistic expectations of weight outcomes, having not expected a large weight loss but a stabilising of their child's weight. SC parents commonly noted that they had hoped that a source outside of the family might be able to help with their child's motivation to make changes, *'but what I was hoping was that someone apart from me speaking to her would pay attention because I felt I was nagging, I was being awkward, I wasn't listening to her you know what I mean'* (SC2). While NT parents commonly noted that they had been looking for help with their child's confidence, *'cause I asked him before he had come if he wanted to do it and explained what it was all about and he said he did want to do it, he said that it might stop people calling him fat'* (NT2).

6.3.1.2 Appointments

There was widespread agreement across the groups that hospital based appointments were acceptable. Less common were views that hospitals may not be ideal as there was an association with ill health and therefore that treatment should be based in the community, *'I think you have to take it out of the hospital and the clinical environment, although we know it is a clinical thing but for the point of view of the child, somewhere there is more in tune with mainstream society, even in a school would be a possibility'* (NT2).

It was not surprising that those who travelled the furthest, regardless of treatment group, suggested a more local location would be

advantageous. The cost of travel was noted as possibly affecting attendance at outpatient clinics.

Across both groups there was widespread satisfaction with the time of the day appointments had been offered. However concerns were voiced about children missing school and that because of school, work and family commitments, appointments should be in the evening, *'it was quite frustrating to take the kids out of school, if we could get a better time'* (SC1). It was expressed that it was unfair for a parent to be made to choose between education and health.

There was a view in the SC group that appointments could be more frequent, feeling that the 1-3 month gaps between appointments tested the child's commitment, *'well they were every couple of months but to me that still wasn't enough'* (SC2); *'for me seeing the dietitian more often, just seeing a wee bit more often to give us a pep talk up for (the child) so she would keep going cause the gaps in between she was maybe starting to argue with me'* (SC2). A less typical view was that a longer gap between appointments was beneficial, allowing the child to see the results of change over a sustained period, *'after three months when you went back and you know, you could see she had lost a wee bit and that, it benefited, it benefited her as well because if she went back after a short time and nothing had happened it would have put her backwards'* (SC2).

There was widespread feeling among the NT parents that the frequency of appointments was about right. An initial thought, that was not widely expressed, was that eight appointments might have been too many but this opinion changed after treatment, *'eight appointments to begin with I thought oh for goodness sake this is going to be a nightmare, yeah I was wrong but I didn't really mean that 8 was enough, I don't suppose, maybe 8 in that block and then maybe have something afterwards'* (NT1). NT parents strongly suggested that lifestyle diaries and goal setting kept momentum going between

appointments, *'M had a little project to do each time like a worksheet that he had to stick to before he got his reward at the end of it, so it kept the momentum going'* (NT1). However compliance was felt to be a problem when the gap between appointments increased. There was a persistent feeling from both groups that the length of appointments had been acceptable.

There was a strong and widespread view among NT parents that ongoing support from the dietitian after the 6-month treatment period would have been beneficial and a feeling that their child had been more compliant when under review i.e. in the six-month treatment programme. Treatment duration of one year rather than the 6 months offered was generally suggested, ideally with fortnightly appointments to monitor progress, *'Because she wasn't coming to see the dietitian, she didn't have that, she didn't have her chart, she didn't have the goal, she didn't have the person to come and see'* (NT1); *'I think it could have been longer maybe up to a year, I honestly do. You were still trying to keep to it but you do slip, if it had gone on a bit longer it would have benefited K, it would have given them longer to get into the routine. I honestly do think it could have been a wee bit longer up to a year a year and a half'* (NT2).

There was a less frequent view among SC parents that continuing to see the dietitian would have aided compliance, *'it might help with compliance, if she knew she was coming to the dietitian or the doctor she is good on the lead up to it'* (SC2). The more typical feeling from the SC group was that they did not require further dietetic input; either due to being satisfied with the input they had received or a feeling that further appointments would not provide new information, *'by the time we got to the fourth one I really felt that we were going over old ground and there was nothing new coming out of it'* (SC2). An infrequently voiced view was of being glad when the dietitian's visits finished due to unhappiness with the process.

6.3.1.3 Behavioural change techniques

In the NT programme there was an emphasis on the use of behavioural change techniques, in particular the use of the decisional balance chart (pros and cons), goal setting with rewards for meeting goals and recording lifestyle (initially a lifestyle diary and then from appointment 6 a simple tick sheet, see chapter 3). We wished to see if the families had found these techniques useful and if the SC dietitians had used any of these or similar techniques.

6.3.1.3.1 Exploring motivation to make lifestyle changes

NT parents persistently felt that their child's motivation to make lifestyle changes had been explored during the treatment. The parents discussed the reasons their child had given when filling out the pros and cons sheet (decisional balance chart used in appointment one of the NT). The parents recalled their children's motivation for change included wearing fashionable clothes, looking good, slimming down and not being called fat. An interesting exception was a child believing he would be allowed more time to play his Playstation. The process appeared to have alerted the parents to the children thoughts, *'when the dietitian thingmayerd him (asked him for pros and cons) you know what I mean he rhymed them off as if he had obviously been thinking about good and bad reasons'* (NT2).

In contrast SC parents could not recall the dietitian discussing motivation or reasons for wanting to slim down/make lifestyle changes. An exception was the dietitian commenting that health should be the reason to make changes. There was a feeling that exploring the child's motivation would have been beneficial and that children had yet to recognise they had a weight problem, *'it was myself and the doctor that said you want to try and look at what your eating and how much your eating and C thought she was fine, it wasn't something she recognised as a problem'* (SC2).

6.3.1.3.2 Goal setting and rewards

NT parents repeatedly talked about the use of goal setting and rewards in a very positive light. Parents persistently reported that the use of goals had helped the child with motivation and encouragement to first make and then continue with their lifestyle changes and were a positive reinforcement. There was a widespread feeling that the children seemed to enjoy setting and keeping to their goals and these helped with self-esteem, *'children are more aware nowadays, none of us like being told to do things and so it was like forming a partnership and it worked'* (NT2). Parents felt that when children had not met all their goals they had been truthful about this with the dietitian. A more exceptional view was that goals might have been chosen that were easy to meet, *'so he was picking all the easy ones half the time'* (NT2). Agreed written goals were felt to have stopped arguments at home, *'a lot of the time it was just down to the fact that this is what we have to do, end of story'* (NT1). Consistently parents felt that their child had set their own goals, noting that occasionally either the dietitian or themselves had offered suggestions and that the dietitian had ensured that the goals set had been realistic. After the programme there were different degrees of families continuing with goal setting/rewards, those who had stopped generally talked about returning to goal setting.

There was a prevalent, strong feeling among SC parents that they had not received goals or targets for change by the dietitian. Where goals had been provided they appeared aimed at the parent rather than the child or had been targets for weight loss, despite the aim of treatment being weight maintenance. Less typically parents had set goals themselves at home after the appointments, *'we did when we got home, we went through sheets and things and then we would sit down and take away this and added that'* (SC1). It was suggested that goal setting might lead to disappointment if they were not met, *'I think it might have been too disappointing for him if he hadn't achieved it so, it might be like asking him to turn his eyes from blue to brown'* (SC2).

6.3.1.3.3 Self-monitoring of lifestyle changes

NT parents repeatedly noted that they found recording lifestyle burdensome but there was an overwhelming view that the recordings had increased the child's awareness of their lifestyle and necessary changes. There was a strong feeling that keeping the records had helped with compliance to the goals, *'he came home from school he would be marking everything that he ate and everything that he had done, I wasn't allowed to do that he done that himself'* (NT2). Commonly, parents found the long and fuller lifestyle diary (see chapter 3 and appendix 2) hard work, however there was a feeling that it was especially helpful at the start of the programme, *'I was happy for C to watch TV but I wasn't aware of how much TV she was actually watching but when we were recording it I was really surprised. I just wasn't aware of things that is why recording was so good'* (NT1). When parents noted a preference it was for the tick sheet (see chapter 3 and appendix 2), which appeared to be easier to fill in and keep going. It was less typically noted that the tick sheet might have been easier for the child to be economical with truth. There was continued but not widespread use of recordings after the programme had ended.

The SC families generally could not recall being asked to self-monitor lifestyle, the less typical felt they may have been asked but did not remember doing it. There was however a feeling that parents became more aware of the types of foods they were giving their children e.g. in lunch boxes. There were mixed views over whether recording would have been helpful, with views that their child would have been too young to participate in it, *'I think that's (recording lifestyle) awful weight watchery that's what you've got to do at Weight Watchers and Scottish Slimmers and all these things and I didnae want her to look at it as if I'm on a diet'* (SC2).

6.3.1.4 Responsibility for lifestyle changes

There was widespread sense among the NT parents that they had an overseeing role in encouraging their child to keep to their goals and lifestyle changes but not controlling the child, *'if she has a treat of chocolate it will be through the day, she has to decide, she has to tell me'* (NT1). When the child's motivation was waning they reported giving gentle reminders and encouragement. The general view of SC parents was that they controlled and monitored the child's food intake with the child taking no control or responsibility. The SC parents generally appeared to have a dictatorial role and the process was not child focused, *'if she wants coke she is told she is not getting coke and if she wants chips she is told that she is not getting chips, she is lucky to get nuggets and is told that'* (SC1). These views on who took responsibility were commonly expressed in both parent groups regardless of the child's weight outcome.

NT parents repeatedly commented that they had noticed an increase in their child's awareness of their own lifestyle, their need to make ongoing changes and about the family's commitment to lifestyle changes, *'instead of him maybe going for crisps or that he'll go for yoghurt now'* (NT2). Improvement in the child's self-esteem/confidence was also noted, this was generally discussed in terms of styles of clothes they could now wear, enjoying taking part in PE, *'she used to be embarrassed at school cause there were things she couldn't do in PE that she can now do, I mean she couldn't do forward rolls and it really upset her'* (NT1). The SC parents did not talk of awareness in their child of appropriate lifestyle changes and less typically commented on family commitment to changes.

6.3.1.5 Dietary changes during and after treatment

Families in both groups talked frequently of decreasing sugar, fat, sweets and carry out/fast food type meals and changes in family shopping, *'when we're shopping it is habit now we go for things that are*

less sugary and you know she is quite happy to take more fruit and these things' (SC2). It was repeatedly noted that the children ate 'better' snacks and more fresh foods after treatment. SC parents repeatedly commented that more fresh fruit was available in the house, their child's portion sizes had decreased as well as feeling that more healthy options were available at school (particularly sandwiches) and that their child was choosing these, *'well the fruit bowl is always full. If she is hungry she can go to the fruit bowl at any time'* (SC2). Less commonly noted were more 'family meals' and even more exceptional was changing teatime to stop snacking after school. These changes were not always popular with other members of the family.

The NT parents continually and widely talked in 'traffic light' terms particularly about decreasing 'red foods' although there were references to green and amber foods, *'I mean we just stick to it, they are not allowed more than or an average of two red foods, I think that's normal, its not so much that, it's just part of the change'* (NT1).

6.3.1.6 Changes in physical activity and sedentary behaviour

The NT group widely felt their child's level of physical activity had increased and noted continuing involvement in structured activity programmes, *'after school she even goes a longer road down to her child minders and when I offer to pick her up she will say no that she would rather walk and its great'* (NT1). Parents commented on a decrease in the time their child spent watching TV and using the computer, *'we reduced the hours significantly and I think it was no more than a maximum of two hours for TV and computers in a day'* (NT2). The SC parents generally did note an increase in their child's physical activities or at least an awareness of the necessity. Without exception SC parent did not mention any change in sedentary behaviour, this is consistent with the accelerometry results showing that the SC group became significantly more sedentary in their behaviour than the NT group over the six months of treatment (chapter 4 section 4.3.4).

6.3.1.7 Parental suggestions for improvement in treatment experience

When asked what could be done to improve their experience there was a common suggestion across both NT and SC groups for recipes, help with menus, shopping information (particularly regarding labels and products) and cooking skills (mentioned for both parents and children), *'recipes or something, if there was something that could be added on that you could take, you know, that you had there if you did sort of run out of ideas as a back up'* (SC2). More frequent appointments and a longer follow up period were suggested, *'I would say once a fortnight just to keep us on track, you know where sometimes when we could have been a bit more focused'* (NT1).

A repeated view from the SC group was that the interviews were not as child-focused or friendly as they had hoped (Q1 table 6.5). There was a less typical but strong suggestion from SC parents to make the sessions and experience more child-friendly and child-orientated with the information more accessible to children (e.g. using children's activities). Suggestions included group sessions, using good and bad foods, discussing portion sizes, children's games to help with education (Q2, Q3 table 6.5), more appointments and continuity with the dietitian seen. In the SC group there were more exceptional views of very negative experiences of both the clinics and the dietitians, *'I don't really think it was a success 'cause I don't think we both actually like the dietitian, em. I think that wasn't me, he didn't like her'* (SC2). These less typical but strongly held feelings were expressed as dissatisfaction with treatment, a sense that not enough help was given, that they had expected more education (for themselves and their child), *'I am not sure what the right answers are I really don't I just feel there is not enough being done for her'* (SC2) and more than 'just talk' (Q4 table 6.5).

The NT parents overwhelmingly felt that the programme had been child-friendly and child-focused, *'oh fantastic really, you know just that*

control. I thought we would have a real problem and we probably would have problems with our younger daughter but she has been taken on board too and it has given us a focus it has given me a direction to go in if I think things are a bit you know' (NT1). It was repeatedly noted by NT parents that it had greatly exceeded their expectations, it had improved their child's confidence, self esteem and peer relationships, 'to actually put the thought in her head of what she wanted to do and achieve and set her own goals. It has been much better than what I expected' (NT1). Less typical views were that the dietitian should have explored the family circumstances, as these were relevant to the child being able to follow their goals. Interestingly all views whether negative or positive were voiced regardless of the child's weight outcome.

Table 6.5: Standard care parental suggestions for improvement in treatment experience

Q1	<i>'I don't really know em, maybe just a bit more information that was accessible to him I think would have helped, even sort of like you know keeping a chart or something like that, something sort of handout type thing, you know what I mean'</i>	SC2
Q2	<i>'Giving children exercise and educating them in someway and making them work to see how motivated they are instead of coming up to tell the dietitian what they have been eating'</i>	SC1
Q3	<i>'Well yeah, models, pictures of fruit to colour in or something like that. What would be good food, what would be bad food, and how much would be a reasonable amount to eat at each sitting and that kind of thing. Because kids like that sort of you know puzzle, things like that so something that sort of focused him it would be good'</i>	SC2
Q4	<i>'I think I expected more from the dietitian than just speaking to her Interviewer – what did you expect? I don't know I just expected more'</i>	SC2

6.3.1.8 Barriers to lifestyle changes reported by parents

Common barriers to lifestyle changes described by both groups were winter, inclement weather, and Christmas (Q1, Q2 table 6.6). Other barriers mentioned were family circumstances e.g. working hours (Q3 table 6.6), separated parents, buying food for the rest of the family (Q4 table 6.6), bereavement, 'just life' and pressures of life. Also noted was school, the child's own motivation to make changes, the child's lack of confidence in their ability to change and the child's lack of weight awareness (Q5 table 6.6). Parents reported outside family influences (Q6 table 6.6) and the child's interest waning (Q7 table 6.6).

Table 6.6: Parents' views on barriers to achieving lifestyle changes

Q1	<i>'I know I am not right in having biscuits and sweeties in the house because we had some extras for the Christmas period. When they were there he ate them'</i>	NT2
Q2	<i>'Obviously as winter comes and some of the activities get closed off so there wasn't as much'</i>	SC2
Q3	<i>'For instance I don't normally work, but I was working over Christmas and I think he put on at least 10 pounds, cause I wasn't there to make sure he wasn't helping himself'</i>	SC1
Q4	<i>'Well sometimes it is hard, cause the other kids are all eating and we can't tell her to stop eating when they are eating, so it is very difficult when you have other kids'</i>	SC1
Q5	<i>'I notice what she doesn't have is a lot of confidence so what she wont do is team sports'</i>	SC2
Q6	<i>'His friend's mum would take them to the pictures and buy them crisps and sweets and what bairn is going to say he can't have sweets he's not allowed them?'</i>	NT2
Q7	<i>'I think all kids lose interest with things you know it's full of enthusiasm at the beginning and then it wanes, I think it is like most things they do'</i>	NT1

NT parents persistently discussed recognising these barriers and that when their own commitment and motivation, as well as their child's could slip they talked of using their commitment and enthusiasm to overcome them, *'I have tried to tempt her to see if she would break away from it but she says no it actually got her into the routine where she likes walking, because I was really surprised and I didn't think she would stick to it never in a million years'* (NT1). Repeatedly parents noted that barriers to continuing with changes after the programme revolved around family (particularly grandparents) and family circumstances. Family support is discussed in section 6.3.2.2.1.

6.3.2 Results 2 - The parents' journey to and through treatment – Crying out for help

This section describes in detail the parents' feelings as they journey from recognising their child's weight problem, seeking/accepting treatment – the pre-treatment phase; through the treatment – during treatment phase; and their reflections on the outcomes – post treatment phase. Table 6.7 summarises the emotions expressed by the parents at these stages in their journey, as can be seen this is an exceedingly complex, emotional and often contradictory issue for the parents.

Table 6.7: Parents emotions through the journey

Pre-treatment	During treatment	Post treatment
Guilt	Focused	Made lots of changes
Thoughts of own childhood weight problems	Ambivalence	Raised awareness
Being the baddie	Horrid to say no	Always on parents mind
Hurt	Guilt	Child got into dress trousers
Upset	Frustrated/exasperated	Child more confident
Avoidance of subject	Forceful	Child more aware
Panic	Took control	Healthier
Denial	Shouldered responsibility	Focused
Desperate for help	Fighting	Parent and child in control
Shock	Tension in house	Did not enjoy
Worried it would spiral out of control	Became the baddie	Gave us a wake up call
	Arguments	Helped parent to get through to child
	A struggle	Felt like a bad parent
	Avoidance of arguments/confrontations	

In qualitative research it is common practice to describe and group the participants by how they describe and cope with the phenomena being studied. When analysing our data it became clear that the parents had distinctive and common groupings (typologies – see chapter 5, section 5.4.1) that could be used to label the parents at the different stages through this journey. The typologies appeared to be in discrete stages, with the pre-treatment phase the most distinctive and strongly described. We have therefore not been able to map the same typology labelling throughout these parents' journey.

6.3.2.1 Beginning the journey – why enter treatment?

It emerged from the interviews that in each family one parent appeared to have the significant 'lead' parenting role regarding the child's weight management and lifestyle changes; this lead parent was generally, but not exclusively the mother.

Prior to seeking help for their child's weight there were varying levels and degrees of awareness among parents regarding their child's weight. This ranged from being highly aware and actively seeking help to being oblivious to any problem. Parents who discussed being aware of their child's weight commonly mentioned the child being called names, clothes not fitting and the child having a huge appetite as factors raising their awareness. Cues for parental awareness are listed below -

- Other people commenting to parents about child's weight
- Child saying they are being called fat (often by 'friends')
- Parents aware of others calling child names
- Child being bullied
- Clothes not fitting / having to wear large sizes (occasionally adult size)
- Awareness of child being big eater / having a big appetite / constantly eating

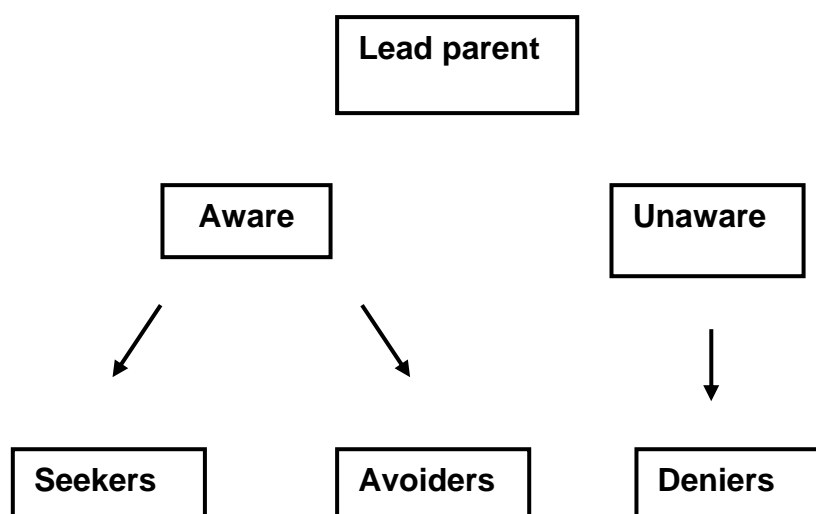
- Awareness of weight / size
- Did not realise so overweight
- Child's self esteem low / poor
- Mentioned by doctor / school nurse

At this pre-treatment stage we noted the most distinctive parent typologies in the journey. We first identified a distinction between those parents who appeared to be aware their child had a weight problem and those who felt the child's weight was similar to their peers. From these aware and unaware groupings we recognized three main typologies – 'seekers', 'avoiders' and 'deniers' see figure 6.1 below.

Within the set of parents who talked of being aware of their child's weight problem there were two groups - those who on realising there was a problem sought help we have called 'seekers', *'I did because of the amount of food he was eating constantly and I thought I need to do something before it spirals out of control. Then going out and getting clothes nothing would fit him and I thought you know I need to do something'* (SC2). Among these 'seekers' there was a varying scale of the strength of feeling with some expressing almost a desperation for help, *'It was basically that I felt A had been putting on a wee bit too much weight for her age and I was gonna get a wee bit panicky'* (SC2).

There was an interesting second group of aware parents who felt unable/unwilling to discuss their concerns with the child and/or raise the issue with health professionals. This group typically talked of knowing there was a weight problem but doing nothing and not being able to approach the subject with their child we called this group 'avoiders' *'A. Well I know for a fact because I've been at his school a couple of times because he was getting bullied. A couple of wee boys were saying he was fat. Q. Did you discuss that with K before he came? A. No I never'* (NT2); *'Not as sitting down and saying you're over (weight), because at the age she was at your frightened you're going to push them the other way'* (NT1).

Figure 6.1: Diagram representing parents' typologies at beginning of the journey



Legend:

Lead parent – parent who takes most responsibility for the child's weight

Aware – parents who have recognised their child has a weight problem

Unaware – parents who have not recognised that their child has a weight problem

Seekers – parents who actively seek help for their child's weight

Avoiders – parents who avoid discussing their child's weight

Deniers – parents who are unaware of their child's weight

The parents who appeared to be unaware that their child was overweight and required intervention generally described their child as a normal weight for their age, *'She wasn't that overweight I mean she was overweight for her height but compared to me she's not too bad'* (SC1); *'I didn't realise he was so overweight, I didn't realise he was that, because he doesn't actually look it because he's broad, so he carried it well, but I was quite shocked to find out his actual weight'* (SC1). Since all these children had BMIs above the 98.4th centile (UK 1990 charts) we have called these parents 'deniers'.

Approaching the subject of their weight with the child appears to be difficult for parents. There was a persistent feeling among 'avoiders' that it had remained unspoken, even those 'avoiders' who knew the

child was aware did not discuss the issue. Typically the first time the parent discussed the weight issues was after a referral to the dietitian had been made. For those ‘seekers’ who had discussed the subject there had been mixed reactions from the child including the child appearing to not have any interest in being helped, *‘No, K didn’t want to watch her weight when she came. K thought she was fine, it wasn’t something she recognised as a problem’* (SC2).

Overwhelmingly GPs appeared to be the main gatekeepers to dietetic referrals for weight management for the families in the present study. ‘Seekers’ approached their GP asking for help, while ‘avoiders’ and ‘deniers’ were typically attending for another reason and the GP brought up the child’s weight. It was not unusual for ‘avoiders’ or ‘deniers’ to actively become ‘seekers’ once the weight concerns had been pointed out to them. Less typically concerns about the child’s weight were first raised by hospital paediatricians or by the school nurse. Although not widely discussed there was a strong feeling that occasionally the health professional that first raised the issue had done so in an insensitive manner that had been hurtful to the child and/or the parent, *‘It was a young paediatrician that we initially saw and I was quite upset because she said you know H is and then she mouthed the word obese and whispered it. H was frightened’* (NT1).

This pre-treatment phase highlighted the parents’ intense and often conflicting feelings and anxieties, *‘all my childhood bad feelings that I had were coming back. It is cruel to let a child overeat, I know that, but some times and I’m not a stupid person I’m quite a bright person, but some times commonsense doesn’t come into it, when you love someone you want to make them feel happy’* (NT1). Table 6.7 illustrates the range of strongly described parental emotions at this phase such as guilt, panic, shock, upset and denial.

It is important to note that the typology of the parents at this initial stage leading to referral did not appear to influence the final outcome of the

treatment i.e. in the present study children of all three typologies had just as successful or unsuccessful weight outcome. These initial typologies of 'seekers', 'avoiders' and 'deniers' are returned to in the discussion.

6.3.2.2 During the treatment – the need for support

The parents strongly and persistently voiced their need for support and help. One of the strongest areas of support the parents discussed was '*a wake up call*' for the child. Repeatedly the parents talked of looking for '*someone*' outside of the family who could motivate the child or the child would listen to more than the parents (Q1, Q2, Q3, Q4 table 6.8). Support and help was also being sought for the child's self esteem, for focus on necessary changes and to reinforce changes already implemented. Less persistent but very strongly voiced was the need for support in justifying to other family members (including the other parent) the necessity for an intervention and lifestyle changes, '*I just knew I wanted help cause I felt that my husband wasn't listening to me, my friends, my mum was very similar. I needed someone then to say, so I could say to my husband I have been to the doctor and there is a problem with (the child)*' (SC2). More exceptionally parents were looking for an answer to the question of any underlying medical cause of the child's obesity. Interestingly for those who had sought this none felt it had been answered.

Table 6.8: Quotes from parents on needing an outside influence

Q1	<i>'But what I was hoping was that someone apart from me speaking to her she would pay attention because I felt that I was nagging, I was being awkward, I wasn't listening to her'</i>	SC2
Q2	<i>'Well I thought maybe T might wake up and realise he has got to make an effort, but then he is a child and he doesn't register everything and I think it is really up to me at the moment'</i>	SC1
Q3	<i>'Yes just somebody to get into (the child) you know, this is what's going on. And how it is affecting his health. I think someone could really talk to (child) as I find I have done the best I could and I thought I wasn't getting anywhere and I thought someone else can try'</i>	SC2
Q4	<i>'I think she was in a bout of denial, she was saying I don't think I'm overweight but I think she knew she was. With it coming from someone else other than me, it obviously dawned on her yes, there is (a problem) and I have to (do something)'</i>	NT2

6.3.2.2.1 Support from family

When talking about the treatment phase the parents consistently and strongly discussed the level of support they felt they received from family and friends and their emotions around this issue (see table 6.7). The type of support the parents described they were looking for from significant others can be summarised as -

- **not** offering/giving/tempting the child with foods they should be avoiding/cutting down. Commonly mentioned were sweets, chocolate biscuits, cakes
- **not** undermining the actions and lifestyle changes agreed with/being imposed by the lead parent
- reinforcing to the child, both by action and verbally, the agreed lifestyle changes
- backing up the initial decision to seek and enter treatment.

Parents often conveyed a distinction between the level of support given from within the nucleus family - those who all live together in the same house; and the extended family e.g. grandparents, separated parents, aunts, cousins and significant family friends including the child's school friends and their parents.

The parents' feelings about the level of support they received are exceedingly complex, often contradictory and obviously very important to them. The nucleus family was generally discussed as being supportive, it was however less typical for the extended family and friends to be seen as supportive (Q1, Q2, Q3, Q4, Q5 table 6.9).

Table 6.9: Quotes from parents on lack of support from the nucleus and extended family

Q1	<i>'We knew it would be difficult when her cousins came over but because they are boys they were running about all the time, they would have a bag of crisps or something'</i>	NT1
Q2	<i>'He sees his brother,' he's gonna eat pizza why can't I eat pizza' and that's part of our problem'</i>	SC1
Q3	<i>'At times I think I was struggling as well because his older brother keeps calling him fatty and things like that'</i>	SC2
Q4	<i>'Its sort of friends and visits to friends, classmates and sleepovers and things like that then if he spends time with other children then he will get into a habit of eating sweets that he wouldn't eat at home'</i>	SC2
Q5	<i>'I think he cheated when he was with his mum, if mum wasn't watching he took the opportunity because I just changed what was in the house which is different from the way he was with mum'</i>	NT2

There was occasional but limited movement such as an unsupportive nucleus becoming supportive once they appreciate the strength of feeling of the lead parent. Interestingly fathers were often seen by the mothers interviewed as being on the periphery of support, even not

expected to be supportive, due to their work hours or not being there often, *'He's (dad) not really responsible. He'll be away mid week so he's not really responsible for making meals, breakfast or anything so he's not so involved in it'* (SC2). Within supportive nucleus families there could be an exceptionally supportive member such as a brother or sister and conversely there may be a less supportive member. The level of support could fluctuate and this was most commonly found in the child in treatment. Repeatedly the parents mentioned fighting/arguing in the house, tantrums from the child or the child playing on one parent's sense of guilt. On the other hand parents who felt that the child had taken some responsibility or control of their own lifestyle changes or goals did not commonly mention this. Occasionally the interviewed parent would describe their own level of support as the lead parent for 'overseeing' the lifestyle changes as being inconsistent.

The grandparents were the group outwith the nucleus family most persistently mentioned as being unsupportive (Q1, Q2, Q3 table 6.10). The parents consistently talked of the grandparents as not understanding, of giving types of foods the parents had repeatedly asked them not to, of sneaking little treats to the child. This appears to be more of a particular problem when other family members such as cousins or aunts were present. However, when the extended family including grandparents were supportive this obviously was much appreciated, *'no even his gran was helping and his aunty was helping, was saying to him try this and your not having this. Try and maybe give him a bit of fruit and he was quite happy with that, because if it was going to help him no one was too bothered'* (NT2).

Table 6.10: Quotes from parents on lack of support from grandparents

Q1	<i>'With granny and granddad, if they are hungry they will let them eat anything. Because they couldn't give us these things, they see these foods as a celebration. I don't think they really understand that it can be cruel to just give in all the time'</i>	NT1
Q2	<i>'His granddad has never changed. The waine wants it the waine will get it. I try not to take him anymore'</i>	NT2
Q3	<i>'Granny just likes to buy them sweeties to spoil them'</i>	SC1

Very interestingly, when the grandparents were the child's main guardians and the grandmother in the lead parent role the child's natural parents took over the typical unsupportive grandparent role, *'They (mum and dad) want to treat them, but you know that is what I was saying to my husband I often end up as the baddie'* (NT1). Table 6.11 lists the people parents mentioned as being unsupportive.

Table 6.11: People perceived by parents as being unsupportive

Family
Friends - of child
- of family
Cousins
Grandparents
Parents (when grandparents guardians)
Child
Ex wife/husbands
Dads
Parents of school friends
Classmates
School

6.3.2.3 Post treatment – was it all worth it?

The parents were interviewed from 6 – 9 months after the completion of the child's dietetic treatment and this therefore gave them an

opportunity to reflect on their overall thoughts and feelings regarding the outcome of the interventions.

The persistent feeling of the parents was that their and their child's overall experience had been positive and successful. Parents repeatedly talked of the interventions being worthwhile, educational, the best thing they had done and being treated with respect by the dietitian (Q1, Q2, Q3, Q4, Q5, Q6 table 6.12). Although those who felt that the experience had been negative were more exceptional they voiced these views very strongly and talked of the treatment as not as successful as they hoped and not successful due to the (poor) relationship with the dietitian (Q1, Q2, Q3, Q4 table 6.13). Table 6.7 summaries the feelings and thoughts expressed by the parents on reflecting on their treatment experience.

Table 6.12: Quotes from parents on positive feeling about the dietetic treatment

Q1	<i>'I think it was good for her self-esteem, she was really starting to feel good about her self. Which is more important she has really taken it on'</i>	NT1
Q2	<i>'It has just been the best thing that she had the opportunity to go on it, I am just so thankful. The whole thing was made to be fun and I didn't expect it to be like that'</i>	NT1
Q3	<i>'I feel it was worthwhile I think if I was to ask I know he would be pleased that he took part'</i>	NT2
Q4	<i>'She wants to pick her own clothes now and for a seven year old I think that is amazing'</i>	SC1
Q5	<i>'I think it was positive as far as M was concerned and it educated me as well.'</i>	NT1
Q6	<i>'I think he (the child) has (found it helpful) I think it maybe given him a wake up call as well. A lot of advice in helping us to change the way he had to eat and including more ways to exercise'</i>	SC2

The parents, regardless of the child's weight outcome, expressed these positive and negative views. Indeed when discussing their child's weight the parents' comments had varying degrees of ambivalence and ambiguity. Parents did comment on being happy with the weight, the weight being maintained, weight expectations not met, however the most repeated comment was that even though the weight was going up it probably would have been worse if they had not taken part (Q1, Q2, Q3, Q4, Q5 table 6.14). What parents did note as the positive outcomes for their child were an improvement in the child's self-esteem/confidence. This was generally discussed in terms of styles of clothes they could now wear, enjoying taking part in PE and improved peer relationships.

Table 6.13: Quotes from parents on negative feeling about the dietetic treatment

Q1	<i>'To me it wasn't that successful, I think it was good because it raised her awareness of the weight factor. I think she did get something out of it maybe not as much as I had hoped. I think I expected more from the dietitian than just speaking to her. I don't know, I just expected more'</i>	SC2
Q2	<i>'I think we were all kind of glad when the dietitian's visits finished, didn't do an awful lot of good I'm afraid'</i>	SC2
Q3	<i>'I don't think it was a success 'cause I don't think we both actually liked the dietitian. I think it wasn't me, he didn't like her'</i>	SC1
Q4	<i>'I didn't think it would make a difference where it was, I just think he felt that the whole experience was a bit negative for him I don't think he enjoyed any of it. That's why I left and never came back'</i>	SC1

Parents commonly felt that the outside support had stopped when the treatment had finished. They noted that keeping going would have benefited the child, that they needed continuous support such as that

given by Weight Watchers or to be successful it would still need to be happening. The widespread view was that the parents and child had not kept 100% to all of the changes implemented during the treatment phase but there was a strong feeling that they continued with relevant positive lifestyle changes. Parents talked of having made lots of changes, a complete change in what was eaten, still trying to keep to the changes, doing well until going to high school. Those who had behavioural change techniques used in their treatment also noted that they returned to the written information and occasionally used the techniques, in particular keeping a lifestyle diary.

Table 6.14: Quotes from parents on weight outcomes

Q1	<i>'But it's not really making a lot of difference on his weight, although he probably isn't gaining as fast as he would have been if there was no checks on what he ate, but I am sort of controlled now about what he eats'</i>	SC2
Q2	<i>'I mean it was the big huge jump in weight had sort of stopped which is what we wanted and as she will grow into it and that is about as much as we could have hoped for'</i>	SC2
Q3	<i>'Because she is still gaining weight, I don't know why. She's had tests again for thyroid and diabetes but they've come back negative and she's still gaining weight'</i>	SC2
Q4	<i>'Well she kept that weight that she originally had but when she stretched up she slimmed down rather than losing it all at the same time she kept it the same'</i>	SC1
Q5	<i>'Overall I think he has just put on slightly compared to what he started at. Which again wouldn't be too bad over the year, what I mean because if he hadnae been doing it he'd have probably put on a lot more I would say'</i>	NT2

Although parents often talked about being happy with the outcome of treatment there was an undercurrent theme that the child still lacked motivation, these parents offered thoughts on what may make the child more aware and motivated in the future. Going to high school, getting

older and understanding, clothes and a less typical thought that they might grow out of the weight problem (Q1, Q2, Q3, Q4, Q5 table 6.15).

Table 6.15: Quotes from parents on their child's future weight perception

Q1	<i>'He's actually due to go to high school this year so, I don't know if maybe high school will make a difference with him. I don't know how he'll cope with high school because of his weight and this might give him the wee push into you know want to lose it'</i>	NT2
Q2	<i>'Well she is going to be a bridesmaid but she can't get into the bridesmaid dress so maybe that's influencing her. She is starting to notice now'</i>	SC2
Q3	<i>'I don't think there is any motivation just now, I think if she starts really getting into clothes and going out I think that will be motivational for her'</i>	SC2
Q4	<i>'When he goes to high school, which is next year, he'll have to walk to the bus, he'll be up and down stairs, so he'll be having more exercise anyway and I think peer pressure he'll start to lose weight'</i>	SC1
Q5	<i>'Cause I've spoken to friends who have had children that at some point in their lives were overweight and it sorted itself out and all the banning crisps and stuff like that didn't really work anyway'</i>	SC2

6.4 Discussion and interpretation

The undertaking of the present study was exceedingly useful and produced rich data that raised many complex issues, not only for the treatment programmes but also around parents' attitudes, their struggles and coping mechanisms with their child's weight problems. This qualitative study has helped to complement the SCOTT quantitative study; indeed it is particularly pertinent as there was no statistically significant difference between the two treatment groups in the primary outcome measure, change in BMI SD score. It has allowed

an insight in to how the parents perceived and reflected on their treatments as well as giving thick and rich data on how parents of obese children feel and act before, during and after treatment programmes. However acknowledgement must be given to the limited numbers of participants interviewed in this study despite all efforts to recruit more eligible SCOTT parents. The results in this chapter should therefore been seen as pointers to possible areas of concern and all interpretations and discussion as tentative.

The use of qualitative research in the area of childhood obesity is still relatively new and unlike in adult obesity research there are a limited number of studies for comparison with this study or help to build theories upon. Therefore although the discussions below should be seen as tentative the present study does add to the body of evidence in childhood obesity and indeed has highlighted areas of possible future research. While well-conducted childhood obesity RCTs fail to show significant results in changes in BMI SD score (or other primary outcome measurements) the use of qualitative methods to elicit from the patients (both parents and children) what they wish from treatment and how health professionals can engage with them in a motivational manner would seem an essential strategy.(11)

6.4.1 Discussion and interpretation results 1 - qualitative evaluation

We found this qualitative evaluation to be an exceedingly complex issue; in the present study the child's weight outcome appeared not to be the most significant factor for parents when discussing the treatment. Indeed parents seem to appreciate or criticise their experiences with and without a positive weight outcome. It should be remembered that the median change in weight was a statistically significant *increase* in weight of 7kg in the NT groups and 7.2kg in the SC group over 12 months (see chapter 4 section 4.3.2).

Parents who had found the treatment a positive experience persistently described it as child friendly/focused, educational, and motivating both to the child and parent. NT parents commonly talked of a partnership having been formed between the dietitian, child and parent. It is therefore interesting that only SC parents voiced the less typical view of dissatisfaction and frustration, *'I expected more than just talk'* (see table 6.13). When asked what could make the experience more positive these parents suggested treatment being more child friendly/focused, more educational and a better rapport with the dietitian. Possibly suggesting that they had not found the support from the health professional they were looking for during treatment.

The NT followed a set protocol and the dietitians had formal training in behavioural change techniques. These techniques are now being recommended in treatment of chronic childhood conditions (160) but are not yet typically used in the UK. We particularly wished to find out if the parents had found these acceptable and helpful. From the small number of NT parents interviewed here, including those from the pilot study, there was widespread applauding of their experiences and the techniques used – particularly recording, goal setting and the traffic light diet scheme; and the parents appeared to find them both helpful and acceptable (see table 6.16). This suggests that these techniques used for many years successfully in the USA (122) may have a place in the UK NHS.

In SC rewards and monitoring of lifestyle are not routinely used, therefore it is not surprising that SC parents did not recall them. On the otherhand the setting of goals is commonly used in SC and it is unexpected that the typical feeling of the SC parents was that goals had not been used. An audit of the SC dietitians after treatment had stopped showed that they had given parents goals on a routine basis (see appendix 8b). It could perhaps be suggested that the reasons the SC parents did not remember was that little emphasis was placed on

keeping to the goals or that the families felt they were not included in setting the goals.

There was a general belief among all parents that their child had increased their level of physical activity. However there was a persistent feeling in the SC group that this approach had not been recommended by the dietitian. The NT parents repeatedly talked of their child decreasing their sedentary behaviour whereas this was not a phenomenon noted by SC parents (see table 6.16). As has already been noted, the SC children did in fact become more sedentary over the period of the study, with a significant difference in the changes in total physical activity (cpm), sedentary time and light intensity activity between the two groups in favour of the NT group (see chapter 4 section 4.3.4).

In the NT group there was a common feeling that the child's motivation had been explored and that the child had an awareness of the lifestyle changes. This was not a typical view held by the SC parents. There was a general feeling in the NT group that the child had taken some responsibility for change whereas the SC parents consistently talked of the parents being responsible. The NT group persistently mentioned their child's self-esteem/confidence increasing, mention of this was more exceptional from the SC group. These differences in perception of treatment and the reason why only the NT parents talked of some features may be due to the techniques used in the NT and to the particular targeting of diet, physical activity and sedentary behaviour as recommended in various guidelines.⁽⁵⁾ Due to the limited numbers of parents interviewed we would not like to suggest the superiority of one treatment over another. Indeed it must be remembered that there was no statistically significant difference in BMI SD score change between the two treatment groups at six and 12 months.

Table 6.16: Summary of common and distinctive themes

Relationship /rapport with dietitian	<ul style="list-style-type: none"> - Persistently and generally describe as friendly, supportive, child orientated - Less typically described as unsupportive, unhelpful, contradictory, not child friendly
Use of behavioural change techniques	<ul style="list-style-type: none"> - NT discussed by parents and well received - SC little or no use of techniques, parents unsure if would have been acceptable to children
Recommendations on physical activity levels	<ul style="list-style-type: none"> - NT emphasis in treatment of changes to level of physical activity and sedentary behaviours - SC lack of or no emphasis on physical activity and sedentary behaviour
Suggestions for further helpful information	<ul style="list-style-type: none"> - Written menu suggestions - Shopping lists - Recipes - Cooking lessons – parents and children
Suggestions for period of follow up and support	<ul style="list-style-type: none"> - Up to a year - No time limit
Barriers to change	<ul style="list-style-type: none"> - Other members of the family; particularly mentioned grandparents - Holidays; particularly summer - Winter, dark nights, bad weather - Parties, special occasions - Christmas - Bereavement - Day to day hectic family life

There were a number of common themes across the groups that we believe may be useful for those delivering as well as planning treatments for obesity in the future (see table 6.16). When asked what further information/advice would be helpful parents repeatedly mentioned menu planning, shopping lists and cooking skills. There was a feeling that a longer duration of treatment may help with continuing motivation. Parents did not necessarily feel that this required to be with

a dietitian; follow up and monitoring of progress could be carried out by school or practice nurses.

There were widespread and common barriers to change noted by the parents. From table 6.16 these can be seen to generally revolve around family occasions, certain times of the year, the weather and other family members – predominantly grandparents. Future treatment programmes may wish to incorporate raising awareness of these barriers and offering support for the parents/guardians and children to cope with them.

6.4.2 Discussion and interpretation results 2 - The parents' journey

The parents' journey we have described is complicated, highly emotional and often contradictory for the parents interviewed. It has shown that family dynamics and parenting skills are highly significant in trying to ensure a whole family approach to treating the obese child. The support mechanisms within the family are of great importance and the lead parent needs the help and full co-operation of all the nucleus family in implementing the lifestyle changes and strategies, *'before they (dad and child) would have had a snack between 12 and 4, so now what they do is take a Caprisun from the house, piece of fruit and they'll eat when they go out and then he'll bring her back and its like oh god mum what is it I'm starving'* (SC2).

Typically during the SCOTT intervention only one of the parents/guardians attended the dietetic appointments. The role of the extended family in helping the child to manage their weight has emerged as an important but complex issue from the present qualitative study. The strength of feelings voiced by the parents (see tables 6.9 and 6.10) regarding the unsupportive extended family raises issues for those working with obese children and their parents that should not be ignored. Those developing treatment programmes and clinicians directly delivering treatment need to carefully consider the need to

directly engage the whole nucleus family. Perhaps, in the future these issues need to be openly discussed near the beginning of a treatment intervention to help the parents recognise the potential problems and consider coping strategies.

It is an acceptable and often-used statement that treatment of childhood obesity should only be commenced when the parents of obese children are ready and willing to make the necessary lifestyle changes.(5;31) Although no formal assessment of readiness to change was carried out for entry into the SCOTT study we believed that the parents who took part in that project had been motivated to make family lifestyle changes. As is discussed in chapter 4 we believed that we would capture a motivated group due to their willingness to undertake a research project that could have entailed 11 visits to the hospital. However, the present qualitative study has shown that these parents had very complicated and varying reasons for attending obesity treatment.

The parents interviewed cited child's pre-treatment low self-esteem, awareness of the child being called names and worries about the child's future self esteem (particularly once teenagers) as reasons for seeking help, although health was mentioned this was not common. Being a parent who actively sought out treatment was not an indicator of family motivation during treatment nor of a successful clinical outcome. Once the subject of weight management had been raised with 'avoiders' or 'deniers' they could be as enthusiastic and motivated as 'seekers'. Gatekeepers to services such as GPs, school nurses, general paediatricians should not be afraid to raise the subject with parents in the first place but should be careful do so in a sensitive, empathetic manner. They should also engage the parents in a discussion about their readiness and willingness to make the necessary family lifestyle changes before discussing the issues with the child and considering a referral for treatment.

The clinical goal of both dietetic treatments in the SCOTT trial was weight maintenance and the SCOTT project's primary outcome measure was change in BMI SD score. As discussed in chapter 4 there was no significant difference between the groups for weight and BMI SD score and although statistically significant, only a modest decrease in BMI SD scores *within* both groups. For clinicians, researchers as well as health service managers outcomes such as weight and BMI SD scores are of fundamental importance for measuring success or failure of a service/treatment. However for parents in the present study the change in BMI was never mentioned and there was a considerable ambivalence towards the child's weight change. Parents could see the intervention as positive and successful even if the child's weight had continued to increase (see table 6.14). Overwhelmingly for these parents a positive change in their child's self esteem, confidence and happiness, such as being able to confidentially partake in PE (e.g. forward rolls – see section 6.3.1.4) or to get into a pair of dress trousers, *'he used to wear jogging bottoms for comfort but we managed to get him to dress trousers for school. He was saying its really good isn't it, it has been really good for him.'* (NT2) were their significant outcomes. Indeed *within* both groups there was a statistically significant increase in the child self reported qualitative of life as shown by the PedsQL™ 4.0 Total Scale Score.(150) These results suggest that even taking part in an intervention can help increase a child's self worth and that the rapport and 'partnership' formed using the behavioural change techniques can significantly boost this sense of self esteem. There is perhaps a need for health care professionals, health service managers and senior commissioning agents to reconsider their outcome measures and view changes in self-esteem and quality of life as important and significant outcomes in future treatments for childhood obesity.

6.4.3 Study limitations

The most significant limitation to the present study was the sample size, as discussed in section 6.1.2 the original expected sample size was 32. However due to the difficulties encountered in recruiting we attained the smaller number of 17. This group still provided us with the range of criteria as described in the sampling matrix (see section 6.1.2). It is perhaps a feature of this group of parents that many of them did not wish to return to be interviewed as they may have been ambivalent or unhappy about the treatment programme and its outcome. Indeed a number of parents did cite their unhappiness with the treatment as their reason for not wishing to be part of this further research programme. There was a self-limiting sampling pool as the families had to have completed the 12-month data measurements for the SCOTT project and the total was 79. As discussed in section 6.1.2 much effort was put into contacting the parents and ensuring that they attended arranged appointments.

This number of interviews has still provided us with an immense amount of rich data. We are unsure that saturation (see chapter 5) was reached in all of the areas discussed therefore caution needs to be used in interpreting our results. All the interpretation and discussion in this chapter should be seen as tentative and only indicative of ways forward and of possible further areas of research.

The inexperience of the two research dietitians in qualitative research could also have been a limiting factor due to possible poor interview techniques. Although both attended training courses in conducting, interviewing and analysing of qualitative data neither had previously undertaken this type of research. Both research dietitians were highly skilled in many of the techniques used for qualitative interviewing such as use of open questions, active listening skills and summarisation; these skills were independently assessed for the novel treatment intervention and discussed in chapter 3. Initial interviews took under an hour to conduct while later ones took up to an hour and a half, an

indication of conducting fuller more in depth interviews. The research dietitians and Dr Poustie peer reviewed a number of the typed interview transcripts giving advice on interviewing style during the interviewing phase.

Using the novel treatment research dietitians as interviewers to assess both dietetic interventions may have introduced bias both in the interviewing and analysing process. It may have been possible that they favoured the novel treatment intervention. We have dealt with this possibility in a number of ways, first by acknowledging the possibility and ensuring continuing peer review and supervision from Dr Poustie. Second by using the framework analysis (184) we used a method which is well recognised in qualitative research as being systematic, methodical and open to cross checking. Jane Ritchie, one of the authors of this method and an expert in the field of research in both social policy and health care, kindly reviewed the initial analysis of the data giving advice and guidance.^q Lastly the design and methodology used in the present study has been explicitly explained in this chapter and we have kept a transparent audit trail with all tapes, charts and relevant writings available for review.

No *children* were interviewed for their thoughts and feelings on the dietetic interventions in the present study. This had been originally planned but due to circumstances outwith every ones control these could not be conducted. Although these interviews would have added to this body of work the fact that the children were not interviewed does not in itself detract from the interpretation and theories raised in this chapter. Indeed the WATCH IT(131) researchers in Leeds, UK carried out focus group interviews with 20 of the children who took part in their programme (see chapter 4 section 4.6.4). The children interviewed voiced surprisingly similar opinions to the parents in our study (195) and these are discussed in the next section.

^q During the completion of this work Jane Ritchie retired from active research and therefore could only contribute to the first draft of the data analysis and interpretation.

6.4.4 Qualitative study implications with reference to other studies

Taking these limitations in to account, this qualitative work tentatively raises a number of important issues and this section discusses these with reference to other studies. Some of the studies discussed have been carried out in the USA and due mainly to cultural differences caution is required when directly comparing their results with the UK population. To help readers put these studies into context an evidence table of all the studies referred to in this section can be found in appendix 17.

We have identified some parents whom we called 'deniers' and others as 'avoiders'. A number of papers have reported that parents often do not appear to recognise the health implications of their child's weight. Carnell et al 2005 (196) reported that out of a total of 564 children from the UK, the parents of the 145 classified as overweight or obese (using the IOTF cut off points), only 6% described their child as 'overweight' and very interestingly none as 'very overweight'. These authors suggested the possibility of the parents feeling unable to voice their awareness of their child's weight or of being able to recognise obesity in other children but not in their own. Jeffery et al 2005 (197) also in the UK, reported that only a quarter of parents correctly recognised their child as overweight (using the SIGN criteria, (5) BMI $\geq 91^{\text{st}}$ centile), with more correctly recognising obesity (BMI $\geq 98^{\text{th}}$ centile). More mothers than fathers were able to correctly assess their child's weight and parents were less likely to identify a weight problem in boys. These authors also suggested denial, avoidance of the issue or possibly a desensitisation to overweight in the general population. Similar findings have been reported in the USA (198;199) and Australia,(200) however cultural differences particularly in the Jain et al (2005) (198) should be taken into account when drawing conclusions from these studies.

Work from Dixey et al (2006) (201) reflects our observations, while Murtagh et al 2006 (195) supports some of these observations but from the child's point of view. Both of these authors carried out focus

groups with 24 parents and 20 children aged 7 to 15 years old (respectively) who had taken part in the weight management programme WATCH IT in Leeds, UK. Some of these children talked of being aware of their own weight as a problem for some time but that the cue for change had needed to be an external one - usually coming from their mother. Some of the children appeared to be aware of a delay between their own recognition of the problem and their mother's recognition and/or in her taking action. The general consensus from these papers is that health professionals should be more pro active in raising the subject of their child's weight with parents.

Edmunds 2005 (202) interviewed 40 parents who had concerns about their child's weight, similar to the interviewed parents we labelled 'seekers', these parents appeared to be very determined to find professional help for their child and talked of looking for support from an 'outside person'. Interestingly all the parents Edmunds interviewed had tried their own strategies before seeking professional help. This was not the experience of the 'seekers' we interviewed.

An overwhelming theme that emerged from the parents we interviewed was a positive outcome regarding their child's self esteem, indeed this appeared to be more important than a successful weight outcome. Murtagh et al 2006 (195) and Dixey et al (2006) (201) illustrated how important self esteem is for the children, they talked of being bullied, called names, having low self esteem and of wanting to 'fit in'. For the children in the study by Murtagh et al (2006) it was a desire to be 'socially acceptable' in the school playground and not long-term health issues which had led to their wish to make lifestyle changes. The children discussed that bullying because of their weight had become generally accepted both to themselves and those doing the bullying.(195) Indeed Latner and Stunkard 2003 (203) noted that the stigmatisation of the obese child in the US was greater in their 2001 study than in a previous similar study in the early 1960s. They interviewed 415 children in 5th and 6th grade in the US, when presented

with drawings of a healthy child, one with a face disfigurement, a hand disfigurement, one using crutches, one in a wheelchair and an obese child these children ranked the obese child as the 'least liked'. Health care professionals need to be aware of the importance of this issue for the parents and the child and have more understanding of the need to support self-confidence and self esteem in obese children.

Rhee et al 2006 outlined four main parenting styles – authoritative (respect for child's opinion, but maintains clear boundaries); permissive (indulgent, without discipline); authoritarian (strict disciplinarian); and neglectful (emotionally uninvolved and does not set rules).(204) They showed that children brought up with an "authoritarian" style of parenting were at a higher risk of being obese in the first grade than other parenting styles. Indeed the ideal style of parenting appears to be "authoritative" where the parents give the children boundaries but allow them to make choices within these boundaries. In the present qualitative study the SC parents described being controlling and taking responsibility for the lifestyle changes and appeared to be generally more authoritarian than the NT parents who discussed forming a partnership. The authoritative parenting style is analogous to that encouraged in the behavioural change techniques used in the novel treatment and appears to be reflected in how the NT parents describe their attitudes to their child's goal setting. Dietz and Robinson 2005 (205) discussed the importance of parenting style in successfully engaging in paediatric obesity management. Indeed Golan 2006 (206) suggested that childhood obesity could be managed exclusively by targeting change through the parents and their parenting skills. Therefore parent's attitudes and parenting styles are important for successful treatment outcomes and health professionals should have an understanding of these issues.

Another major theme to emerge from our data analysis is the need for support particularly for the "lead parent". For the parents the support and attitude of the health professional can be of vital importance to

them continuing with the programme and also in their perception of the outcome of the treatment. Since obesity is a chronic condition a patients perceptions of the last health professional to treat them could be very important in whether they are likely to engage in further treatment episodes. Barlow and Ohlemeyer 2006 (207) cited that of 43 families who attended 2 or less weight management appointments (i.e. non completers), the single highest reason reported by 37% for not returning was that the programme “was not what they were looking for” and specifically they were dissatisfied with the attitude of the health professional. For the children interviewed by Murtagh et al 2006 the authors report the attitudes of dietitians as a barrier to change, *‘dietitians never listen’* and *‘they just tell you what to eat, what to do’*.(195) The parents interviewed by Edmonds 2005 (202) appeared to have a mixed view on the attitude of health professionals particularly GPs and dietitians. Although some of these parents had encountered positive and empathetic attitudes from health professionals there were strong feelings voiced on the negative, unsympathetic and unhelpful attitude of some GPs and dietitians.

Parents from both treatment groups found the experience positive, successful and could be happy with the outcome. That only SC parents voiced negative views and had been *‘looking for something more’* is interesting. None of the standard care dietitians had any type of formal training in childhood obesity or behavioural change techniques/counselling in the present study. Indeed when answering the audit questionnaire at the end of the study (see appendix 8b) some of the standard care dietitians noted that they realised they required further training in this area. In both departments where the standard care took place it was common practice for the least experienced dietitian to be asked to see overweight/obese children; this raises issues regarding priorities, attitudes and training of managers as well as practitioners. Many of the issues discussed above could be addressed within the NHS with effective training programmes for health professionals that not only increase their knowledge but also help to

positively alter their attitudes. The issue of training health professionals in this area is an exceedingly important issue and is discussed in depth in chapter 7.

In conclusion this present qualitative study has complemented the SCOTT quantitative study and has added to the understanding of the RCT results. This study has revealed pointers as to how parents would like to be treated in a clinical setting and has highlighted an applauding of the behavioural change techniques used. It has emphasised the intensive emotions for parents at this time and the need for support from family and health professionals. These issues are returned to in chapter 7

CHAPTER 7

Discussion and interpretation of results

7.0 Introduction

There is general agreement in respected reports, papers and systematic reviews (5;7;11;125) that there is a lack of evidence from well conducted RCTs on the treatment of childhood obesity. The original purpose of the SCOTT quantitative research project was to test a novel dietetic treatment, which incorporated the 'best bets' from systematic reviews on the treatment of childhood obesity, compared to standard dietetic treatment in the Scottish NHS. Although the present quantitative study did not show any significant difference between the novel treatment group and the standard dietetic care group in terms of changes in BMI SD scores the study adds to the debate on the possible treatment programmes for a number of reasons. The study was a well-conducted RCT, which followed the CONSORT guidelines,(122) and in all areas of scientific research negative results should be of as much importance as positive ones. There were a number of interesting results in the difference between the groups in physical activity and sedentary behaviour at six months.

The qualitative study was of benefit in complementing the results from the quantitative study. It was very useful in helping to tease out how the two treatments were considered by the parents and in showing the possible benefits from using a client centred behavioural change approach that were imperceptible from the comparison of the primary outcome measurements of the quantitative study. Although not part of the original purpose of the qualitative study the data that emerged relating to parents' approaches to identifying their child's weight as a problem, seeking help, and the support system they sought from nuclear and extended family all help to build up a body of evidence and point to future areas of possible research.

The parents in the present qualitative study commonly talked of wishing to have information on menu planning, shopping list and cooking skills. Suggestions that future treatment programmes could incorporate such as easy to follow, child accessible menus with associated shopping lists, as well as sessions on basic cooking skills for both parents and children.

The NT programme which was developed by the SCOTT team is highly transferable within the UK NHS and indeed beyond the UK. It requires one trained health professional with the necessary skills and attributes to undertake the programme. The programme can be delivered in a number of setting dependent on local circumstances such as primary care, secondary care or a non health care setting. To facilitate the transferability of the programme the full treatment protocol has been made available in appendix 1 of this thesis and a summary outline has been published.(156)

7.1 The novel treatment programme

There are a number of issues regarding the novel treatment programme that are pertinent to be expanded on in this final chapter and these are discussed below.

7.1.1 Length and intensity of treatment

The novel treatment in the present study was always intended to be reproducible within the UK NHS and at the time of it's conception (2001/2002) it was considered intensive in comparison to the typical dietetic care within the Scottish NHS. Many NHS Trusts are unable to offer an integrated multi-disciplinary team service and clinical psychologist services in childhood obesity are particularly lacking. The treatment was designed to be uniprofessional, that is to be undertaken by a well-trained paediatric dietitian as this was seen as the most cost effective way to deliver such a programme within NHS constraints. However this present study has shown that a dietetic led treatment

programme with 5 hours of direct individual clinical time was not sufficient to produce a decrease in BMI SD score in the magnitude of -0.25 or more. As the study was sufficiently powered for a -0.25 decrease in BMI SD score this would imply that programmes successful in significantly reducing BMI SD scores require to be more intensive than this novel programme. The need for more intensive and perhaps longer treatment programmes may well have an influence on how many UK NHS Trusts and UK dietetic departments feel able to offer a clinical service to obese and overweight children.

The parents interviewed in the add-on qualitative study talked throughout the interviews for their need of support and discussed the importance of support from outside the family. They voiced feelings that this key outside support stopped at the end of treatment and appeared to find the ending of the treatment programme a particularly difficult period. There was a strong feeling that long term follow up would be supportive and fruitful in ensuring continuing compliance with lifestyle changes, 'Q: *do you still think it's a success. A: I would have to still be doing it now*' (NT1). Opinions varied on the ideal length of the programmes, however continued follow up need not necessarily be with a dietitian but could be with a school nurse, practice nurse or community health care assistant. This long term follow up and monitoring would also have obvious financial and training implications to the UK NHS. Many Trusts and dietetic departments in the UK have already discontinued treatment of overweight and obese children usually due to more pressing clinical priorities. Indeed the dietetic department at the RHSC in Edinburgh had (from early 2006 until summer 2007) suspended the treatment of obese children due to service pressures and higher priorities from acute clinical commitments. A full debate on the funding of childhood obesity services within the UK NHS is outwith this thesis but is a crucial debate that requires to take place at the highest levels of Government and NHS management.

7.1.2 Use of behavioural change techniques

The use of motivational interviewing and behavioural change programmes in the treatment of childhood obesity has been highlighted in a number of expert reports. These approaches are considered to be important for encouraging weight management however these expert reports note that further research is required.(7;10;11) The decision to utilise behavioural change techniques in the SCOTT study was taken after a discussion with Prof. Bryan Lask (Professor of Child and Adolescent Psychiatry, St. Georges Hospital Medical School, London), who strongly suggested that it was essential for any successful weight management intervention to explore motivation to change behaviours. As discussed in chapter 3 the programme used was conceived from the work of Epstein,(122;123) the experience of the whole SCOTT team, training in behavioural change techniques and motivational interviewing by Dypmna Pearson, Freelance Dietitian and recognised trainer in behavioural change, and reading around the subject but in particular the work of Rollnick and Miller.(155)

Although many of the principles used in the SCOTT programme were derived from behavioural change treatment and from motivational interviewing as described by Rollnick and Miller (155;161) it was felt that it did not meet all the criteria to be correctly described as either motivational interviewing or a behaviour change treatment. It was therefore agreed to use the term 'behavioural change techniques' to best describe the interviewing and intervention style employed in the SCOTT programme. The behavioural change techniques used in the novel treatment have not been commonly used with children in the NHS and especially with children as young as five years old (167;168) and therefore the outcomes of the parental interviews have been very illuminating.

As described in chapter 3 the dietitians delivering the novel treatment in the present study required good listening skills, in particular the use of mirroring, paraphrasing, reflecting back, affirmation and summarising,

as well as the use of open questions to elicit information.(141;155;161) They required a key recognition that the child and parent may not wish to make all the necessary changes and that it is not knowledge of health consequence that drives behaviour change but the motivation and aspirations of the child and parent.(161) These may seem subtle but in fact are key differences between the more traditional interviewing style used by many dietitians of directing the client to the changes they require for their health or by the dietitian telling them what they should change and why.(161;165) From the interviewed parents it was the NT parents who talked of a good rapport with the dietitian and of forming 'a partnership'. Perhaps tellingly only parents from the SC group noted unhappiness with treatment and with the attitude of the dietitian indicating that some of these dietitians did not have the necessary interviewing skills or attitude. The results from the SC dietitians' audit and this author's own experience confirms that all the SC dietitians did not have these skills. Indeed since the completion of the present study the author has been asked by members of the RHSC dietetic department to train them in behavioural change skills. Training issues around these skills are discussed below in section 7.1.4.

In appointment 1 asking the child to complete the simplified decisional balance chart (see appendix 2) and to score their perceived importance of making changes was regarded as a key aspect of exploring motivation and of eliciting 'change talk'.(141;155;167) The children particularly seemed to find the decisional balance chart thought provoking and during the qualitative interviews this was highlighted by some of the parents. Overwhelmingly the most common reason given by the children for wanting to make changes was to stop bullying and name-calling and table 7.1 shows the most common answers given by the children as described by Stewart et al.(156) In appointment 6 both the parent and the child were asked to reassess how they perceived the importance to make changes and all of the children increased their importance score with a significant number giving 10/10 for importance.

When asked why, the children often answered that they now knew they could make the changes and that they felt more confident.

Table 7.1: Common answers given by children to the decisional balance charts(156)

Pros of lifestyle change	Cons of lifestyle change
<ul style="list-style-type: none"> • Will not be bullied • Will not be called names • Will be able to run faster • Will be happy • Will be able to fit into nice/fashionable clothes 	<ul style="list-style-type: none"> • Will miss sweeties • Will miss crisps • Will miss watching TV • Will miss playing X box

This increase in the child's confidence in their own ability to change may be explained by the child being in 'control' in the exploring of options, problem solving and goal setting. Goal setting and the receiving of rewards for meeting goals were seen as useful by both the children and parents during the treatment and were applauded by the parents interviewed. The use of a 'contract' was intended to reinforce the importance of the goals and reward, however this is an area that none of the parents touched on during their interviews. During the clinical sessions joint discussions took place between the child, parent and dietitian on whether goals had been achieved and if the reward should be given. Parents did note during the qualitative interviews that the children tended to be honest as to whether they had achieved their goals or not. The parents also underlined the value and the importance in raising awareness of current behaviours from the lifestyle monitoring. Not unexpectedly the children themselves appeared to prefer the tick sheets as these were less time consuming and did not depend on handwriting abilities. The parents in the NT group described their

parenting role as being an over seeing one while the SC parents discussed being more controlling and authoritarian. There is work that shows that children respond better and take more control themselves when parents are authoritative (giving boundaries and allowing the child to choose within the boundaries) and not authoritarian (having set non-negotiable rules).(204;205;208)

Although the group of parents interviewed in the qualitative study was small (8 NT parents and 3 families from the pilot study) the overwhelming feeling was that the behavioural change techniques had been useful in promoting lifestyle changes and in helping raise the child's self esteem. Both dietitians involved in this present study (this author and JC) have also noted that they enjoyed using all of the skills and techniques discussed here. They felt that the clinical sessions were more rewarding and both have continued to use these techniques and skills in their day to day practice. It is therefore a tentative suggestion that they should be used in future childhood treatment programmes. However it was also clear from these parents interviewed that there appears to be no 'one size fits all' treatment programme. The idea that different strategies are required in promoting behaviour change and health care has been discussed in adults (162;209) and was highlighted as crucial in childhood obesity by the NICE 43 guidelines (10) and the BMA (2005).(4) Health Board's and Health Authorities' developing strategies and clinical pathways for the management of childhood obesity should take this in to account and perhaps develop structured patient care flow plans that recognise the diverse individual needs of children and their families.

7.1.3 Use of the traffic light healthy eating plan

The history of the use of traffic light diet schemes in the UK was discussed in chapter 3. It is fair to say that a traffic light diet approach was not in common use in the UK at the start of the SCOTT project and this remains the case at the time of writing this thesis. However,

Epstein has used a traffic light diet for many years, his version is somewhat complicated and includes a calorie restriction of between 900 – 1200 kcal per day.(123) For the SCOTT project the Epstein traffic light diet was modified, keeping the format of placing foods (particularly the amber foods) in food groups but did not use calorie counting. Interestingly Edwards et al (2006) who used the traffic light scheme in a pilot study also avoided calorie counting, noting that it was not acceptable practice for children in the UK.(130)

From the qualitative study interviews it appears that the NT parents felt the traffic light diet was a useful tool. The parents, 6-9 months after completing the programme, still talked in traffic light terms and discussed how the children had interacted well with the concept. Although the SC parents did talk about changing family meals and different shopping habits the main dietary change they discussed was an increased use of fruit as snacks. This in itself is not a negative point nevertheless there did appear to be stronger reinforcement in the NT group on the need to decrease the high energy and 'empty calories' of the red foods as well as to use lower energy snacks from the green list. These qualitative results would suggest that the use of the traffic light diet scheme is acceptable in the UK and can educate children and families on the appropriate dietary changes required for healthy lifestyle and weight management. The author as a clinical dietitian who had never used a traffic light diet scheme before found using the traffic light diet scheme very helpful and continues its use in day-to-day clinical practice.

7.1.4 Training issues for health professionals

As mentioned in chapter 6, the two present studies raised issues regarding professional training. The NICE clinical guidelines 43 (2006) (10) on overweight and obesity in adults and children recommended that research is required not only into effective and sustainable interventions but also importantly into the training that health

professional staff may require to implement effective strategies. The NICE guidelines noted that staff's motivational skills are important and that they need to be able to tailor interventions to individual children and family needs.(10) The BMA in their 2005 position paper on childhood obesity recognised a requirement for health professionals with sufficient time, motivational skills and funding to establish and sustain quality training programmes for NHS staff.(4) The results of the present studies have illuminated a number of these training issues, those particularly related to behavioural change skills have been discussed in section 7.1.2 above and others are expanded below.

The qualitative study in particular raised a number of issues around training not only for dietitians but for all health professionals working with overweight children and their families. Our mapping of the feelings and emotions during the parents' journey highlighted the need for treatment programmes to be undertaken by highly skilled practitioners who are able to give appropriate behavioural change guidance while being non-judgemental and employing empathy. As stated in chapter 6 none of the standard care dietitians had training in the treatment of childhood obesity or in behavioural change interviewing, indeed it was often the least experienced dietitian who undertook the obesity clinics without clinical supervision.

The SIGN 69 guidelines (5) were published in 2003 and the RCPCH code of practice (9) was available from 2002. Both these documents emphasised that treatment strategies for childhood obesity need to incorporate targeting increasing levels of physical activity and specifically decreasing sedentary behaviours along with dietary changes. However, in answering the audit questionnaire at the end of the study the SC dietitians appeared not to have incorporated these guidelines recommendations into their treatment programmes. Indeed in the qualitative study the SC parents talked less about physical activity than the NT parents and did not discuss sedentary behaviours at all. This supported the findings from the physical activity monitoring,

which demonstrated that the SC group became even more sedentary at the end of the six months of treatment programme. This draws attention to the need for training of dietitians and other treatment providers not only on attitudes and interviewing skills but also on the substance of treatment programmes.

Parents in the present study also voiced unease over how the subject of their child's obesity had been initially communicated with them and/or their child. Although there are a number of studies suggesting that parents do not recognise their child as overweight or obese (196-200) the present study is one of the first to explore parents attitudes at this stage and to illustrate how highly emotionally charged a period it can be for the parents and family. Gatekeepers to treatment services – who may be GPs, school nurses or hospital paediatricians need to have an understanding of how to correctly diagnose childhood obesity and of the best means of approaching the subject with the parents and child. This author would like to strongly suggest that in this complex and emotional area of childhood obesity that health care professionals who undertake treatment programmes as well as those who may be gatekeepers to services should have appropriate training.

Although no similar surveys have been carried out in the UK there are a number of very applicable papers from the USA that highlight the need for training and support for health professionals employed in childhood obesity.(210;211) Story et al (2002) reported the results on a survey of attitudes, skills and training needs of paediatricians, paediatric nurse practitioners and registered dietitians in the USA. They reported that the area most perceived by the health professionals surveyed being poorly skilled were in the use of behavioural management skills, guidance on parenting skills and addressing family conflicts.(211) These are all areas highlighted by the present qualitative study either as skills lacking in some of the SC dietitians or areas where the parents recognized a need for more help. Kolagotla and Adams (2004) in their survey of family practitioners and paediatric doctors in the USA found

that only a small percentage were aware of, or adhered to, national guidelines on the management of childhood and adolescent obesity. Interestingly those who were aware of the national guidelines were more likely to have a positive attitude regarding their own interviewing and behavioural change skills and to the efficacy of treatment strategies.(212) As noted above the SC dietitians appeared not to adhere to the national guidelines published before the start of the SCOTT project. Barlow et al (2002) (213) and Kolagotla and Adams (2004) (212) both found that a very low percentage of paediatricians and family doctors used BMI and/or appropriate cut off points to diagnose childhood and adolescent obesity in the USA. Even with the difference in how the two countries manage and run their health services this author believes that the results of such surveys would not be dissimilar if carried out within the UK. The results from these USA surveys can be taken as an indication of the need for good quality training for all health professionals involved in the area of childhood obesity, that encompass correct diagnostic tools and the use of effective strategies, including good interviewing and motivational skills.

7.2 Comparisons with other work

As discussed in chapter 1 the SCOTT project was conceived subsequent to the systematic literature review for the SIGN 69 guidelines,(5) which showed that there were no high quality RCTs on the treatment of childhood obesity. This guideline recommended that well conducted studies should be carried out within the UK NHS. There are indeed a large number of papers and studies published in this area but unfortunately there are numerous concerns with the quality of these studies mainly around study numbers and sufficient power, randomisation procedures including concealment and blinding, as well as poor descriptions of the treatment protocols.(5;7) Quite surprisingly this paucity of good quality evidence for treatment programmes continued up to the writing of this thesis, as demonstrated by a systematic review on dietetic interventions in childhood obesity by

Collins et al in 2006.(125) It is therefore difficult to compare the results from the present study with other well-conducted RCTs. However, it is important that the SCOTT results are set in the context of other research into childhood obesity treatments and this section endeavours to compare the results of the SCOTT project with other relevant studies.

7.2.1 Epstein

Many of the 'best bets' for the treatment of childhood obesity had come from the work carried out in the USA by the team led by Dr L.H. Epstein. His studies have demonstrated good results, with follow up and published long term results of some patients for 10 years.(122) As discussed in chapter 1 there are unfortunately a number of flaws in how many of these studies have been reported. However Epstein's work did have a major influence on the SCOTT treatment protocol, namely in the use of the traffic light diet plan, the involvement of the whole family, targeting of sedentary behaviour as well as physical activity levels, the use of goals, self monitoring and contracting. It therefore seems appropriate to compare the results of the SCOTT quantitative intervention with some pertinent Epstein work, although concerns over study techniques and in particular small sample size need to be taken in to account. Some of Epstein's published works make a fuller direct comparison difficult as these reported outcomes mainly in changes in percentage overweight and the SCOTT primary outcome was the change in BMI SD scores. However, it can be seen that the studies carried out by Epstein have reported better clinical outcomes than those seen in the SCOTT project.

Study 1 - Epstein et al (2000) 'Decreasing sedentary behaviours in treating pediatric obesity'.(135) In this study Epstein et al compared the targeting of decreasing sedentary behaviours and increasing physical activity at two levels of intensity in obese children aged 8 – 12 years old. Ninety families were recruited into the study and both an obese

child and one parent actively took part in the interventions. The participants were randomised into one of four groups - low or high doses of each decreased sedentary behaviour and increased physical activity. The intervention took place over 6 months with 16 weekly meetings followed by 2 biweekly and 2 monthly meetings. All groups followed the traffic light diet restrictions, self-monitoring, behaviour change techniques and maintenance of behaviours. The primary outcome measurement was change in percentage overweight at six and 24 months.

Seventy-six families completed the study and there was no statistically significant difference between any of the groups at six or 24 months. There was a significant decrease in mean percentage overweight from baseline to six months and to 24 months across all groups and the results discussed here are across all groups. There was a decrease in mean percentage overweight from baseline to six months of 25.5%, due to a mean growth of 3.5cm in height and a mean weight loss of 6.0kg. At 24 months there was a reduction in mean percentage overweight of 12.9%, due to a mean growth of 11.4cm in height and a mean weight gain of 9.0kg.

Study 2 - Epstein et al (2000) 'Problem solving in the treatment of childhood obesity'.(159) In this study 67 families of obese children mean age 10.3 (1.1) years were randomised to either Epstein's standard behavioural weight control programme, the standard programme plus problem solving for parent and child or the standard programme plus problem solving for the child only. The treatment programme was over six months and consisted of 16 weekly sessions and 2 monthly sessions. There were short individual meetings of 15-30 minutes with a therapist and then parallel parent and children groups. All groups followed the traffic light diet scheme, were encouraged to increase physical activity levels and received behavioural change techniques including goal setting, self monitoring and preplanning. The principles of problem solving were used in both problem-solving groups

at group and individual sessions as well as in homework. In the no problem-solving group questions were dealt with in what is described as a didactic manner.

Sixty-two families completed treatment, BMI SD score was the primary outcome and measurements were taken at baseline, six, 12 and 24 months. The studies overall conclusion was that problem solving did not add to the standard treatment programmes clinical outcomes. There was no significant difference in the mean BMI SD score between the groups at the end of the treatment at six months however the parent and child problem solving group did significantly increase their BMI SD score compared to the standard group from 6 to 24 months. The results discussed here are for across the three groups. At 12 months the overall mean BMI SD score had decreased from 2.7 (0.9) to 1.5 (0.9) and the overall mean weight had decreased from 59.8 (13.1) kg to 58.1 (13.0) kg. At 24 months the mean weight across the groups had increased to 68.5 (14.5) and the mean BMI SD score had increased to 1.9 (1.0).

Study 3 - Epstein et al (1994) 'Ten-year outcomes of behavioural family based treatment for childhood obesity'.(122) In this paper Epstein et al reported on the outcomes of a 10-year follow up on 158 children who had taken part in four separate studies by the Epstein group. All four studies had included weekly meetings for 8-12 weeks followed by monthly sessions for 6-12 months. Behavioural modification techniques were used in all the studies, as was the traffic light diet scheme. There were exercise components in most but not all of the four studies. The four studies had incorporated various combinations of comparison groups within each study.

At the 10-year follow up most of the 158 subjects attended for weight and height measures while 18% were self-reported. Using percentage overweight the authors report that at 10 years post treatment 30% of

the 158 children had reached non-obese status and that around 33% had a decrease to at least 20% overweight.

These studies show that over a number of years and in a variety of treatment protocols Epstein and his team have demonstrated successful clinical outcomes. Possible explanations as to why Epstein's studies are more successful than the SCOTT study need to be considered. The treatment programmes carried out by Epstein usually involved a large number of health professionals and his programmes were usually highly time intensive for example study 1 involved around 20 hours of treatment while study 2 was around 18 hours. Indeed Newman et al (2004), when discussing self-management in chronic disease described a brief intervention (for asthma) as around 12 hours and by comparison a study on diabetes had a maximum of 58 hours and one on arthritis 40 hours of treatment.(162)

Epstein always used group sessions, although many of his interventions had a short individual time they all included separate but parallel sessions for the parents and children. These compare to the 5 hours of one to one time spent with a single health professional in the SCOTT project, although family lifestyle changes were constantly emphasised and one parent was required to attend all sessions the intervention was targeted at the obese child. In many of the Epstein programmes one obese parent also directly took part in the intervention for example in study 1 the parents who completed treatment from baseline lost 12.0kg in weight at six months and 7.1kg at 24 months. Having parents actively taking part could be one important mode to ensuring the whole family is making changes, however this approach does exclude families where neither parent is obese. At least some of these differences described above could be accounted for in the differences in health care delivery and funding between the USA setting, in which Epstein works, and the UK NHS.

The SCOTT programme utilised many of the behavioural change techniques employed by Epstein in his studies. Although the SCOTT programme had long term goals of no more than 1 red food per day, 60 minutes of activity time per day and no more than 2 hours of sedentary time per day it retained the client centred approach of guiding the child towards setting their own goals and of ensuring that the goals were SMART (small, measurable, achievable, realistic, time-phased). For example a child who ate 4 red foods per day may have only reduced this to 2 by the end of the programme and may have reduced time on the computer from 6 hours per day to 4 hours. Although these did not meet the long-term goals of the intervention they were accepted and applauded as the child's own chosen goals. However, in Epstein's programmes the children were set more prescriptive goals; within the traffic light scheme there was normally a calorie restriction of between 900 –1200kcal per day.(123) The targeted amount of time spent on physical activity and sedentary time varied between studies but were more directional than in the SCOTT programme.

There is generally a very high reported compliance rate in all of Epstein's studies, for example in study 1 98% completed the treatment phase and in study 2 97% completed the 6 months treatment. However, when there had been difficulties in participants attending outcome measurement sessions Epstein had accepted self reported weight and heights. Interestingly in all of Epstein studies the participant families pay a deposit, usually of \$75 which is returned to them only after they have completed 75% of the intervention sessions and most are paid around \$50 for attending the follow up measurement sessions. The participants in the SCOTT project only received refunding of their travel expenses. The idea of asking people to pay for treatment in the NHS, even a returnable deposit, may indeed help with retention to treatment programmes but this author believes this would currently be politically unacceptable.

7.2.2 Studies within the UK NHS

As has been touched on in chapter 4 there is a lack of high quality RCTs of childhood obesity treatment reported to date within the UK NHS. There are however results of two pilot studies (130;131) and preliminary results from the intervention arm of an RCT (132); a summary of these studies has been given in table 4.20 of chapter 4. Caution is required when comparing these studies with the SCOTT results as all have small numbers and data from uncomparated groups are likely to over estimate study effect. There is one UK RCT, the SHOT study from Sheffield, looking at the effects of exercise therapy sessions in obese children.(126) As with the Epstein studies there is some difficulty in directly comparing the results from these studies (with the exception of the WATCH IT study) due to the reported primary outcomes differing from the SCOTT project.

With the exception of the SHOT study, all of these recent studies in the UK were group based and involved the child and their parents being seen in parallel but separate sessions and aimed to change diet, physical activity time and to decrease sedentary behaviour. Two of the studies also involved separate exercise sessions run by the treatment organisers.

Study 1 - Edwards et al (2006) 'Family based behavioural treatment of obesity: acceptability and effectiveness in the UK'.(130) This study was carried out at UCL, London and was the closest in design to the SCOTT project. It was closely based on Epstein's work, used the traffic light diet scheme, self-monitoring goal setting, positive reinforcing, stimulus control and relapse prevention. Parents and children (aged 8 – 13 years) were seen separately. Twenty seven completed the programme of 12 sessions each lasting 1½ hours over 4 months. Follow up measurements were taken 3 months after the end of the treatment programme. The primary outcomes were changes in BMI SD score and percentage BMI. BMI SD score reduced in the 7 months from 3.23 (0.48) to 3.08 (0.53), percentage BMI reduced from 187.6 (26.4) to

179.3 (27.1) and weight decreased from 74.7(17.2) kg to 73.3 (17.4) kg; all changes were statistically significant. Self-esteem as measured by the Piers-Harris test showed a statistically significant improvement at follow up measurement.

Study 2 – Rudolf et al (2006) 'WATCH IT: a community based programme for obese children and adolescents'.(131) This treatment programme was delivered by WATCH IT trainers (non-health professional staff) in Leeds who had received training from a dietitian, a clinical psychologist and a paediatrician. The treatment was delivered away from clinical settings in local sports and community centres. The programme used motivational and solution focused approaches and included one-hour group physical activity sessions at a local sports centre led by a sports coach. The overall programme involved individual sessions lasting up to 30 minutes, initially weekly for the child and parent. Group parent sessions started after this initial intensive phase. The families agreed to take part for three months and then were offered sets of three monthly follow-ups for a year. Ninety-four children, mean age 12.2 (2.0) enrolled for the programme and BMI data were available for 48 children at six months (three months after the end of the intensive treatment phase). There was a significant change in mean BMI SD score from baseline to six months of -0.07 (0.16) $p<0.01$. These results are similar to those seen in the SCOTT study.

Very interestingly, as discussed in chapter 6, this project team also undertook two qualitative studies using focus groups. The first with 20 of the children and adolescents who had taken part in the WATCH IT programme.(195) Although from the young person's point of view, many of the themes described in this paper were similar and complementary to the themes illuminated by the parents' interviews in the present SCOTT qualitative study. The young people interviewed talked of wishing to manage their weight due to name-calling and bullying, with self-esteem being a major theme. The young people also talked of negative attitudes of dietitians and other health professionals

with some imposing unrealistic, strict regimes. These authors underlined the importance of engaging obese young people at an individual level and of the need for health professionals to be flexible and able to utilise motivational skills.(195) The other WATCH IT qualitative study was similar to the SCOTT in that it interviewed 24 parents of the children who had taken part in the WATCH IT programme.(201) Reflecting the results of our qualitative study this paper reported an increase in the child's self-esteem as being an important outcome for the parents, as well as the effects of the child's obesity and seeking treatment as being highly emotional for the parents.

Study 3 – Sacher et al (2006) 'The MEND programme: effectiveness on health outcomes in obese children'.(132) This was a 9 week community based programme that involved twice weekly sessions, one exercised based and the other involving behavioural therapy and nutritional education. Dietitians, nutritionist and physical activity professionals delivered the programme and the presented results were from a variety of sites in England. The preliminary results of 45 children mean age 10 (1.2) years who had completed the 9-week programme were reported in this paper. At the end of the 9-week programme mean BMI SD score had reduced by 0.16, broadly similar to that observed in the SCOTT project, and mean waist circumference SD score had reduced by 0.25. Both these changes in mean SD scores were statistically significant. The results from the comparison arm of the RCT were not presented.

Study 4 – Daley et al (2006) 'Exercise therapy as a treatment for psychopathologic conditions in obese and morbidly obese adolescents: A randomised controlled trial'.(126) The 81 study participants (11-16 years) were randomised to either an exercise therapy group, an exercise placebo group or usual care. The exercise interventions involved 3, one to one sessions per week for 8 weeks and then a home programme for a further 6 weeks. This exercise therapy group received a range of aerobic exercises during their sessions as well as

behavioural change counselling. The exercise placebo group had the same amount of exercise time but were instructed on less aerobic physical activities such as balancing and ball control. The usual care group received no intervention. The study's primary outcomes were changes in physical self worth (PSW) and in psychological conditions. Measurements were taken at baseline, 8 weeks, 14 weeks and 28 weeks. BMI SD score was a secondary outcome measurement.

At 28 weeks there was a statistically significant positive change in PSW as well as self-esteem and physical activity in favour of the exercise therapy group. There was no between group significant change in BMI SD scores.

All of these programmes were delivered within the UK NHS and therefore avoid the differences in cultural values, health care delivery and funding that can make comparisons with studies from the USA and other countries complex. All of these studies showed a small positive difference in the primary outcome measurement. All these studies would appear to have not dissimilar results to those of the SCOTT study in terms of change in BMI SD score. As discussed above the data presented did not enable direct comparison of the same clinical and statistical outcomes and only one study presented results of an RCT. All of these programmes were more intensive than the SCOTT programme and with the exception of the SHOT study, all involved more than one health professional in the programme delivery. The WATCH IT programme was delivered by non health care professionals but had an over-seeing team of a number of health care professionals. WATCH IT, MEND, and UCL programme, similar to SCOTT, targeted changes in diet, physical activity and sedentary behaviour, as well as all involving some elements of behavioural change techniques. All included some manner of seeing parents separately from the children to facilitate discussions on parenting attitudes and methods for reinforcing behaviour change, although in the SCOTT project this was a minimal one appointment. Even with the greater intensity and more

professionals involved in these three studies the effects on BMI SD score of the Edwards et al (2006) (130), the MEND programme (132) and the WATCH IT (131) was very similar to SCOTT. The SHOT study targeted changes in physical activity using an intensive programme delivered by one professional and showed similar changes in BMI SD score to the other four studies discussed.

At a national meeting of researchers in childhood obesity held in Leeds in June 2006, attended by representatives from all the research teams in studies 1-4 (126;130-132) and the SCOTT team, it was agreed that a change in BMI SD score of around -0.25 should be the target of any intervention. Indeed Reinehr and Andler (2004) have recommended that a decrease in BMI SD score of greater than 0.5 over about one year is required to produce significant changes in cardiovascular risk factors.(175) Hunt et al (2007) recommend a reduction in BMI SD score of between 0.5 to 0.6 to ensure a real reduction in percentage body fat.(174) None of these UK studies, including the SCOTT project, have reached this level of change in BMI SD score recommended by Reinehr and Hunt or the level of change reported by Epstein. This suggests that although all of these programmes have something to offer in approaches to treating childhood obesity that further research is required into the intensity, types and method of treatment programmes if changes in BMI SD score of -0.25 or greater are to be achieved.

7.2.3 Studies from outside the UK

Although relevance to the UK NHS was fundamental for reporting the outcomes of the SCOTT study comparison to other studies carried out beyond the UK is also noteworthy. Two studies from Australia and one from the USA that have been published in the last 12 months are discussed below.

Study 1 – McCallum et al (2006) 'Outcome data from the LEAP (Live, Eat and Play) trial: a randomised controlled trial of a primary care

intervention for childhood overweight/mild obesity.(127) This study compared an intervention involving 4 GP sessions over 12 weeks using solution-focused therapy with a control group who received no intervention. 163 children aged 5 years – 9 years 11 months, classified as overweight or obese (using IOTF cut off points) but with a BMI SD score of < 3 SD took part in GP surgeries across Melbourne, Australia. The primary outcome measure was BMI, measurements were reported for nine and 15 months.

At nine months the mean BMI SD score had reduced for the intervention group from 2.0 (0.5) at baseline to 1.96 (0.64) and changed for the control group from 1.9 (0.5) to 1.93 (0.57). While at 15 months the mean BMI SD score was 2.0 (0.68) for the intervention group and 1.92 (0.59) for the control group. There was no significant difference for the BMI SD score between the two groups at either measurement point.

Study 2 – Golley et al (2007) ‘Twelve-month effectiveness of a parent-led, family-focused weight-management program for prepubertal children: A randomized controlled trial’.(128) This study involved a parent-based intervention with parents randomised to either a parenting-skill training group, a parenting-skill training group with lifestyle education or a 12-month waiting list control group. 111 participants were recruited in two hospitals in Adelaide, Australia. The children were aged between 6 – 9 years, classified as overweight (using IOTF definition) with a BMI SD score < 3.5 . The primary outcome measure was BMI SD score, measurements were taken at six and 12 months. Metabolic variables were also measured as secondary outcomes.

The parenting skills programme was based on the Positive Parenting Programme and involved 4 weekly 2-hour group sessions, then 4 weekly individual sessions then 3 monthly telephone sessions. The parenting skills and lifestyle education had the same first 4 sessions

and this was followed by 7 lifestyle support group sessions. The waiting list control group had minimal contact over the 12 months.

For all three groups there was a significant decrease in mean BMI SD score from baseline to 12 months but no significant difference *between* groups at 12 months. For the parenting skills only group the mean BMI SD score changed from 2.76 (0.58) at baseline to 2.56 (0.79) at 12 months; the parenting skills and lifestyle education group changed from 2.74 (0.58) to 2.43 (0.68); and the waiting list group changed from 2.75 (0.39) to 2.60 (0.57) There was no difference in any metabolic variables between baseline and 12 months.

Study 3 – Savoye et al (2007) 'Effects of a weight management program on body composition and metabolic parameters in overweight children'.(129) This study recruited 209 children aged 8 to 16 years with a BMI above the 95th centile (USA growth charts) from the Yale Pediatric Obesity Clinic, New Haven, USA. Participants were randomised in a ratio of 2:1 into either the Bright Bodies programme or a control group seen every six months. The Bright Bodies programme consisted of twice weekly sessions for six months and then fortnightly sessions for six months. During the first six months the participants took part in two 50 minute exercise classes and one nutrition/behaviour modification session per week.

The primary outcome measurement was change in BMI and BMI SD scores were not presented in this paper. Outcome measurements including metabolic variables were measured at baseline, six and 12 months. Missing data was imputed and the authors presented 12-month data for 105 of the intervention group and 69 of the control group. The intervention group had a change in mean BMI of -1.7 at 12 months (change in weight $+0.3\text{kg}$) with the control group a change of $+1.6$ (change in weight $+7.7\text{kg}$). Insulin resistance (measured by HOMA) changed by -1.52 in the intervention group and $+0.90$ in the control group.

Study 1 (LEAP) which is a low intensity programme shows virtually no change in BMI SD score at 12 months. However study 2 shows a more promising change in BMI SD score particularly in the parenting and lifestyle group. Using parents as agents of change is discussed further in areas of possible research below. However study 3 reports a decrease in mean BMI of -1.7 and weight remaining virtually static at $+0.3\text{kg}$ at 12 months. The Bright Bodies programme was highly intensive involving weekly sessions over 6 months, including 2 exercise sessions and a nutrition/behavioural change session each week, followed by fortnightly sessions for a further 6 months. Perhaps this study demonstrates the level of intensity that is required to make clinically significant changes in BMI.

7.3 Main strengths of the present study

As discussed above the present quantitative study set out to be a well conducted RCT with a robust study protocol that followed the CONSORT guidelines.(122) The study had sufficient power to show the primary outcome of expected change in BMI SD score of -0.25 at six months. A clear and transparent record of all the eligible candidates was kept and a participants flow diagram is shown in the results in chapter 4. Randomisation procedures, concealment and blinding to study group are exceedingly important for any well conducted RCT.(122) This study's randomisation was carried out remotely using a computer-generated sequence by a statistician who knew only the participants name, study code, age and sex and was unaware of any clinical details. The postdoctoral research fellow who undertook all the outcome measurements remained blinded to group allocation until after completing her data analysis. Procedures were put in place to ensure that participants did not discuss their group allocation and that measurement sessions were held away from outpatient clinical areas. Contamination between the dietitians delivering the treatments was prevented by keeping all of the patient records of the NT group, study details and the NT protocol in separate and secure locations from the

SC dietitians. Discussions on the NT treatment and protocol were avoided between the two groups of dietitians until after all the 12 month follow up measurements were taken.

Attempts were made to ensure that the treatment protocol in SCOTT was delivered as described and stated. Interviews during the pilot and main study were taped and then independently analysed to ensure that the behavioural change and motivational interviewing techniques were being appropriately undertaken by both of the research dietitians (see appendix 6). These taped interviews showed that both dietitians scored highly in the techniques employed in the treatment protocol. Completion of the audit on the SC dietitians at the end of the study (see appendix 8b) was a helpful adjunct as it proved to be valuable in clarifying and detailing the treatment regimes used in the SC arm of the study and for triangulation with in the qualitative study.

In the qualitative study there was awareness at all stages of the importance of ensuring quality and transparency in the process.(184) Mentoring, peer reviewing and supervising was used throughout the development stage, interviewing, analysis and the development and interpretation of themes, concepts and stories. Most of the analysis of the data was carried out prior to the results of the quantitative study being known and this helped to lessen any effect of bias in the interpretation. The group studied were typical of the overall SCOTT group and in turn this group were typical of families referred for dietetic treatment in both centres.

By the nature of size and design both the quantitative and the qualitative studies reported in this thesis required to be carried out by a research team. This author had been involved in the project grant application, however once a project team was in place the team developed a close working relationship and ensured that there was on-going and regular communication. Full team meetings took place weekly initially and then a minimum of monthly throughout the funded

project time i.e. February 2003 to January 2006. The postdoctoral research fellow visited Edinburgh on a weekly basis, while regular emails and telephone conversations took place between all team members as necessary. The two research dietitians particularly remained in close contact and formed a mentoring type relationship discussing individual cases, debriefing from difficult cases, ensuring that the treatment protocol was being adhered to and giving each other peer support in the use of the behavioural change interviewing techniques. Although this author took a lead role this close working relationship was essential during the qualitative study when there required to be a high degree of agreement in the development of themes, the interview style followed, in the coding of the transcribed tapes and in the development of the final themes, stories and concepts.

7.4 Main weaknesses of the present study

It is possible that in the novel treatment employed in the present study there were too many new concepts and strategies implemented in the NT compared to the standard dietetic treatment. There were more appointments than typical, the appointments times were longer, the traffic light diet scheme was used and a variety of behavioural change techniques were employed. All of these were a substantial change from the typical dietetic care in the two centres and therefore make comparison of differences complex.

Although there was independent assessment of interviewer's techniques the study is still open to criticism that the protocol was not adequately followed as described. The possibility of errors in study outcomes using behavioural change and motivational interviewing techniques being due to insufficient training and skills of the interviewers has been raised by a number of commentators.(167) Due to the close peer reviewing and mentoring this author is confident that the protocol and behavioural change techniques as described in the protocol (appendix 1) were adhered to, however regular taping of

interviews throughout the study would have ensured that there was evidence of compliance with the treatment protocol.(214)

No measurement of in changes dietary intake/habits was undertaken. Such measurements may have given a valuable insight into the types of changes undertaken by the children and their families. It was also unfortunate that the 12-month data on physical and sedentary behaviours was not sufficiently complete to be included in the results.

The numbers of parents interviewed for the qualitative study were lower than those in the original proposed sampling matrix. Although sampling size in qualitative studies vary greatly and can be flexible the number of 17 was smaller than ideal. This has led to the results, concepts and theories being discussed tentatively and being used as pointers to other possible research. This smaller number was due to difficulties in finding parents able and willing to take part in the study in the time allowed as described in chapter 6. Therefore a longer period should have been allowed for the recruitment, interviewing and data analysis phases of the qualitative project (see section 7.5.6 below).

The inexperience of the interviewers in the qualitative study and the fact that the SCOTT research dietitians undertook the interviews could be seen as a weakness in the study. Although this has been reflected on and bias taken into account and lessened by peer review more information may have been obtained by more experienced, non-dietetic interviewers.

7.5 Suggested changes to studies for future research

As with all research project this was a learning experience for those involved and there are a number of aspects that could have been carried out differently and these are discussed below.

7.5.1 The pilot study

The project was funded without the NT programme being agreed or written and therefore a pilot of the protocol was necessary. Due to the overall time constraints of the project funding this led to the pilot study being a shortened version of the full novel treatment protocol and ran from April to June 2003 with 5 patients. It would have been more satisfactory if the pilot study had involved the full NT 8 appointments and had involved more than 5 patients. In reality this would not have made major differences to the overall protocol but there may have been some minor changes.

7.5.2 Structure of the novel treatment protocol

There are a number of points in the structure of the NT programme that could have been changed to improve the programme. The parent only interview at appointment 4 was unquestionably in the wrong place. The concept of speaking to parents without the child present was probably correct, however the child was only just getting into the routine of goal setting and of rewards/treats for meeting goals and then they did not see the dietitian for 6 weeks. The break in seeing the dietitian (at least at this point) broke the rhythm of the child setting their goals. This appointment would have been better later in the programme or as a further separate appointment not breaking the rhythm of the child's appointment sessions or as other groups in the UK have done by having a separate parent only group session.(130-132) A one off parents only group session or indeed a number of parents group session could be offered to the parents where there could be a chance of sharing common problems and solutions to some parenting issues. Parenting issues and targeting parents as agents of change are discussed in section 7.6 below.

The home visit was an interesting session and from the dietitians' point of view it was extremely enjoyable to see the family in a relaxed atmosphere in their own home. Looking through the food cupboards

was educational for the child and parent, allowing a good discussion on green, amber and red foods as well as on cooking methods. However many of the parents felt slightly anxious about this visit, particularly the thought of someone looking through their food cupboards. This visit typically took around an hour plus travel time and it would be difficult to justify the time and travel costs of such an appointment in a routine NHS programme. Alternatives to this appointment could be the use of plastic replica food models (a large selection) to go through the same procedure of discussing green, amber and red foods. A group visit to a supermarket could allow the children and parents to have the same discussion with the additional opportunity of discussing food labels.

It is not unreasonable to consider that more, regular appointments may have helped with the setting and reviewing of goals. A possible programme could have been one that had weekly sessions for the first four to six weeks, followed by fortnightly sessions for two months and then two further sessions a month apart.

Due to the nature of the funding grant from the CSO the project was only able to take outcome measurements up to one year from baseline. However as childhood obesity it is a chronic condition, follow up and monitoring may be important to help support children and families in keeping to lifestyle changes. Therefore on going brief weighing sessions that include encouragement to continue with lifestyle changes may enhance any programme and could be carried out by the school or practice nurse or even by telephone.

7.5.3 Content of the novel treatment programme

The treatment protocol used a guiding principle in the approach to the children choosing their own goals.⁽¹⁶¹⁾ This led to the majority of the children not actually reaching the programme's recommended targets of one red food per day, one hour of physical activity per day and no more than two hours of sedentary time per day. Though physical

activity and sedentary behaviour were maintained in the NT group the physical activity levels actually declined in the SC group. The fact that there was no statistically significant difference between the groups in reduction of BMI SD score would suggest that the NT group still required to make further lifestyle changes. Within the guiding principles of allowing the children to choose their goals the sessions could have been more directional with more emphasis on attaining the stated targets of the intervention.

Although there was a statistically significant difference between the NT and SC group at 6 months in overall physical activity level (cpm) and sedentary behaviour. The results in fact indicated not that the NT group became more active and less sedentary but that the SC group became even more sedentary. Therefore although in the qualitative study the NT parents discussed being aware of the children increasing their activity levels these increases were not sufficient to be recorded by the CSA monitors. Therefore more emphasis on the intensity of physical activity could be included and possibly, as with other interventions (131;132) organised activity group sessions added to the programme.

It may be that there should have been more emphasis and overall directing, as in the Epstein studies, to attain the programme's stated goals of change in diet, physical activity levels and sedentary behaviour.

7.5.4 Motivation to change

An audit of obesity referrals to the Dietetic Department at the RHSC, Edinburgh completed in 2003 (138) showed that 52% of patients failed to complete treatment.[†] A number of subsequent papers have also shown high drop out rates from childhood obesity treatment programmes.(215;216) The drop out at the end of the treatment phase of the SCOTT project was 44% for the NT group and 37% for the SC

[†] Defined as failing to attend (DNA) 2 consecutive outpatient appointments.

group. These figures are an improvement on the original RHSC audit of obesity care and may be an indication that families that positively opted into treatment are more likely to complete the treatment programme. Interestingly there was a higher completion rate in the SC group than the NT in the present study. Newman et al (2004) (162) noted that there is an expected higher attrition rate from behavioural change interventions, while Prochaska and Velicer (1997) (217) suggested that there is a 50% drop out rate from behaviour change interventions.

As discussed in chapter 3 it was felt that asking the parents if they wished to take part in the study would lead to self selecting motivated parents. However drop out rates of around 40% of 'motivated' patients entering a treatment appear to be high and indeed are higher than those reported by Epstein. However Savoye et al (2007) also reported a similar dropout rate to SCOTT at six months from their successful study.(129) Although the differences with Epstein's studies may be accounted for by the payment of deposits from the families, there is also a possibility that a formal consideration of the transtheoretical model of health behaviour change (stages of change cycle) may have affected the choice of individuals invited to take part in the study.(217) However, MacQueen et al (1999) did ask obese adult patients, prior to attending a London dietetic outpatient clinic, to complete a questionnaire aimed at assessing their position in the stages of change cycle. They found that using this questionnaire did not predict continuing attendance or success with weight loss.(142) Whereas Prochaska and Velicer (1997) have suggested that retention rates for health behaviour change programmes could be significantly increased by tailoring intervention strategies to the meet the individuals stage of change.(217) It could be that the expectations of 'filtering out' those not yet ready and willing to make changes would provide a highly motivated group in the present study was naive and that a process attempting to discern where parents were on the stages of change cycle could have led to a higher completion rate.

7.5.5 Outcome measurements

A number of measurements carried out for the SCOTT study were not included in this thesis, this was because the author believed that they did not add to the overall interpretations and discussions in this thesis. However, the original intention of carrying out some of these measurements was an attempt to give an indication in changes in estimated body fat or fat distribution in addition to BMI SD score which is itself a proxy for body fat. At the time of writing the original funding protocol (2001/02) arm to waist ratio had been suggested as an important outcome indicator of cardio vascular risk factors.(144) However since that time no other study has replicated these findings and arm to waist ratio is not widely used. Estimation of total body fat mass was carried out in the present study using a Tanita Body Fat Analyser model TBF 300. At the time of starting the study a validated equation to estimate body fat in children from the data given by the Tanita machine was not available. The measurements were taken in the expectation that over the period of the study a reliable equation may be formulated, unfortunately to date there has been no validated equation for use in children with the Tanita. As a result of the doubts over the validity of the Tanita estimates of fat mass and the arm:waist ratio these were not reported in this thesis. However estimation of body fat and importantly changes in body fat particularly visceral fat would add to the outcome measurements of any study into the treatment of childhood obesity. Total body fat can be successfully measured using DEXA scan, while visceral fat can be measured using CT or MRI scans and such measurements would have enhanced the results from the SCOTT project.

There are a number of cardiovascular risk factors associated with childhood obesity that may be affected by weight control. A number of biochemical indices had been in the original research proposal but the CSO as the funding body asked for these to be removed. In retrospect this was an unfortunate decision, as monitoring of these indices (particularly blood glucose, insulin, LDL cholesterol, HDL cholesterol

and triglycerides levels) and blood pressure would have given an interesting picture of clinical changes in children with BMI SD scores over 3.0. Although there was little change in the BMI SD scores monitoring such clinical changes would have been helpful information to demonstrate if there were health benefits from small changes in BMI SD scores in grossly obese children. Therefore the monitoring of blood pressure as well as fasting cholesterol, LDL, HDL, triglycerides, glucose and insulin levels should have been outcome measurements.

7.5.6 The qualitative study

There was a general underestimating of the amount of work required for the whole of the qualitative study. A CSO mini grant of £17 000 was probably not the most appropriate type of funding as the size of the grant restricted the length of funded time on the project. The number of parents interviewed aside, it would have been of great value to this project if focus groups of parents could have been held to expand and explore the themes and concepts raised from the individual interviews. This would have helped with triangulation and with confidence that saturation was reached in all of the themes and concepts. As discussed in chapter 5 there had originally been plans for focus groups to be held with *the children*. This would have been valuable for triangulation with the parents' views and could also have helped build upon and further develop the theories put forward by the WATCH IT group.(195;201)

7.6 Possible future research

The results from both the quantitative and qualitative studies described in this thesis have indicated several areas of possible future research. The fact that neither the NT nor the SC treatment produced a clinical or statistically significant change in BMI SD score showed that health professionals are still struggling to find the right answers. Present treatment programmes do not appear to be meeting the needs and requirements of obese children and their parents. Perhaps current

treatment programmes have started from the points of view of what the health professional and 'experts' consider to be the most relevant for successful treatment programmes. The concepts and stories developed from the qualitative study described in this thesis demonstrated the complexity and emotions of looking for/accepting help and of the treatment process itself. Therefore a well-conducted qualitative study that explored the thoughts of both obese children/adolescents and their parents on what they would wish from a treatment programme, how they could be engaged with both to start and to continue through a programme seems pertinent in order to design improved obesity treatment in future.

Taking into account the comments made in sections 7.4 and 7.5.6 above ideally such a study would incorporate individual in depth interviews carried out by non-health professionals with a reasonable number of children/adolescents and parents. Further focus group work with some of the same participants and new ones would help to ensure triangulation and help with developing robust theories and concepts. These in turn could be used to develop treatment protocols and training packages for health professionals.

Other childhood obesity treatment studies presently being carried out in the UK involve group sessions and indeed these may be cost effective, however there is still room for studies that look at interventions aimed at individuals. Most reviews have discussed the need for flexibility in strategies and therefore a successful individual programme is most likely to be still required. A study that followed on directly from the SCOTT project could take into account the comments made in sections 7.5.2 and 7.5.3. Slight changes to the structure such as more sessions closer together, more directional approach in guiding the children to make appropriate lifestyle changes, the use of organised physical activity sessions and more parent only interviews or concurrent parent only group sessions could be made. Further studies should look at changes in BMI SD score, weight, height, activity levels, quality of life

as well as blood pressure and the biochemical indices discussed in section 7.5.5.

Since the SCOTT project did not produce effective results this author would recommend that any follow on study was carried out in the same primary school aged group. However successful strategies should then be followed with intervention studies in teenage groups.

One of the most challenging aspects of treating childhood obesity is that there is not always an agreement to initiate change, how to make change or on motivation to change between the parent, the obese child or indeed the rest of the family. This raises the possibilities of two different types of future research. The first to study the differences in the stages of change between the 'lead' parent and the child and whether this can affect treatment compliance and outcome. Rhee et al (2006) (204) have shown that parenting styles can influence children's weight by the time they reach first grade at school in the USA. Golan in a recent review of studies comparing parent only sessions with child only or parent and child sessions has shown a significant improvement in BMI and weight outcomes of the children from the parent only groups.(206) The numbers in the studies discussed by Golan were small and there is a possibility of cultural differences however this author has found the concept of parents as the agents of change as very interesting and can see the possibilities of future research in this area in the UK.

7.7 Conclusions

The SCOTT quantitative study and the parent qualitative studies described in this thesis have added to the debate on how the treatment of childhood obesity can best be conducted and implemented within the UK NHS. The SCOTT study showed no difference in the primary outcome of BMI SD score between the NT and SC groups but did show differences between the groups in favour of the NT group for physical

activity levels at six months. The SCOTT project was the first well conducted RCT on the treatment of childhood obesity to be reported in the UK and does not compare unfavourably in terms of effect size to other UK studies that have reported pilot or interim results to date.(130-132) The results of both the quantitative and qualitative study have pointed to other possible useful areas of further research in the treatment of childhood obesity.

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LIST OF APPENDICES

APPENDIX 1 THE NOVEL TREATMENT PROTOCOL	III
APPENDIX 2 WRITTEN MATERIALS FOR THE NOVEL TREATMENT	XLVII
APPENDIX 3 PARENT AND CHILD INFORMATION SHEETS FOR SCOTT STUDY	LVI
APPENDIX 4 CHILD AND PARENT CONSENT FORMS FOR THE SCOTT QUANTITATIVE STUDY	LXIII
APPENDIX 5 PEDSQL QUESTIONNAIRES FOR CHILD AND PARENT PROXY	LXV
APPENDIX 6 ASSESSMENT FORM OF CORE INTERVIEWING SKILLS....	LXXIV
APPENDIX 7 POST PILOT SEMI STRUCTURED QUESTIONNAIRE, WITH PARENT AND CHILD ANSWERS	LXXVII
APPENDIX 8A STANDARD CARE POST STUDY AUDIT QUESTIONNAIRE	LXXIX
APPENDIX 8B SUMMARY OF ANSWERS TO AN AUDIT OF STANDARD CARE DIETITIANS' PRACTICE DURING THE SCOTT PROJECT.....	LXXXIV
APPENDIX 9 WRITTEN MATERIALS USED IN STANDARD CARE.....	XCI
APPENDIX 10 SUMMARY OF DATA DISTRIBUTION AND STATISTICAL TESTS PERFORMED FOR ALL STATISTICAL DATA PRESENTED IN THESIS	CII
APPENDIX 11 FIGURES SHOWING BOXPLOTS OF DATA DISTRIBUTION OVER TIME.....	CIX
APPENDIX 12 SAMPLE EDITED MATRIX CHART	CXX
APPENDIX 13 SUMMARY OF QUESTIONS FOR CRITICALLY APPRAISING QUALITATIVE RESEARCH	CXXII
APPENDIX 14 INFORMATION SHEETS FOR QUALITATIVE STUDY	CXXV
APPENDIX 15 CONSENT FORM FOR QUALITATIVE STUDY	CXXIX
APPENDIX 16 THEMES USED FOR CODING DATA IN NVIVO - BASED ...	CXXX

ON INITIAL 4-5 INTERVIEWSCXXX

APPENDIX 17 EVIDENCE TABLE FOR STUDIES DISCUSSED IN CHAPTER 6
..... CXXXIV

APPENDIX 18 PUBLISHED PAPERS CXXXVII

Appendix 1 The novel treatment protocol

It was an important part of this project to produce a comprehensive novel treatment manual. As has been described in the thesis the programme is based on work carried out by Epstein et al (1-3) however this team has never published a detailed treatment manual and therefore workers in other centres have been unable to replicate his work in full. The novel treatment was always intended to be a reproducible programme delivered by trained professionals within the UK NHS; for that reason it was considered essential to give a comprehensive, in depth description of the novel treatment programme as carried out in the SCOTT project. The protocol described in this appendix therefore gives a detailed explanation of each appointment in the programme and discusses how the dietitian could approach possible scenarios within each session.

All the written patient materials developed for the novel treatment programme and shown in appendix 2.

Description of Appointments in the Novel Treatment

Appointment 1 1 hour duration, in the OPD

No weight and height measurements taken

Greeting and opening phase

It is essential at this first stage of meeting the child and parent(s) that a relaxed and open atmosphere is established between the dietitian and the family; this would include introductions and some small talk. The dietitian should also explain that there is up to one hour for this first interview and this time is mainly for setting the scene and getting to know each other.(4-6)

Establishing Rapport

This will include asking the parent(s) and child to tell in their own words how they were referred to the clinic. Using phrases like

'It would be helpful to me if you could described how you were referred to this clinic'

If the parent has told most of the story it is important to include the child and ask if they have anything to add.

At this stage the child should be asked what they expected of this clinic appointment and the overall programme, and if they have any particular fears or worries. Once the child has had time to answer the question can be directed to the parent(s).

It is important for the dietitian to address any particular fears, worries or misconceptions at this point of the interview. One of the most common 'fears' that children have is that they will be given a diet or be told what to eat. Therefore, the dietitian should emphasis that the programme is patient centred, that is within a framework of targeted lifestyle behaviours the child decides their own goals. It is also good to tell the child and parent(s) that although they will be leaving this appointment with material to read and some

'homework' they will not be expected to make any immediate changes to their lifestyle, although they will be asked to think about possible changes they could make for the next appointment.

Establish Current Scenario

In a majority of interviews establishing the current situation will flow from discussions around the family's worries and expectations. The dietitian should summarise the whole treatment programme including number and duration of visits and structure of visits (i.e. home visit, parent(s) only interview) as well as the child setting their own lifestyle change goals.

By this point in the interview it will have been established that the child is attending due to concerns over their increasing weight. The **energy balance sheet** (see appendix 2) should be used to help explain to the child and parent(s) the concept that energy taken in food needs to be balanced with the energy used up in physical activities and it is when there is an imbalance that a person gains weight. This simple pictorial representation of energy balance on this sheet is very effective in explaining this concept to children. The dietitian should explain that the aim of the programme is weight maintenance with an expected growth in height thus leading to the child 'slimming' down and a decrease in the BMI.(7;8) This aim will be achieved by making lifestyle changes to diet (mainly focusing on high fat and high sugar foods, described in the **healthy eating plan** [see appendix 2] as 'red' foods), increasing physical activity and reducing "non active" time spent watching TV, videos, and playing computer games etc.(2;9;10) As emphasis will be on behaviour change and not weight change it should be explained that weight will only be measured 3 times over the 6 months of the programme. (For the purpose of the SCOTT study this excludes the baseline and follow up measurements – as the post doctoral research fellow took these as the study outcome measurements).

If not previously discussed then it is important that the dietitian explains the main principle of the treatment is to allow the child, with help from their family, to choose their own lifestyle changes over the coming sessions, that

none will be set at this interview and that they will not be given a 'weight reducing diet'. Some families appreciate an explanation that this is the main difference between this novel approach and the standard treatment. It should be highlighted that all the lifestyle changes will require family involvement and support.(1;7;8)

Assess Importance of Making Changes to Lifestyle

In the experience of the author, discussing the importance of change next flows very well with most clients. This should be directed to the child first and then to the parent (if both parents are present it would be usual to direct this question to the mother). This can be a difficult concept for younger children to understand and using the **importance sheet** (see appendix 2) may be introduced as

- *'It would be really helpful if you could give me an idea of how much you feel you need to make these changes which will help your tummy slim down. Using this chart where 0 means it is not important to you at all, 5 means important but not the most important thing to you and 10 is very important to you. Where would you put yourself on this line?'* Ask them to mark on the chart, this can be done by drawing a line, making a circle or colouring in the line.
- For older children you may wish to use language such as *"At the moment, how important is it to you to make some changes to your lifestyle?"* Ask them to mark on the chart.
- The same question should be asked of the parent(s) (mother) of how important is it for them that their child makes the necessary lifestyle changes. They should also mark a position on the sheet.

It is not unusual for the child and parent(s) (mother) to score the importance differently. It is necessary to acknowledge in a positive manner the position on the **importance sheet** that both the child and parent(s) (mother) have

made. Any issues that arise should be discussed before exploring the pros and cons of change.

Explore the Pros and Cons of Change

Using the **making your mind up sheet** (see appendix 2) it is very helpful to ask the child to think about the good things and not so good things about making changes to their lifestyle. This exercise helps both the child and the parent(s) to focus on the positive reasons for making lifestyle changes.(5;6) For younger children this may need to be simplified even further.

- “*What would be the good things about making some of these lifestyle changes and your tummy becoming slimmer?*”
- Elicit, record and summarise.
- “*What would be not so good about making some of these lifestyle changes?*”
- Elicit, record and summarise these slowly.
- Summarise both sides of the change position using the child's own words.

Ask the parent(s) for their comments on what the child has said.

Problem Solving Barriers to Change

Discussions around barriers to lifestyle changes for the child and/or family should be explored and the ‘cons of change’ side of the making your mind up sheet will influence this discussion. It is helpful to take each perceived ‘problem’ in turn and discuss possible ways in which they could be overcome.(5;6) For example a child who has concerns over ‘*never being able to eat crisps again*’ it is essential to explain that they will not have to give up all crisps and that they will be in control of their own goals during the programme. Past failed attempts should also be discussed to help explore reasons why they failed and to draw out any lessons that could be learnt.(5;6)

Typical Day

At this stage it is good to ask the child to give an outline of a typical day in their own words by asking them to *'tell me a typical Johnny day and tell me where food, active time and non active time fit in'*. The child should be allowed to tell their own story with only occasional prompts from the dietitian.(4;5) In practice many parents help if the child appears stuck. The dietitian should record this using the **typical day sheet** (see appendix 2).

Establishing Support

At this point the child, parent(s) and other family members should be given the **healthy eating plan, activity sheet and non-active sheet** (see appendix 2) to be read at home. In practice we have found that not all families do this jointly and therefore the value of the child and parent(s) taking the time to read the information together should be emphasised. This information is used to help reinforce the educational aspect of the programme and the discussions that have previously taken place on the significance of energy balance on weight management. It is valuable to emphasise the overall longer-term goals of lifestyle change –

- no more than 1 red food per day,
- to increase physical activity initially to 30 minutes of moderate-vigorous activity and then to 60 minutes at least 5 times per week,
- non active time should be restricted to no more than 2 hours per day or the equivalent of 14 hours per week.(7)

It should be explained to the child and parent(s) that they need to record what the child eats and drinks, their physical activity and non-active time for 7 days before the next session, (this is usually best in the second week). It should be discussed how this recording is helpful for raising self-awareness of present lifestyle behaviours.(1;2;5) The **lifestyle diary** (see appendix 2) should be given out and the printed examples shown. Who actually fills out the charts is not as important as the discussion and interaction between parent(s) and child. However, if the writing abilities allow it the child should be

encouraged to fill out the form to help them with ownership. These recordings should be completed on a daily basis (possibly after school and later at night) by the child and parent(s) reviewing the day together. Again the idea of doing this task collectively should be stressed.

The notion of the child choosing their own lifestyle change goals and being rewarded for meeting these goals is central to the whole programme.(1;2) The child and family are more likely to continue with the goals if these have not been imposed but self-chosen.(5;6) This important concept should be explained to the child and family and the child should consider 2-4 lifestyle change goals for the next appointment. These should be based on the discussions that have taken place, the written information given and the lifestyle recording. These goals should be small and realistic (SMART goals – see interview 2).(4-6) These can be discussed with their parent(s) prior to the next appointment and any possible ideas could be noted in the lifestyle diary. They are also asked to discuss as a family possible rewards (these should be small and non food) to be given by the parents to the child for attaining their goals.

It is also good to let the child take home the **energy balance sheet**.

Ending the Interview

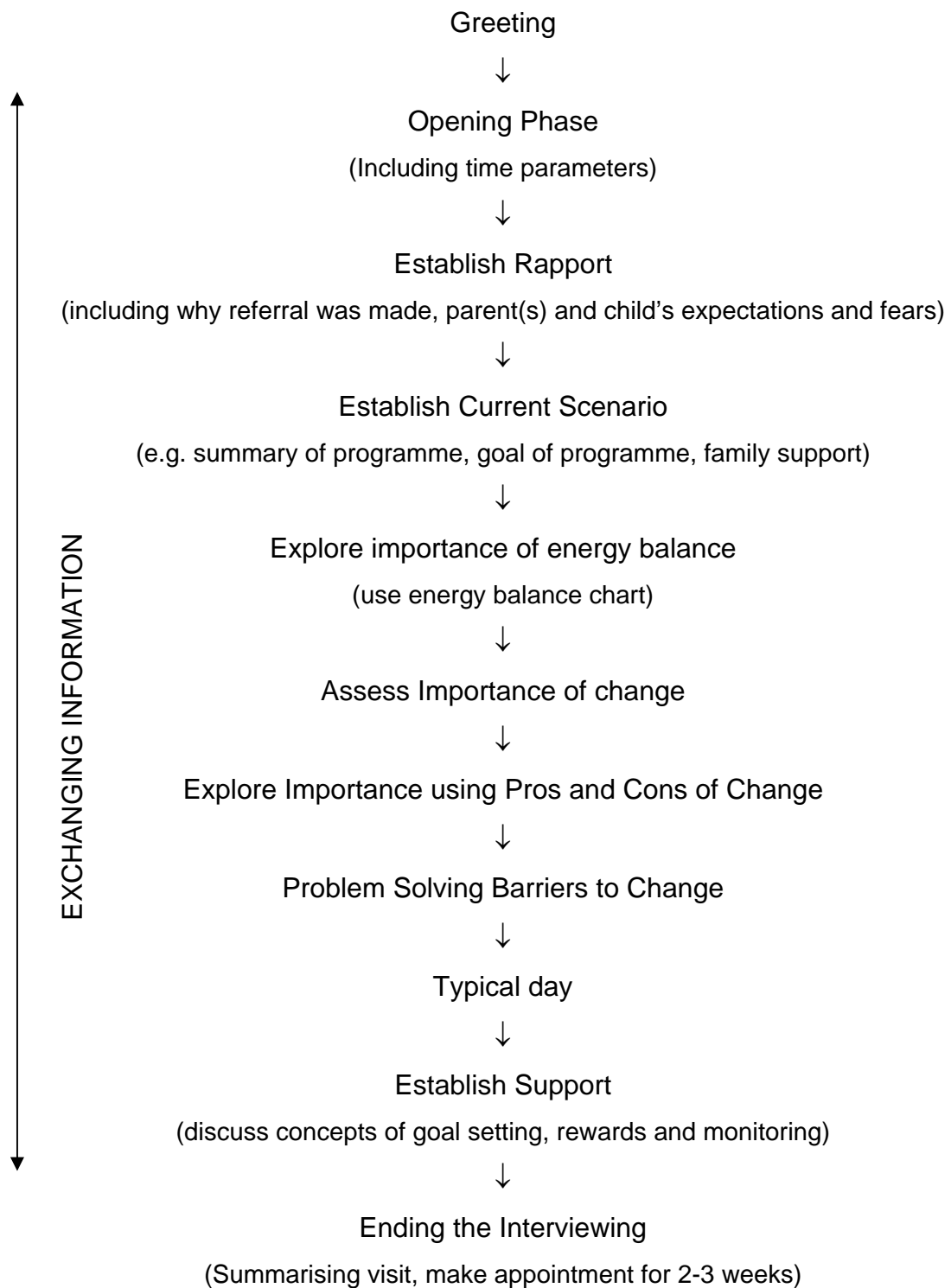
- Summarise the discussions in appointment one
- Request that the child and at least one parent read the written information together before the next appointment
- Reiterate the importance of recording current behaviour in the lifestyle diary and of doing so jointly
- Suggest that the child and parent jointly consider possible lifestyle change goals and a reward before appointment 2
- Ensure the child has
 - Healthy Eating Plan
 - Be Active!
 - Don't just sit there!

My lifestyle diary

Energy balance sheet

- Arrange next appointment for 2-3 weeks time at the OPD

Figure 1 - Summary of Appointment 1



Appointment 2 2-3 weeks after appointment 1

30 minutes duration, in OPD

Weight and height measured

BMI calculated and plotted

Greeting and opening phase

As in appointment one it is important to keep this first stage of the meeting relaxed with an open atmosphere.(4;5) The dietitian should explain that this interview will take up to 30 minutes.

Weight is measured at this appointment, as this could be an area of conflict it is best carried out after the greeting by the dietitian rather than by other staff. No judgements should be made on the present weight but it should be used to reinforce the need to make lifestyle changes. Any concerns arising over the weight measurement should be addressed before proceeding. The child and parent(s) should also be reminded that the aim of the intervention is weight maintenance with growth in height and thus the child slimming down.(7;8)

Summary of appointment 1 and review the lifestyle diary

It is important at this stage of the interview to ask the child and parent if they have read through the materials (**healthy eating plan, activity sheet and non active sheet**) together. After dealing with any points of discussion that arise from the written information the lifestyle diary should be reviewed. As the concept of recording lifestyle is fundamental to the programme, the dietitian should ensure positive reinforcement is given by taking time to read through the recordings, to make appropriate comments on entries, to stamp 'well done' on a number of pages and to praise the child for carrying out the task.

Not all families will have either read the materials or filled out the diaries together and this is an ideal opportunity to emphasise the value of the child and parent(s) as well as other members of the family working together.

Explore Options for change

Discussions on possible lifestyle changes that the child feels confident to make for the next appointment flow well from reviewing the lifestyle recordings. The concept of goal setting should be re-explained to the child and parent(s).(1;2) It is essential that ideas come from the child, with where necessary some help from the parent(s).(5;6). Time should be allowed for the child to identify a range of possible options. When setting goals the dietitian should not be afraid of periods of silence while the child thinks of possibilities, in practice parents often help their child to explore options. Where the child is struggling to come up with any options the dietitian can refer them to the **energy balance sheet** and to their lifestyle recordings. For some people it may be necessary to provide some suggestions by saying “*some families have found it useful to*”, although in practice parent(s) usually help a child who cannot think of any suggestions themselves. If the child has great difficulty suggesting options and setting goals then the focus of the consultation will be recognising and dealing with resistance, it can be a good idea to revisit their importance sheet as well as the pros and cons of change.(4-6)

While discussing goals it should be emphasised to the child and parent(s) that the long term goals for lifestyle change are up to 1 ‘red’ food per day, increasing physical activity to a short term target of a minimum of 30 minutes of moderate intensity activity increasing long term to 60 minutes per day at least 5 days each week and limiting non active time to less than 2 hours per day.(7)

Goal Setting/Rewards

The dietitian should now help the child and parent(s) to use these options to set appropriate goals for the next appointment. 2 – 4 goals for lifestyle changes should be set using the SMART principles (i.e. specific, measurable, achievable, realistic and time-phased). As each goal is being discussed it is important to also review possible barriers to change e.g. parties, holidays, wet weather. The goals can then be refined to make them more realistic (4-6). For example a child who has identified a goal of ‘*never eating chocolate*

again' may change this to *'only eating sweets at the weekends'* and that during holidays this goal may have to be altered. The dietitian should explore the child's confidence in their ability to achieve their goals by asking for example *'how sure are you that you will be able to keep sweeties to the weekend only?'* (5;6). It should be explained that the child receives their reward only if 100% of goals are met. This connection between goals and rewards can help some children to be more realistic in setting goals. It should be explained that if the child does not meet 100% of their goals these can be revised and new ones set. It can also be helpful at this stage to look back at previous attempts to change to learn what was good and what was difficult.

Rewards are very important to increasing and maintaining the child's motivation. Rewards should involve praise and encouragement daily from family members.(1;2) In addition, the child will be rewarded for reaching 100% of their goals. This reward will be discussed and agreed during the appointment between the child and parent(s) and will be written on the goal sheet. The dietitian needs only to emphasise that the reward should be small, affordable and not food related e.g. magazine, rental of a video, staying up late one night per week. The parent(s) must agree to give the child this reward if the child reaches 100% of their goals. And the child needs to be aware that they will not receive their reward unless they achieve all their goals. The child should only receive the reward after the next clinic appointment when discussion and agreement on whether the goals have been achieved will take place between the dietitian, child and parent(s).

The goals and reward should then be recorded on the **goal-setting sheet** (see appendix 2) and a 'contract' signed between the child, parent(s) and dietitian.(1) Explain that placing the goal sheet in a prominent place such as fridge or notice board will help remind the whole family about the child's goals.

Establish support /Lifestyle diary

The significance of family support should be emphasised as well as the need for the whole family to make changes.(1;7;8) Ways in which the family can

help the child achieve their set goals can be explored e.g. if sweets are only to be taken at the weekend then other family members do not offer them to the child during the week or mum/gran does not buy them.

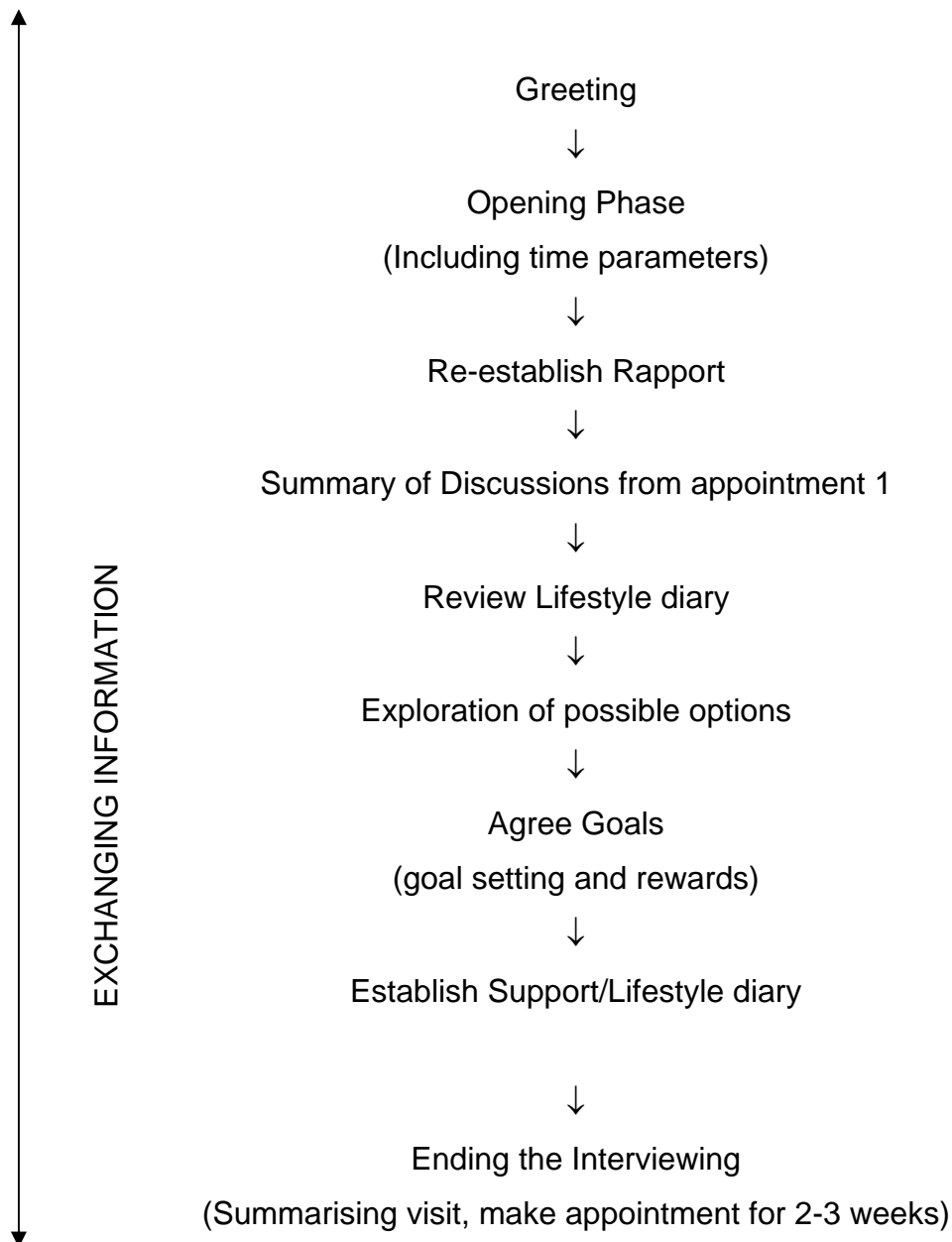
The child and parent(s) should be asked to record the lifestyle diary for 7 days (1;5); a new **lifestyle diary** should be given to the child. Who actually fills out the charts is not as important as the discussion and interaction between parent(s) and child. However if the writing abilities allow it the child should be encouraged to fill out the form to help them with ownership. These recordings should be completed on a daily basis (possibly after school and later at night) by the child and parent/s reviewing the day together. Again the idea of doing this task collectively should be stressed.

The child and parent(s) should be made aware that the recording continues to aid them in examining present habits and now also assists in the monitoring of the child's goals. It should also be used to identify further behaviours for change and additional goals that will be set at the next appointment.

Ending the Interview

- Summarise the discussions in appointment two
- Confirm the set goals and reward
- Reiterate the importance of recording lifestyle diary and of doing so jointly
- Suggest that that the child and parent(s) jointly consider possible Further lifestyle change goals and a reward before appointment 3
- Ensure the child has
 - Goal sheet
 - My lifestyle diary
- Arrange next appointment for 2-3 weeks time at the OPD

Figure 2 – Summary of appointment 2



Appointment 3 2-3 weeks after appointment 2
30 minutes duration, in OPD

No weight and height measured

Greeting and open phase

By appointment 3 there should be a good rapport between the dietitian and family and the opening remarks should be kept friendly and informal. The dietitian should state that the interview will last up to 30 minutes. The child and parent(s) should be asked how they feel they have been progressing since the last appointment and if they have any concerns they wish to discuss first. All comments and concerns should be addressed before continuing with the remainder of the interview.

Review goals and monitoring charts

The lifestyle diary should be reviewed to ascertain whether the set goals have been met. The dietitian should reinforce the importance of keeping the lifestyle diary and achievement of goals by reading it thoroughly, stamping 'well done' where appropriate and praising the child for recording in the diary. Comments on the substance of the recording should be made but kept non judgemental. While reviewing the diary the dietitian should check if the goals have been met and confirm this with the parent(s). There are two possible scenarios in this visit, which will determine the content of the remainder of the visit:

1. If the child and parent(s) agree that all the goals have been met and this is reflected in the recordings then the child should receive their agreed reward. The child should then be asked to explore further options for extending their goals. They should keep their present goals and can either expand these e.g. a goal of eating fruit every second day could be increased to eating fruit every day. Or new goals could be added (see below)
2. If they have not met 100% of their goals then they should be praised for those goals they have achieved but should not be given their reward from

their parent(s). It is essential to look at the possible reasons why the goals have not been achieved and to review the barriers to making lifestyle changes.(5;6) The present goals should be refined or completely new ones made.

Goal setting (continuing and new)

When setting further goals the dietitian should not be afraid of periods of silence while the child thinks of possibilities, in practice parent(s) often help their child to explore options. If necessary the dietitian can use the energy balance chart to help the child think of goals. If the child has great difficulty suggesting options and setting goals then the focus of the consultation will be recognising and dealing with resistance, it can be a good idea to revisit their importance sheet as well as the pros and cons of change.(4-6)

While discussing further goals it should be emphasised to the child and parent(s) that the long term goals for lifestyle change are up to 1 'red' food per day, increasing physical activity to a short term target of a minimum of 30 minutes of moderate intensity activity increasing long term to 60 minutes per day at least 5 days each week and limiting non active time to less than 2 hours per day as noted earlier.(7)

As the next appointment with the child is 6 weeks away (appointment 4 is parent(s) only) it could be suggested that the child may wish to have a staged goal e.g. in the first two weeks decrease TV watching and computer playing to 4 hours per day then in the next four weeks limit the time to 2 hours per day.

As in appointment two the dietitian should explore the child's confidence in their ability to achieve their new goals by asking for example *'how sure are you that you will be able to keep sweets to the weekend only'*.(5;6) The relationship between meeting 100% of their goals and receiving their agreed reward (see below) should again be emphasised. This connection between goals and rewards can help some children to be more realistic in setting goals.

The new goals should be noted on a new **goal sheet** and two new rewards (small, inexpensive and non food) should be agreed between the child and parent(s) and recorded on the sheet. For the child to get the reward they should be aware that they must meet 100% of their goals, these will be reviewed with the parent(s) in appointment 4 and then with the parent(s) and child in appointment 5 (home visit).

Establish support/agree on monitoring

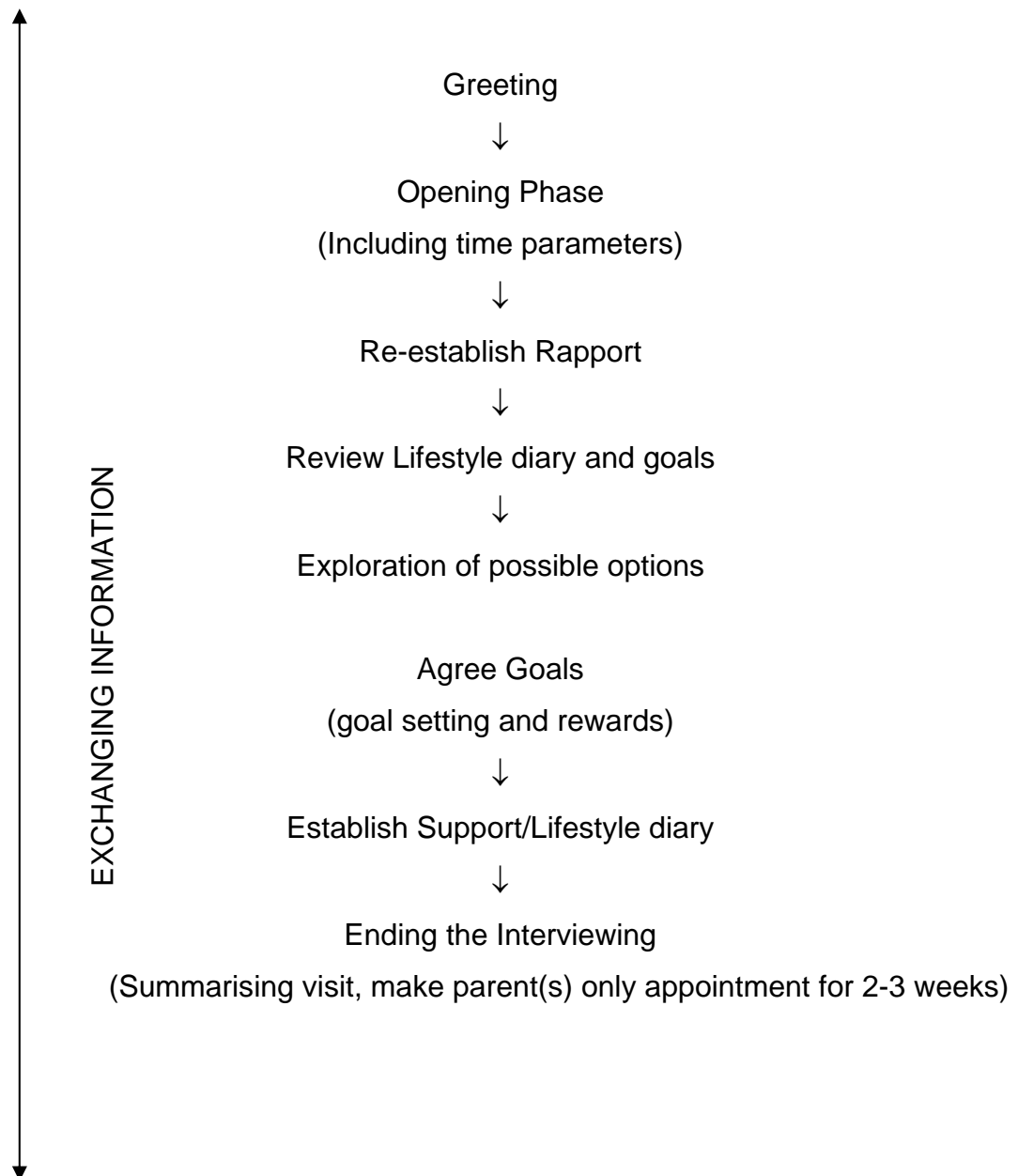
The family should be given a further lifestyle recording diary for 1 week. As previously discussed it is good to stress the importance of these being filled out by the child and parent(s) together.

Ending the Interview

- Summarise the discussions in appointment three
- Confirm the set goals and reward
- Reiterate the importance of recording lifestyle diary and of doing so jointly
- Suggest that the child and parent(s) jointly consider possible further lifestyle change goals and a reward before appointment 5
- Ensure the child has
 - Goal sheet
 - My lifestyle diary (1 week supply)
- Arrange next appointment for parent(s) only in 2-3 weeks time at the

OPD

Figure 3 - Summary of Appointment 3



Appointment 4 2-3 weeks after appointment 3
30 minutes duration in OPD

This session will involve the parent(s) and dietitian only.

Greeting and opening phase

By this stage in the programme there should be a good rapport between the dietitian and parent(s) and this session should be very relaxed and informal. The dietitian should remember to tell the parent(s) that this session will last up to 30 minutes. Then explain that the purpose of this appointment is to give the parent(s) the opportunity to ask questions, express comments and concerns about the child's goals and their progress with lifestyle changes. Before proceeding the dietitian should address any such concerns or comments.

Review goals and monitoring charts

The lifestyle diary should be reviewed to ascertain whether the set goals have been met. The dietitian should reinforce the importance of keeping the lifestyle diary and achievement of goals by reading it through thoroughly and commenting on the contents to the parent(s). Comments on the substance of the recording should be made but kept non judgemental. While reviewing the diary the dietitian should check if the goals have been met and confirm this with the parent(s). If the goals have been met then the parent(s) should give the agreed reward to the child. If they have not been met then discussions should take place on why not and the barriers to making the changes.(5;6)

Decisional balance

This session is a good opportunity to help focus the parent(s) on their reasons for wanting their child to make lifestyle changes. It is good to revisit the original **making your mind up sheet** completed in appointment 1 and ask the parent(s) if they have anything extra to add. Parent(s) often feel more able to explore subject areas that they felt unable to do so in appointment 1 when the child was present, such as concerns about their child's self esteem.

Exploration of options

It is important to re-emphasise the main long term goals of the programme i.e. up to 1 'red' food per day, increasing physical activity to a short term target of a minimum of 30 minutes of moderate intensity activity increasing long term to 60 minutes per day at least 5 days each week and limiting non active time to less than 2 hours per day.(7)

Discussions around long-term behavioural modification should then lead on to concentrating on parenting strategies and skills for supporting and maintaining change as well as managing behaviour and setting boundaries. Emphasis should be on whole family involvement (1;7;8) and ways in which parental support can be given to the child should be discussed e.g. parents and particular adult members of the family can;

- lead by example,
- be consistent in situations around food and activities,
- set boundaries,
- limit pocket money,
- find reasons to praise the child's behaviour and give them positive feedback, instead of rewarding with food use e.g. outings, CDs,
- establish family meals and snacks,
- decide when and what food is offered and let the child decide if they will eat it,
- remove temptation.(7)

Some parent(s) find it useful to hear how these strategies have been helpful to other families and parent(s). For some parent(s) this is a good opportunity to introduce discussions on coping with 'tricky' situations (see below) and why it is important for the parent(s) to consider how to deal with these occasions (5;6). If appropriate the parent(s) should be given the '**tricky situation' sheet** (see appendix 2) to take home and read. In this context 'tricky' situations refer to situations where the child and family may find it particularly difficult to keep to the set goals e.g. parties, family gatherings, rainy days and holidays. The '**tricky situation' sheet** gives examples of

tricky situations and also asks the child to consider planning for such occasions e.g. when going to a party saving up red foods for 3-4 days before hand. If these are not discussed at this appointment then they should definitely be introduced by appointment 6.

From the above discussions it is important that the parent(s) leaves with an overview of longer term goals for the families' and child's lifestyle changes and with possible strategies for coping with these. It is also ideal to mention to the parent(s) that as part of the home visit it is helpful for the family and dietitian to take the opportunity to look through the kitchen cupboard to discuss the difference between red, amber and green foods and to review food labels.

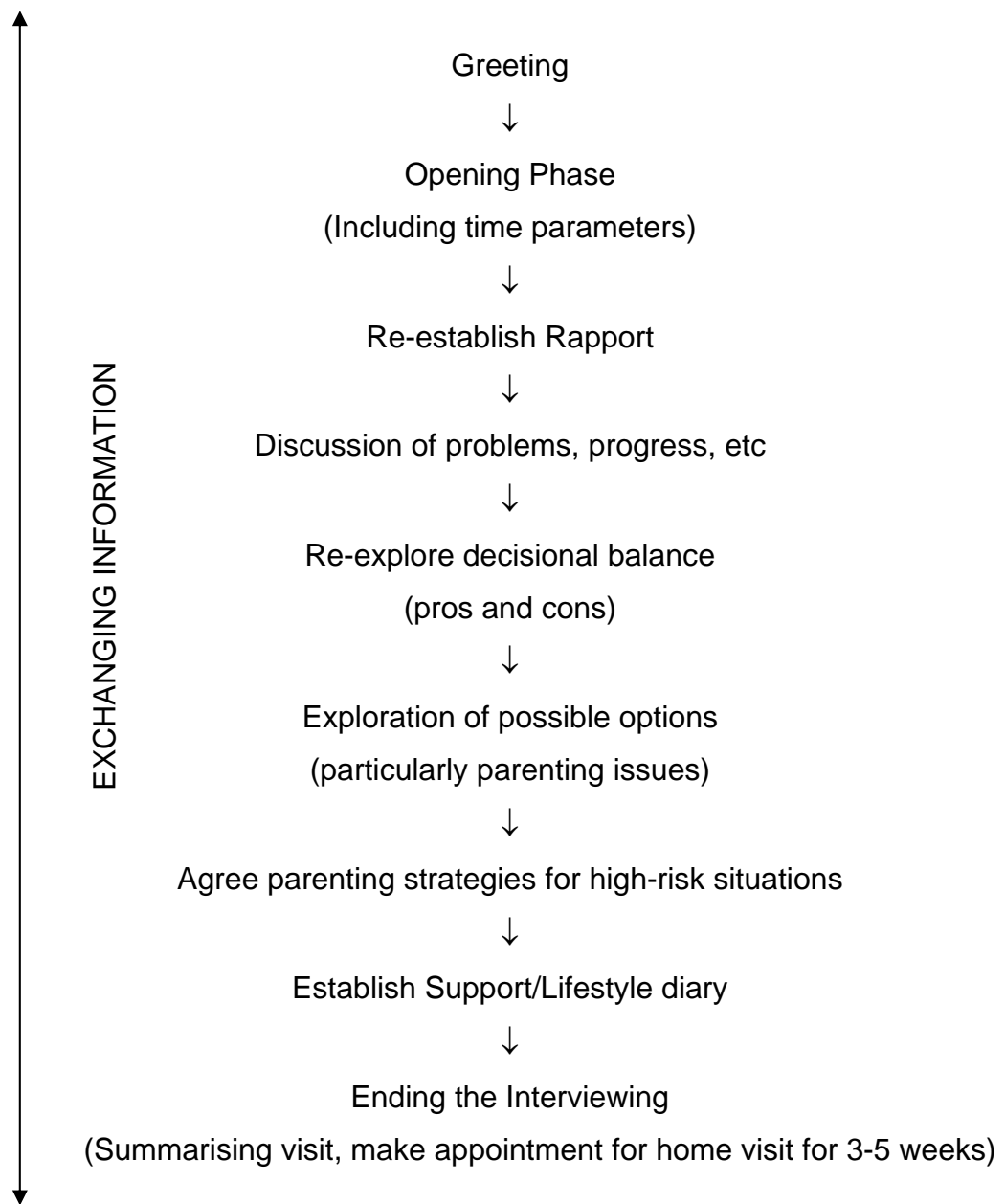
Monitoring strategies

Remind the parent(s) to continue with the lifestyle diary with the child for 2 weeks before the next appointment. Once again emphasise the importance of doing this together.

Ending the Interview

- Summarise the discussions in appointment four
- Confirm the goals and reward set in appointment three
- Reiterate the importance of recording lifestyle diary and of doing so jointly
- Suggest that the child and parent(s) jointly consider possible further lifestyle change goals and a reward before appointment 5
- Give the parent(s) further lifestyle diaries (2 weeks supply)
- Give out the 'tricky' situation sheet (if applicable)
- Arrange next appointment for 3-5 weeks time (aim for week 10 but definitely by week 12) at family home

Figure 4 - Summary of appointment 4



Appointment 5 3-4 weeks after appointment 4, aim for week 10 but definitely by week 12

Home visit up to 1 hour plus travel time

No weight and height measured

Opening phase and re-establishing rapport

Most families are more relaxed in their own home than at clinic, therefore re-establishing rapport by this stage of the programme should be easy. The dietitian should state that they have up to an hour and take time to meet other family members and listen to any short stories of what the child has been doing since they last met at appointment 3.

Summary of previous appointments

The home visit should be used to summarise all of the previous advice and behavioural change issues, as well as discussing with the child, parent(s) and family members the child's progress with lifestyle changes and for the dietitian to view family dynamics. The precise order of this interview is usually dependant on the child and family, many children are anxious to review their goals as it is six weeks since they have seen the dietitian, if this is the case this should be done first.

Food cupboards

This home visit is an ideal opportunity to look through the food in the cupboards and fridge and offer appropriate advice e.g. using semi skimmed milk instead of full fat milk as well as helping the family decide whether foods are red, amber or green. The child may also wish to show the dietitian some of the items they use for physical activities e.g. bike, dance mat.

Review goals and monitoring charts

This will involve reviewing the lifestyle diary and whether the goals have been met. The dietitian should reinforce the importance of completing the lifestyle diary by reading it thoroughly, stamping 'well done' where appropriate and praising the child for recording in the diary. While reviewing the diary the

dietitian should check if the goals have been met and confirm this with the parent(s). The importance of continuing with recording in the lifestyle diary should be emphasised. There are two possible scenarios in this visit, which will determine the content of the remainder of the visit:

Agree new and continuing goals

1. If the child and parent(s) agree that all the goals have been met and this is reflected in the recordings then the child should receive their agreed reward. The child should then be asked to explore further options for extending their goals. They should keep their present goals and can either expand these e.g. a goal of eating fruit every second day could be increased to eating fruit every day. Or new goals could be added.

2. If they have not met 100% of their goals then they should be praised for those goals they have achieved but should not be given their reward from their parent(s). It is important to look at the possible reasons why the goals have not been achieved and to review the barriers to making lifestyle changes.(5;6) The present goals should be refined or completely new ones made.

When setting further goals the dietitian should not be afraid of periods of silence while the child thinks of possibilities, in practice parent(s) often help their child to explore options. If necessary the dietitian could use the energy balance chart to help the child think of goals. If the child has great difficulty suggesting options and setting goals then the focus of the consultation will be recognising and dealing with resistance,(5;6) it can be a good idea to revisit their importance sheet as well as the pros and cons of change.

While discussing further goals it should be emphasised, as described above, to the child and parent(s) that the long term goals for lifestyle change are up to 1 'red' food per day, increasing physical activity to a short term target of a minimum of 30 minutes of moderate intensity activity increasing long term to

60 minutes per day at least 5 days each week and limiting non active time to less than 2 hours per day.(7)

As the next appointment with the child is in 4 - 5 weeks, it could be suggested that the child may wish to have a staged goal e.g. in the first two weeks decrease TV watching and computer playing to 4 hours per day then in the next 2 weeks limit the time to 2 hours per day.

As in previous appointments, the dietitian should explore the child's confidence in their ability to achieve their new goals by asking for example *'how sure are you that you will be able to keep sweets to the weekend only?'*.(5;6) The relationship between meeting 100% of their goals and receiving their agreed reward (see below) should again be emphasised. This connection between goals and rewards can help some children to be more realistic in setting goals.

The new goals should be noted on a new **goal sheet** and a new reward (small, inexpensive and non food) should be agreed between the child and parent(s) and recorded on the sheet. For the child to get the reward they should be aware that they must meet all of their goals over the next 4 – 5 weeks and this will be reviewed at the next appointment.

Establish support/agree on monitoring

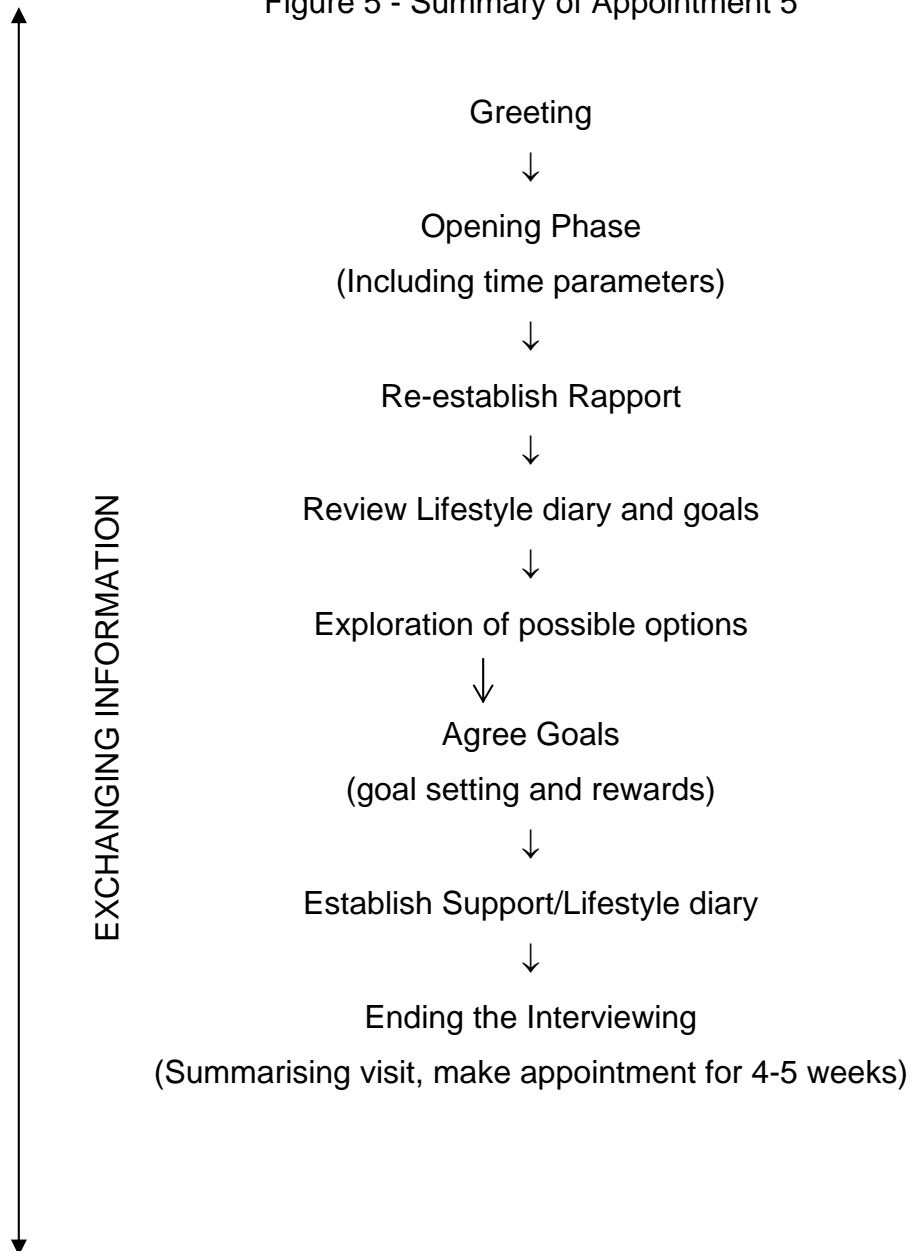
The family should be given a further set of lifestyle diaries for 2-3 weeks for the next appointment. As previously it is good to stress the importance of these being filled out by the child and parent(s) together.

Ending the Interview

- Summarise the discussions in appointment five
- Confirm the set goals and reward
- Reiterate the importance of recording lifestyle diary and of doing so jointly
- Suggest that the child and parent(s) jointly consider possible further lifestyle change goals and a reward before appointment 6

- Ensure the child has
 - Goal sheet
 - My lifestyle diary (2-3 weeks supply)
- Arrange next appointment for 4-5 weeks time at the OPD

Figure 5 - Summary of Appointment 5



Appointments 6 4-5 weeks after appointment 5
30 minutes in duration in OPD

Weight and height measured
BMI calculated and plotted

Opening phase and re-establishment of rapport

After greeting and opening phases the dietitian should explain that the interview will last up to 30 minutes and that the last three appointments of the programme will concentrate on strategies to help maintain lifestyle changes once the programme has finished. These will include the setting of long-term goals, monitoring and support as well as discussing coping strategies for 'tricky' situations.

Weight and height are measured at this appointment. As this could be an area of conflict the dietitian rather than other staff should carry it out after the greeting. No judgements should be made on the present weight but it should be acknowledged if there have been changes or not and indeed if this has been an increase or decrease. The parent(s) in particular may wish to discuss the weight and any concerns they have, however the measurement should be used to positively reinforce the need to make lifestyle changes. The child and parent(s) should also be reminded that the aim of the intervention is to maintain weight while continuing to grow in height.(7;8)

Review goals and lifestyle diary

This will involve reviewing the lifestyle diary and whether the goals have been met. The dietitian should reinforce the importance of continuing to monitor, record and meeting goals by reading the diary thoroughly, stamping 'well done' where appropriate and praising the child for recording in the diary. While reviewing the diary the dietitian should check if the goals have been met and confirm this with the parent. If the child has met 100% of their goals then they should receive their agreed reward, if they have not then they should be commended for meeting those they have however they should not get their reward.

Reviewing importance

Before moving on to discuss longer-term goals, the interview should revisit the child and parent's importance for the changes using **the importance sheet**. Importance should be reviewed at this interview, as it is more than half way through the programme and should be used to further reinforce the changes of those who are doing well and to help refocus those who have been having problems sticking to their goals. This conversation will be influenced by the child's weight, for example, a child who has put on 5kg since appointment 2 will not be in as positive a frame of mind as one who has maintained their weight or even lost 1-2kg.

The question should be directed to the child first and then to the parent(s) (if both parents are present it would be usual to direct this question to the mother). This can be a difficult concept for younger children to understand and using the importance sheet may be re-introduced as

- *'You might remember we have done this before, well it would be really helpful if you could give me an idea of how much you feel that you should keep going with the lifestyle changes you have made over the last few months. Using this chart where 0 means not at all, 5 means important but not the most important thing and 10 is very important. Where would you put yourself on this line?'* Ask them to mark on the chart.
- For older children you may wish to use language such as *'At the moment, how important is it to you to keep going with the lifestyle changes you have already made?'* Ask them to mark on the chart.
- The same question should be asked of the parent(s) (mother) of how important is it for them that their child continues with the necessary lifestyle changes. They should also mark a position on the sheet.

Acknowledgement should be made of the position on the **importance sheet** that both child and parent(s) (mother) have made. Any particular issues that

require discussion should be dealt with at this point in the interview. There are a number of possible scenarios in this visit, which will determine the content of the remainder of the visit; an attempt was made, during the development phase of the treatment programme, to anticipate these and devise strategies for them, the following are the three most likely:

Agree continuing and longer-term goals

Situation 1.

A child who has met all their goals on a regular basis and marks their importance for change close to the previous score. This child is ready to explore how to convert their present goals into long term, sustainable goals. This could involve either expanding present goals e.g. a goal of eating fruit every second day could be increased to eating fruit every day, or modifying present ones e.g. playing football 5 times a week could be change to a more realistic long-term goal of playing 3 nights a week in summer and in doors twice a week during the winter months.

When setting further goals the dietitian should not be afraid of periods of silence while the child thinks of possibilities, in practice parent(s) often help their child to explore options. If necessary the dietitian could use the energy balance chart to help the child think of goals. While discussing long term goals it should be emphasised again to the child and parent(s) that the long term aims for lifestyle change are no more than 1 'red' food per day, increasing moderate physical activity to a minimum of 30 minutes per day and now trying to increase this to 60 minutes of moderate intensity activity at least 5 days per week and limiting non active time to less than 2 hours per day.(7)

Situation 2.

A child who has not been meeting all their goals but still marks their importance for change close to the previous score. It is important to look at the possible reasons why the goals have not been achieved and to review the barriers to making lifestyle changes.(5;6)

Situation 3.

A child who has not been meeting all their goals and marks their importance for change significantly less than the previous score.

In situations 2 & 3 it is important to return to the 'making your mind up sheet' and explore the pros and cons for change (see below).(5;6)

Explore the Pros and Cons of Change

Using the making **your mind up sheet** it is very helpful to ask the child to think about the good things and not so good things about making changes to their lifestyle. For younger children this may need to be simplified even further.

- *“What would be the good things about making some of these lifestyle changes?”*
- Elicit, record and summarise.
- *“What would be less good things about making some of these lifestyle changes?”*
- Elicit, record and summarise these slowly.
- Summarise both sides of the change position using the child's own words.

At this stage if the dietitian feels the child is able to understand it may be a good opportunity to also ask the child to think about what are the good things and not so good things about not making any changes.

- *“What would be the good things about not making lifestyle changes?”*
- Elicit, record and summarise.
- *“What would be less good things about not making lifestyle changes?”*
- Elicit, record and summarise these slowly.

Summarise all sides of the **making your mind up sheet** using the child's own words. The aim is to make the child realise that the good things about

change outweigh the not so good things and that the not so good things can be overcome.(5;6)

Ask the parent(s) for their comments on what the child has said. It is very important to move the discussion on to the barriers to change that the child and family have encountered and to ask them both for possible solutions to overcome these barriers.(5;6) For most children this will lead into being able to think of more realistic goals for the next appointment. Discussions on how to plan for 'tricky' situations (see below) may be particularly helpful for these children at this stage. 2-4 goals should be set for the next appointment.

For the few children who remain ambivalent it may be necessary to end the interview here asking them to review the written advice given in appointment 1 and to record their lifestyle diary for 2 weeks before the next appointment and to consider what changes they would feel able to make. They may leave with one small goal e.g. to walk to school 3 days per week.

As in previous appointments the dietitian should explore the child's confidence in their ability to achieve their new goals by asking for example *'how sure are you that you will be able to keep sweets to the weekend only?'*.(5;6) The relationship between meeting 100% of their goals and receiving their agreed reward (see below) should again be emphasised. This connection between goals and rewards may help some children to be more realistic in setting goals.

The new goals should be noted on a new **goal sheet** and a new reward (small, inexpensive and non food) should be agreed between the child and parent(s) and recorded on the sheet. For the child to get the reward they should be aware that they must meet all of their goals over the next 4 – 5 weeks and this will be reviewed at the next appointment.

Tricky situations

As part of helping the child and parent(s) start to develop longer-term strategies for continuing with lifestyle changes and prevent relapses

discussions should start on developing coping strategies to deal with 'tricky' situations.(5;6) In this context 'tricky' situations refer to situations where the child and family may find it particularly difficult to keep to the set goals e.g. parties, family gatherings, rainy days and holidays. This follows on from the brief discussion of tricky situations with the parent(s) in appointment 4. **The 'tricky' situation sheet** gives the child examples of tricky situations and also asks them to think of possible situations in their own life and to consider planning for these occasions e.g. when going to a party saving up red foods for 3-4 days before hand.

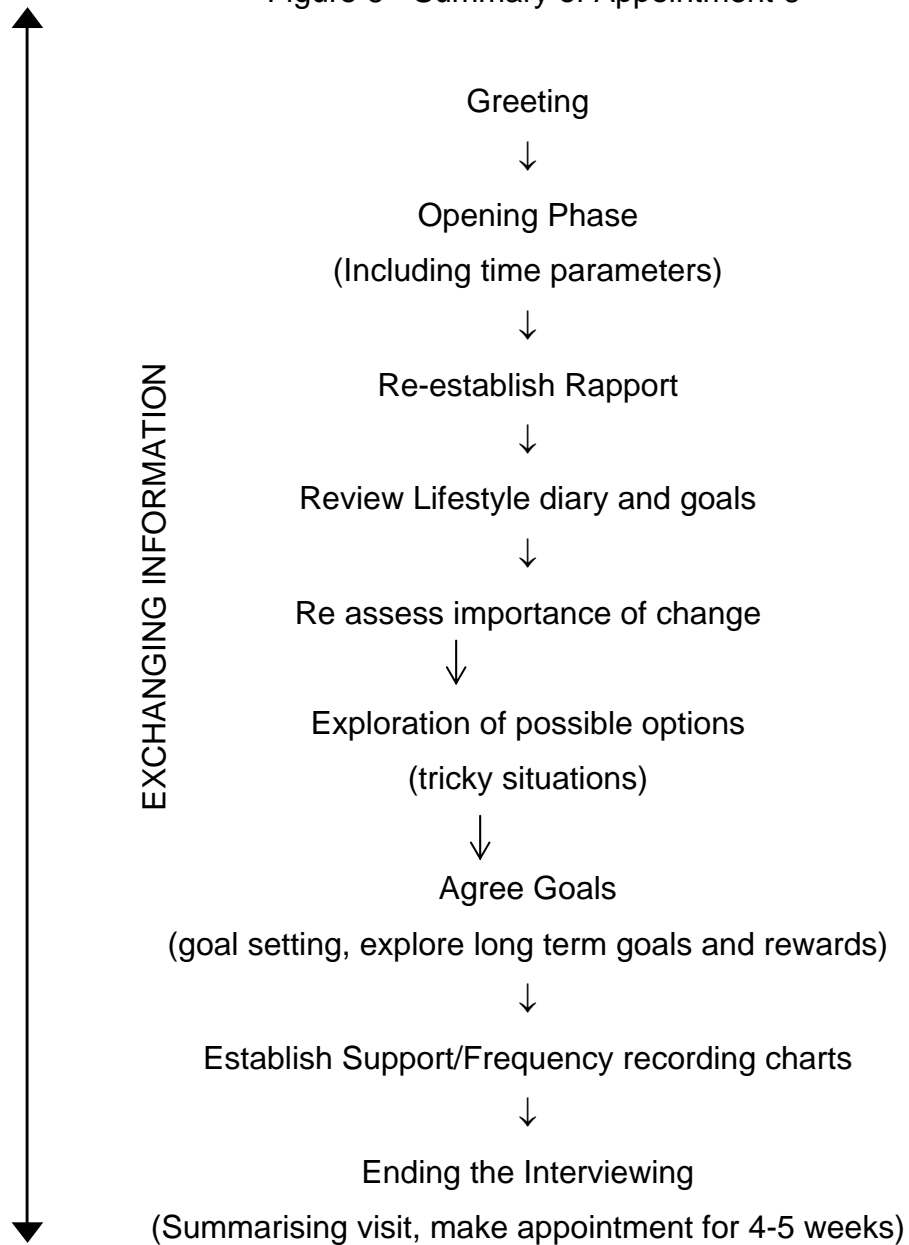
Establish support/agree monitoring

The method for recording changes at this stage to a simpler version that will be easier to continue on a long-term basis. The child and parent(s) should be introduced to the **frequency-recording sheet** (see appendix 2) which should be used daily until the next appointment and the family should leave with enough sheets to keep them going to appointment 7.

Ending the Interview

- Summarise the discussions in appointment six
- Confirm the set goals and reward
- Reiterate the importance of keeping the frequency-recording sheets and of doing so jointly
- Suggest that that the child and parent(s) jointly consider possible long term lifestyle change goals and a reward before appointment 7
- Ensure the child has
 - Goal sheet
 - Frequency recording sheets (4-5 weeks supply)
 - Tricky situations sheet
- Arrange next appointment for 4-5 weeks time at the OPD

Figure 6 - Summary of Appointment 6



Appointments 7 4-5 weeks after appointment 6

30 minutes duration, in OPD

Weight and height not measured

Opening phase and re-establishment of rapport

After the greeting and opening phases the dietitian should explain that the interview will last up to 30 minutes and that once again it will concentrate on setting long-term goals, monitoring, support and planning for 'tricky' situations.

The dietitian should ask if there are any questions arising from the last interview and then deal with these.

Review goals and recording sheets

This will involve reviewing the **frequency recording sheets** and whether the goals have been met. The dietitian should reinforce the importance of continuing to monitor and record by reading the sheets thoroughly, stamping 'well done' where appropriate and praising the child for recording. While reviewing the sheets the dietitian should check if the goals have been met and confirm this with the parent(s). The child should only get their reward if they have met 100% of their goals.

There are three possible scenarios for the rest of this interview-

Situation 1.

For those children who set long term, sustainable goals the dietitian should review how successful they were and agree on consolidating these goals. This could involve either expanding present goals e.g. a goal of eating fruit every second day could be increased to eating fruit every day, or modifying present ones e.g. playing football 5 times a week could be change to a more realistic long-term goal of playing 3 nights a week in summer and in doors twice a week during the winter months.

Situation 2.

A child who has not started to consider longer-term goals should do so at this stage.

Situation 3.

For the child who has not meet their goals or for those few who remain ambivalent then it is important to look at the possible reasons why the goals have not been achieved and to review the barriers to making lifestyle changes (5;6). However even for these children at this point in the programme it is necessary to focus on making realistic longer-term lifestyle changes.

When setting further goals the dietitian should not be afraid of periods of silence while the child thinks of possibilities, in practice parent(s) often help their child to explore options. If necessary the dietitian could use **the energy balance chart** to help the child think of goals. While discussing long term goals it should be emphasised to the child and parent that the long term aims for lifestyle, as noted above, change are no more than 1 'red' food per day, increasing physical activity to a minimum of 30 minutes per day and now trying to increase this to 60 minutes of moderate intensity activity at least 5 days per week and limiting non active time to less than 2 hours per day.(7)

As in previous appointments the dietitian should explore the child's confidence in their ability to achieve their new goals by asking for example *'how sure are you that you will be able to keep sweets to the weekend only?'*.(5;6) The relationship between meeting 100% of their goals and receiving their agreed reward (see below) should again be emphasised. This connection between goals and rewards can help some children to be more realistic in setting goals.(5;6)

The new goals should be noted on a new **goal sheet** and a new reward (small, inexpensive and non food) should be agreed between the child and parent and recorded on the sheet. For the child to get the reward they should

be aware that they must meet all of their goals over the next 6-8 weeks and this will be reviewed at the next appointment.

‘Tricky situations’

It is important to again review longer-term strategies for continuing with lifestyle changes and prevent lapses and to discuss developing coping strategies to deal with ‘tricky’ situations.(5;6) Discuss if situations have arisen since the last appointment and how the child dealt with them or anticipate events that might be happen in the near future e.g. birthdays, Christmas, summer holidays and ask the child to consider plans for such times.

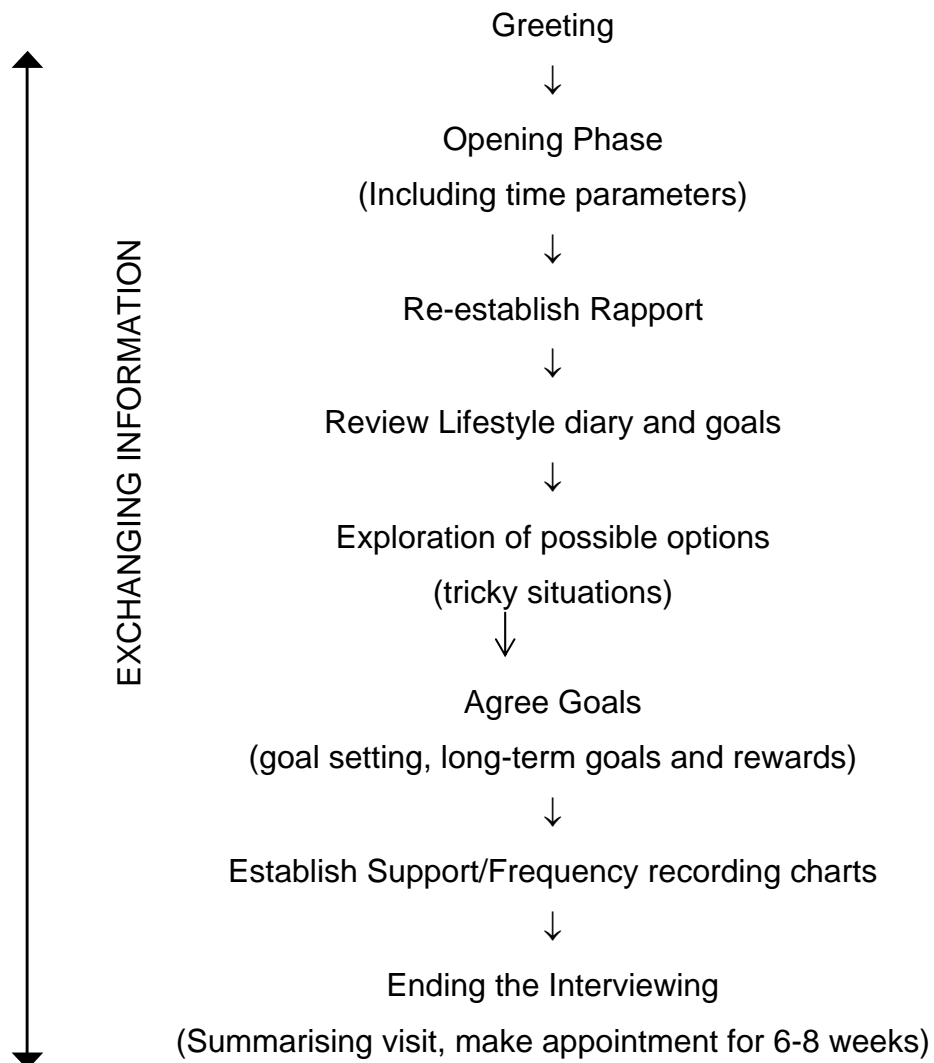
Establish support/agree monitoring

Continue with daily use of **the frequency-recording sheet** the family should leave with enough sheets to keep them going to appointment 8. It should be explained to the parent(s) and child that the use of goal setting, monitoring and rewards should continue after the programme. The family will be expected to review if the child has continued to meet their goals every month via their frequency recording sheets and if they have meet all their goals they should receive their reward. If they do not meet their goals then the family should use the technique of reviewing barriers and setting new more realistic goals for the child themselves.

Ending the Interview

- Summarise the discussions in appointment seven
- Confirm the set goals and reward
- Reiterate the importance of keeping the frequency-recording sheets and of doing so jointly
- Suggest that that the child and parent(s) jointly consider firm long term lifestyle change goals and a reward before appointment 8
- Ensure the child has
 - Goal sheet
 - Frequency recording sheets (6-8 weeks supply)
- Arrange next appointment for 6-8 weeks time at the OPD

Figure 7 - Summary of Appointment 7



Appointment 8 (the final appointment)

6-8 weeks after appointment 7

30 minutes in duration OPD

Weight and height measured

BMI calculated and plotted on age and sex appropriate BMI centile chart (UK 1990)

Opening phase and re establishment of rapport

After the greeting and opening phases the dietitian should explain that the interview will last up to 30 minutes and that once again it will concentrate on the setting long-term goals, monitoring, support and preventing lapses.

Weight and height are measured at this appointment and as this could be an area of conflict the dietitian rather than other staff carry it out after the greeting. No judgements should be made on the present weight but it should be acknowledge if there have been changes or not and indeed if this has been an increase or decrease. The parent(s) in particular may wish to discuss the weight outcome and any concerns they have, however the measurement should be used to positively reinforce the need to make lifestyle changes. The child and parent(s) should also be reminded that the aim of the intervention is to maintain weight while continuing to grow in height.(7;8)

The dietitian should ask if there are any questions arising from the last interview and then deal with these.

Review goals and recording sheets

This will involve reviewing **the frequency recording sheets** and whether the goals have been met. The dietitian should reinforce the importance of continuing to monitor and record by reading the sheets thoroughly, stamping 'well done' where appropriate and praising the child for recording. While reviewing the sheets the dietitian should check if the goals have been met

and confirm this with the parent(s). The child should only get their reward if they have met 100% of their goals.

It is essential to ensure that children have agreed long term goals that are realistic enough for them to continue with once the programme has finished.

If necessary the dietitian could use the energy balance chart to help the child think of goals. While discussing long term goals it should be emphasised to the child and parent that the long term aims for lifestyle change are no more than 1 'red' food per day, increasing physical activity to a minimum of 60 minutes of moderate intensity activity per day and limiting non active time to less than 2 hours per day.(7)

Children who have not managed to reach these long term aims of the programme, it can be explained to them that they could still strive to obtain these and that the family needs to continue to monitor achievement of goals through recording and to give rewards every month where goals are being achieved 100% of the time.

As in previous appointments, the dietitian should explore the child's confidence in their ability to achieve their new goals by asking for example *'how sure are you that you will be able to keep sweets to the weekend only?'*.(5;6) The relationship between meeting 100% of their goals and receiving their agreed reward (see below) should be emphasised. This connection between goals and rewards can help some children to be more realistic in setting goals.

The final long-term goals should be noted on a **long-term goal sheet** (see appendix 2) and a new reward (small, inexpensive and non food) should be agreed between the child and parent(s) and recorded on the sheet. For the child to get the reward they should be aware that they must meet all of their goals over the next month and the parent(s) will have to monitor themselves if these have been met.

Further discussion should take place around possible 'tricky situations' and for the dietitian to try and ensure that the family and child have thought through robust plans and continue to plan a head for such occasions.(5;6) It is also helpful to emphasis that a 'slip' is a lapse and not a relapse and if one occurs they should return to their agreed plan and goals the next day.(4-6)

Along with the long term goal sheet the family should be given enough monitoring charts for 3 months and asked to either photocopy more or to make up their own charts and if possible for the child to be involved to help with ownership. The family should be encouraged to continue recording daily however if this is not possible then at least daily for a week once every fortnight, the most important factor is that this monitoring regime suits the family.

Ending the interview and the programme

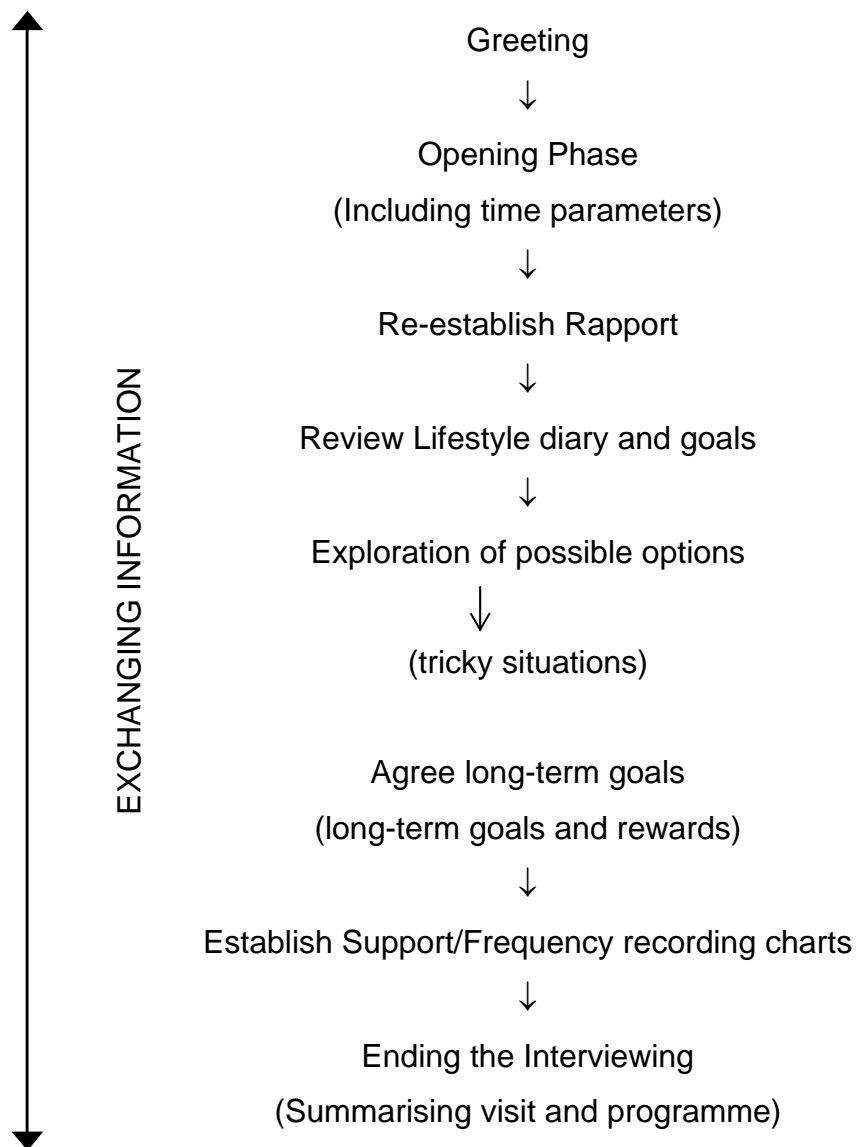
- The importance of lifestyle changes in the three main areas of diet, activity and non active time should be reinforced
- The long term goals should be summarised
- The aim of weight maintenance should be stressed
- The important of the family continuing to monitor and offer rewards should be emphasised
- Ensure the child has
 - Long term goal sheet
 - A supply of frequency recording sheets (12 weeks) and recommended to either photocopy more or create their own sheets for continuing monitoring

Some families may wish advice on continuing weight monitoring, if so it should be recommended that the child be weighed no more than every 8 weeks either on their own or at the GP practice/ practice nurse and continue to aim for weight maintenance.

After the end of the 12 month study a letter will be sent to the GP detailing changes in weight and BMI and asking for the continuing encouragement of

the GP for the child and family to maintain lifestyle changes and weight maintenance.

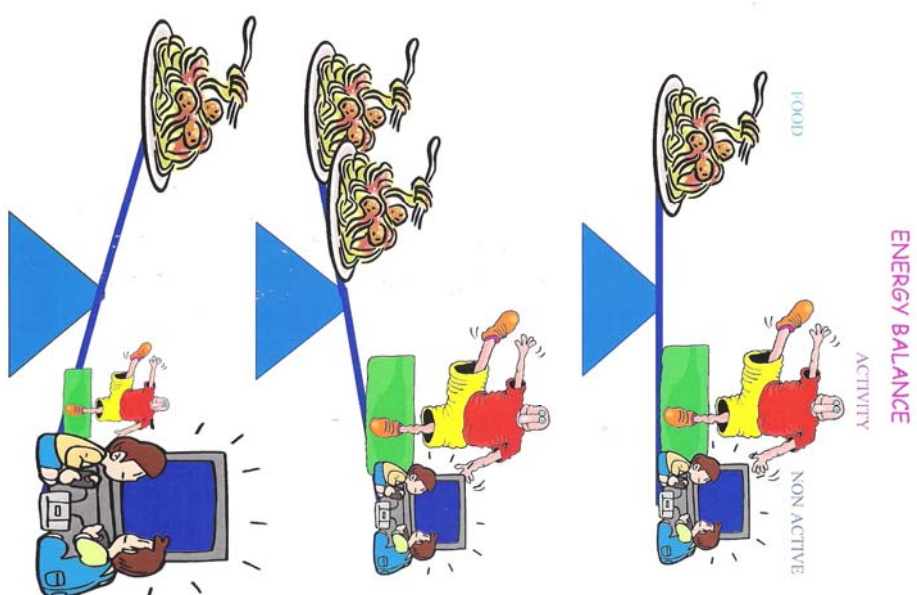
Figure 8 - Summary of Appointment 8



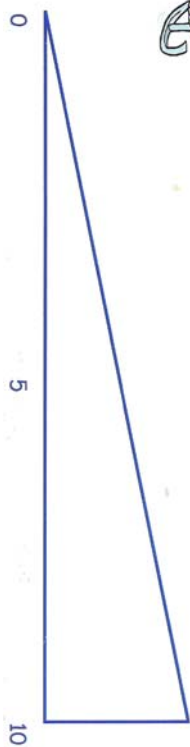
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Appendix 2 Written materials for the novel treatment



Is it important to change?





Making your mind up!

	GOOD THINGS	LESS GOOD THINGS
Not Changing		
Changing		



Plan

Red foods

Are high in fat and sugar, try not to eat too many.

Amber foods:

Are important for a healthy body, choose the low fat option

Green foods

Are packed full of vitamins and are low in fat and sugar, eat these freely.

RED FOODS

- Red foods are unhealthy because they are very high in fat and sugar and don't have many Vitamins or Minerals.
- Try very hard to eat less of these foods.
- Aim to have only one Red food each day, you could swap some **RED** foods and have **GREEN** foods instead.
- You don't need to have a Red food every day and you can save them up for special occasions.

Red Foods Are: -

- Fried food
- Crisps
- Pies, pastries, buns
- Carry out meals
- Chips and burgers



- Sugar
- Sweets
- Chocolate
- Chocolate biscuits
- Fancy biscuits
- Cakes
- Fizzy and diluting drinks containing sugar
- Puddings
- Sugar or honey coated breakfast cereals

AMBER FOODS

- Amber foods are important to keep your body healthy and to help you grow properly.

Amber Foods Are: -

Meats, Fish and Alternatives

- Have one of these foods **TWICE** a day and try to keep them to meal times.
- Grill, boil, cook in the oven or microwave meats and eggs rather than frying.
- Lamb, pork, beef
- Sausages and burgers - try not to have these too often.
- Chicken and Turkey
- Fish - haddock, tinned fish, fish fingers
- Eggs and cheese
- Vegetarian main meals



Starchy foods



- Bread / Chappati
- Potatoes boiled, baked, mashed
- Rice - boiled
- Pasta
- Plain breakfast cereals
- Have a starchy food at each meal.
- Try wholemeal bread and high fibre cereal to fill you up more.

Milk and Dairy

It is important to eat these foods daily and best to take the low fat alternatives. Up to one pint of milk per day is healthy for you.

- Milk - semi skimmed or skimmed
- Butter/margarine - low fat spreads
- Yogurts - low fat/low sugar yogurts, and fromage frais



Green Foods

- Green foods are low in fat and sugar. They are full of Vitamins and Minerals and are very healthy.
- You should try to eat more GREEN foods each day. Try to swap these with some RED foods.
- They are particularly good to take as snacks when you are feeling hungry and after meals instead of puddings.

Green Foods Are: -

- Fresh fruit / Dried fruit
- Tinned fruit in fruit juice
- Vegetables / Salad
- Home made / Tinned vegetable soup



- Sugar free jelly
- Plain breakfast cereals - Weetabix, Rice Krispies and low fat milk
- Plain popcorn, breadsticks
- Sugar free lollies and Ice poles
- Diet or sugar free drinks



Handy Hints For You And Your Family.

Your family and friends can help you make changes to your eating habits by:

- Following the same healthy eating plan.
- Buying more Green foods and less Red foods at the supermarket.
- By having a treat of a:
 - trip to the cinema or the park
 - new book/toy/comic
 - friend to stay overnight
- if you are doing well rather than having a food treat
- Having regular family meal times.

You can help by:

- Only eating when you are hungry, try not to fill up on snacks all day
- Not eating when you are doing other activities, such as watching TV or doing schoolwork.

If you have a bad day, don't worry; it is what you do most days that is most important

Don't Just Sit There!

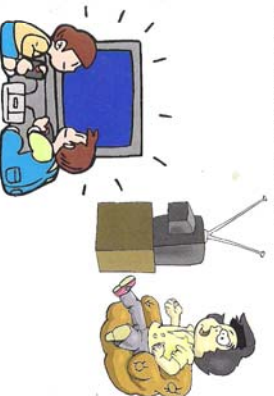
- Spending too much time doing **non-active pastimes** (e.g. watching TV and videos/DVDs, playing computer and video games) can be unhealthy.
- **WHY?**
- Your body does not use much energy when you are doing non-active pastimes.
- Watching TV can encourage you to eat.

- Try to cut down on the amount of time you spend doing "non-active" pastimes. You could swap some of these for more active pastimes.

- **PARENTS** - be a good role model and watch less TV yourself!

Cut Down On

- Watching TV & videos/DVDs
- Playing computer and video games
- Playstation/Playstation 2
- Nintendo/Gamecube
- Gameboy, X-box
- **Schoolwork is not included**



Instead try

- Going for a walk
- Playing with your friends
- See Be Active sheet for more ideas
- Read a book
- Play a board game or draw
- Play with your toys
- Help mum or dad around the house



Did You Know: Children should spend no more than 2 hours per day or 14 hours per week

watching TV & videos/DVDs, playing computer & video games.

Be Active!

- Physical activity is an important part of a healthy lifestyle.
- You and your family should do 30 minutes or more of moderate intensity physical activity (e.g. same effort as a brisk walk), on most days of the week.
- The 30 minutes of activity can be accumulated throughout the day.
- **ALWAYS tell your mum and dad where you are going!**

Adding activity into the daily routine is an easy way to become more active and stay active

- Take the stairs instead of the escalator/lift
- Walk to and from school instead of taking the car
- Walk to the shops or friends' house instead of taking the car
- Play with a friend after school instead of talking on the phone
- Help with household chores - e.g. in the garden or wash the car.



Play inside or outside by yourself or with friends

- Skipping, hula hoop, ball games
- Put music on and dance!
- Play games - e.g. dodge ball, hopscotch, chase, hide and seek



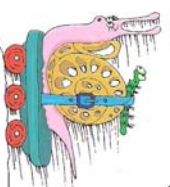
Be active as a family

- Go for a walk
- Visit parks and playgrounds
- Walking your dog/ neighbour's dog
- Go for a swim or cycle
- Leave the car at home when going on short journeys



Take part in individual or team activities that you enjoy

- Football, Swimming, Cycling, Dancing, Rollerblading
- Brownies/Cubs & Guides/Scouts
- Attending PE lessons/outdoor education



TYPICAL DAY

BEFORE SCHOOL	
BREAK	
LUNCH	
AFTER SCHOOL	
EVENING MEAL	
EVENING	
SUPPER	

DATE: _____

My Lifestyle Diary



Name _____

Start Date _____

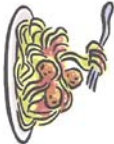
Lifestyle Diary

- Please fill in this lifestyle diary (i.e. food, physical activity and "non-active" time) every day for one week.
- Get your Mum and Dad to help you.
- It is easier to keep an accurate record if you write them down the same day. Try not to leave anything out!



Food

- Make a note of ALL the food you eat each day, including all meals, snacks and drinks.
- Please record meal and snack times, what type of food you eat and amounts left over.



Physical Activity

- Write down ALL the physical activities you took part in throughout the day AND how much time you spent doing these activities.
- Examples of activities to include in your diary are:
 - Walking to school, the shops, a friend's house, up stairs
 - playing with friends, playing in the park
 - Cycling, swimming, skateboarding, rollerblading
 - taking part in PE
 - Skipping or playing football at playtime
 - physical activities at any clubs



Non-Active Pastimes

- Write down how much time you spent during the day watching TV or videos, playing computer or video games (e.g. Playstation, Nintendo, Game cube and Game Boy).



Boy _____

Time	Food	Physical Activity	Non-Active Pastimes
Morning			
Afternoon			
Evening			



Goals for a Healthy Lifestyle

Date: _____

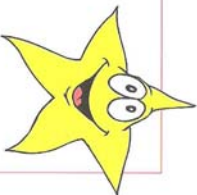
Goal 1 _____

Goal 2 _____

Goal 3 _____

Goal 4 _____

For reaching my goals my treat is:



Signatures

Child _____

Parent _____

Dietitian _____

Use the checklist to record what you do each day. It will help you and your parents on

Check it out!

Reward Day



Note down the number of times you ate the foods below. Write the number in the box that matches the food and the day you ate it.	Mon	Tue	Wed	Thu	Fri	Sat	Sun
CHIPS / FRIED FOODS							
CHOCOLATE / SWEETS /FANCY BISCUITS							
CRISPS							
TAKE AWAY / EATING OUT							
FRUIT + VEGETABLES							
ACTIVE TIME (Write in the activity which you took part in)							
NON ACTIVE TIME (Write in minutes the time spent on inactive postimes)							

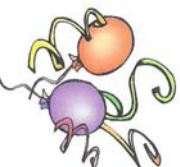
Coping with Tricky Situations Stick to it!

- Tricky situations can make it hard to stick to a healthy lifestyle.
- Having a **plan** to cope with these situations can help.
- Here are some common situations that can make it hard to keep going



- Tricky Situation: It's raining outside. I can't go out to play.
- Plan: Do an active pastime indoors instead.
- Can you think of active pastimes you could do indoors?

- Tricky Situation: I'm going to a party, there will be lots of Red foods.
- Plan: Save up your Red foods for a few days and use up your allowance at the party.



- Can you think of other Tricky Situations you might have?
- Can you make a Plan to cope with these?

Tricky Situation: _____

Plan: _____

Tricky Situation: _____

Plan: _____

My Healthy Lifestyle Goals

When setting your goals each month remember the overall aims are:

- Be active for at least 30-60 minutes each day.
- Eat no more than one Red food each day.
- Don't just sit there for more than 2 hours each day.

Goal 1 _____

Goal 2 _____

Goal 3 _____

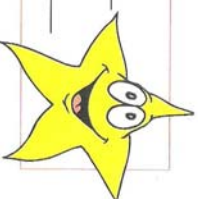
Goal 4 _____

Now you have set your goals you and your parents should agree a Reward Day for the month. You should only get your reward if you stick to your goals 100%.

You should also pick your reward and write it below. Ideas for rewards are: Comic, Magazine, Book, Video or DVD rental, Friend to stay over, Stay up 30mins later, Trip to the park etc.

My Reward Day is the: _____

My Reward is: _____



Signatures: _____

Child _____

Parent _____

Appendix 3 Parent and child information sheets for SCOTT study



SCOTT
Scottish Childhood Overweight Treatment Trial



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Parent information sheet

Invitation to take part in our research study

- We would like to invite you and your child to help with our research project.
- We would like you and your child to understand all about it before you decide.
- Please read this carefully and talk it over with your child.
- If there is something you don't understand or if you would like to know more about the project, please ask us.
- Please take your time to decide if you want to take part.

What is the study about ?

- We want to find the best way to treat children (aged 5 to 11 years) who have been referred to a Doctor or Dietitian about their weight.
- We want to compare our current treatment with a new treatment.
- We don't know which of the two treatments is best; we hope that this study will tell us.

Why has my child been chosen?

- Your child has been referred for treatment for their weight and is of primary school age.

What will happen if we agree to take part?

- A computer programme will decide whether you/your child will get the **current** treatment or the **new** treatment.
- You have an equal chance of being in one group or the other.
- **Current** Treatment involves 3 or 4 visits to hospital to see a dietitian over the next 6 to 10 months.
- **New** Treatment involves 7 visits to hospital to see a dietitian over the next six months and our dietitian would make 1 visit to your house.
- We will also take some measurements from your child.

What happens if I say No?

- Your child will continue to be treated as planned by your Doctor or dietitian.

Who has approved the study?

- This study has been checked over by the Lothian Ethics Committee.

The SCOTT Team are:

Laura Stewart, Senior Dietitian, Royal Hospital for Sick Children, Edinburgh
Dr Adrienne Hughes, Research Fellow, Human Nutrition, Yorkill Hospital
Dr Chris Kelnar, Reader, University of Edinburgh
Dr John Reilly, Senior Lecturer, University of Glasgow
Jan Houghton, Senior Dietitian, Yorkill Hospital

Thank you for taking the time to read this.



SCOTT

Scottish Childhood Overweight Treatment Trial



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Child information sheet (intended for children aged 8 to 11 years)

Invitation to take part in our research study

- We would like to invite you to help with our research project.
- We would like you to understand all about it before you decide what to do.
- Please read this carefully and talk it over with your parent(s).
- If there is something you don't understand or if you would like to know more about the project, please ask us.
- Please take your time to decide if you want to take part.

What is the study about?

- We want to find the best way to treat children who have been referred to a Doctor or Dietitian about their weight.
- We want to compare our current treatment with a new treatment.
- We don't know which of the two treatments is best; we hope that this study will tell us.

Why have I been chosen?

- You/your family have been referred for treatment for your weight and you are of primary school age.

What will happen if I agree to take part?

- A computer programme will decide whether you will get the **current** treatment or the **new** treatment.
- You have a 50:50 chance of being in one group or the other.

- **Current Treatment** involves 3 or 4 visits to hospital to see a dietitian over the next 6 to 10 months.
- **New Treatment** involves 7 visits to hospital to see a dietitian over the next six months and our dietitian would make 1 visit to your house.
- We will also take some measurements from you.

What will we measure?

We would like to take some measurements from you at the beginning of your treatment, 6 months later, and 12 months later.

We would like to measure your:

- Height and weight (using a set of scales) and waist (using a tape measure)
- Physical activity using an activity monitor (a small box, about the size of a 50 pence piece worn on a waist belt), which we would like you to wear for 7 days.
- Body fatness by asking you to stand on a scale, which passes a tiny electrical current through your body. This is painless and you won't feel anything.
- We would like to ask you how you feel about your weight, and about yourself (by asking you and your parent to fill out a questionnaire).

Will this hurt me?

- No - We have made these measurements for many years, and children don't find them painful or frightening.

Will taking part help me?

- This is a research study - taking part in may not help you, but the information we get might help other children in the future.

Who will know I have taken part?

- Only the members of the research team will know you have taken part.

Will I be told the results?

- Yes, we will tell you your results after the end of the study.

Who pays for the study?

- The study is funded by the Scottish Executive Health Department in Edinburgh.
- We will pay you travel expenses to cover the cost of your visits to hospital.
- The researchers will not make any money from the study.

Do I have to take part?

- No - you choose what you want to do.
- Also, if you join the study and then want to leave, that is fine - all you and your parents have to do is tell us.

What happens if I say No?

- You will continue to be treated as planned by your Doctor or dietitian.

Who has approved the study?

- This study has been checked over by the Lothian Ethics Committee.

The SCOTT Team are:

Laura Stewart, Senior Dietitian, Royal Hospital for Sick Children, Edinburgh

Dr Adrienne Hughes, Research Fellow, Human Nutrition, Yorkill Hospital

Dr Chris Kelnar, Reader, University of Edinburgh

Dr John Reilly, Senior Lecturer, University of Glasgow

Jan Houghton, Senior Dietitian, Yorkill Hospital

Thank you for taking the time to read this.



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SCOTT

Scottish Childhood Overweight Treatment Trial

Child information sheet (for children aged 5 to 7 years - to be read by parents)

Invitation to take part in our study - Can I Help?

- We would like to ask you to help with our project.
- We would like you to understand all about it before you decide what to do.
- Please talk it over with your parent(s) and take your time to decide if you want to take part.

What is the study about?

- We want to find the best way to help children who have been asked to see a Doctor or Dietitian about their weight.

Why have I been chosen?

- You/your family have been asked to see a Doctor or a dietitian about your weight.

What will happen if I agree to take part?

- A computer will decide which group you will be put into.
- You have an equal chance of being in one group or the other.
- One group will visit the hospital 3 or 4 times to see a dietitian.
- The other group will visit the hospital 7 times to see a dietitian and a dietitian would like to make 1 visit to your house.

What will we measure?

We would like to measure your:

- Height and weight (using a set of scales) and waist (using a tape measure)
- Activity using a monitor (a small box, about the size of a 50 pence piece worn on a waist belt), which we would like you to wear for 7 days.
- Body fatness - we do this by asking you to stand on a scale.
- We would like to ask you how you feel about your weight, and about yourself.

Will this hurt me?

- No - it doesn't hurt at all.

Will taking part help me?

- Taking part may not help you, but it might help other children in the future.

Who will know I have taken part?

- Only the people involved in the study will know you have taken part.

Will I be told the results?

- Yes, we will tell you and your parents your results at the end of the study.

Do I have to take part?

- No - not if you don't want to do.
- Also, if you join the study and then want to leave, that is fine - all you and your parents have to do is tell us.

What happens if I say No?

- You will continue to be seen by your Doctor or dietitian.

Thank you for taking the time to read this.

Appendix 4 Child and parent consent forms for the SCOTT quantitative study

CHILD CONSENT FORM Scottish Childhood Overweight Treatment Trial (SCOTT)

Please initial box

1. I confirm that I have read and understood the information sheet dated () for the above study and have had the opportunity to ask questions

☐

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

☐

3. I agree to take part in the above Research Project.

☐

Name of person giving consent Date Signature

Name of person taking consent Date Signature
(if different from researcher)

Witness Date Signature

Date

Version Number

1 for volunteer, 1 for researcher, 1 to be kept in hospital notes

PARENT CONSENT FORM

Scottish Childhood Overweight Treatment Trial (SCOTT)

Please initial box

1. I confirm that I have read and understood the information sheet dated () for the above study and have had the opportunity to ask questions

☐

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

☐

3. I agree that my son/daughter can take part in the above Research Project.

☐

Name of person giving consent

Date

Signature

Name of person taking consent
(if different from researcher)

Date

Signature

Witness

Date

Signature

Date

Version Number

1 for volunteer, 1 for researcher, 1 to be kept in hospital notes

Appendix 5 PedsQL questionnaires for child and parent proxy

PedsQLTM

Pediatric Quality of Life Inventory

Version 4.0

YOUNG CHILD REPORT (ages 5-7)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.




Show the child the template and point to the responses as you read.

If it is not at all a problem for you, point to the smiling face

If it is sometimes a problem for you, point to the middle face

If it is a problem for you a lot, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

	Not at all	Sometimes	A lot
Is it hard for you to snap your fingers			

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

PHYSICAL FUNCTIONING (problems with...)	Not at all	Some-times	A lot
1. Is it hard for me to walk down the road a little bit	0	2	4
2. Is it hard for me to run	0	2	4
3. Is it hard for me to do sports or running games	0	2	4
4. Is it hard for me to lift heavy things	0	2	4
5. Is it hard for me to have a bath or shower by myself	0	2	4
6. Is it hard for me to pick up my toys	0	2	4
7. I hurt or ache (<i>Where?</i> _____)	0	2	4
8. I feel very tired	0	2	4

Remember, tell me how much of a problem this has been for you for the last few weeks.

EMOTIONAL FUNCTIONING (problems with...)	Not at all	Some-times	A lot
1. I feel afraid or scared	0	2	4
2. I feel sad or unhappy	0	2	4
3. I feel angry or cross	0	2	4
4. I have trouble sleeping at night	0	2	4
5. I worry about what will happen to me	0	2	4

SOCIAL FUNCTIONING (problems with...)	Not at all	Some-times	A lot
1. I have trouble getting along with other kids	0	2	4
2. Other kids do not want to be my friend	0	2	4
3. Other kids bully me	0	2	4
4. I cannot do things that other kids my age can do	0	2	4
5. It is hard to keep up when I play with other kids	0	2	4

SCHOOL FUNCTIONING (problems with...)	Not at all	Some-times	A lot
1. It is hard to pay attention in school	0	2	4
2. I forget things	0	2	4
3. I have trouble keeping up with school activities	0	2	4
4. I have days off school because of not feeling well	0	2	4
5. I have days off school to go to the doctor or hospital	0	2	4

How much of a problem is this for you?

Not at all



Sometimes



A lot



ID# _____
Date: _____

PedsQLTM

Pediatric Quality of Life Inventory (UK)

Version 4.0

PARENT REPORT for YOUNG CHILDREN (ages 5-7)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has your child had with ...*

PHYSICAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Some- times	Often	Almost Always
1. Walking down the road a little bit	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports or running games	0	1	2	3	4
4. Lifting heavy things	0	1	2	3	4
5. Having a bath or shower by him or herself	0	1	2	3	4
6. Helping to pick up his or her toys	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Feeling very tired	0	1	2	3	4

EMOTIONAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Some- times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or unhappy	0	1	2	3	4
3. Feeling angry or cross	0	1	2	3	4
4. Trouble sleeping at night	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Some- times	Often	Almost Always
1. Getting on with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting bullied by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING (<i>problems with...</i>)	Never	Almost Never	Some- times	Often	Almost Always
1. Paying attention in class					
2. Forgetting things					
3. Keeping up with school activities					
4. Having days off school because of not feeling well					
5. Having days off school to go to the doctor or hospital					

ID#	_____
Date:	_____

PedsQLTM

Pediatric Quality of Life Inventory (UK)

Version 4.0

PARENT REPORT for CHILDREN (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has your child had with ...

PHYSICAL FUNCTIONING (problems with...)	Never	Almost Never	Some-times	Often	Almost Always
1. Walking down the road a little bit	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports or running games	0	1	2	3	4
4. Lifting heavy things	0	1	2	3	4
5. Having a bath or shower by him or herself	0	1	2	3	4
6. Tidying up around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Feeling very tired	0	1	2	3	4

EMOTIONAL FUNCTIONING (problems with...)	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or unhappy	0	1	2	3	4
3. Feeling angry or cross	0	1	2	3	4
4. Trouble sleeping at night	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING (problems with...)	Never	Almost Never	Some-times	Often	Almost Always
1. Getting on with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting bullied by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING (problems with...)	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Having days off school because of not feeling well	0	1	2	3	4
5. Having days off school to go to the doctor or hospital	0	1	2	3	4

ID# _____
Date: _____

PedsQLTM

Pediatric Quality of Life Inventory (UK)

Version 4.0

CHILD REPORT (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for you.
Please tell us **how much of a problem** each one has been for you
during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

In the past **ONE month**, how much of a **problem** has this been for you ...

ABOUT MY HEALTH AND ACTIVITIES (problems with...)	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to walk down the road a little bit	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
3. It is hard for me to do sports or running games	0	1	2	3	4
4. It is hard for me to lift heavy things	0	1	2	3	4
5. It is hard for me to have a bath or shower by myself	0	1	2	3	4
6. It is hard for me to tidy up around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
8. I feel very tired	0	1	2	3	4

ABOUT MY FEELINGS (problems with...)	Never	Almost Never	Some-times	Often	Almost Always
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad or unhappy	0	1	2	3	4
3. I feel angry or cross	0	1	2	3	4
4. I have trouble sleeping at night	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

HOW I GET ALONG WITH OTHERS (problems with...)	Never	Almost Never	Some-times	Often	Almost Always
1. I have trouble getting on with other kids	0	1	2	3	4
2. Other kids do not want to be my friend	0	1	2	3	4
3. Other kids bully me	0	1	2	3	4
4. I cannot do things that other kids my age can do	0	1	2	3	4
5. It is hard to keep up when I play with other kids	0	1	2	3	4

ABOUT SCHOOL (problems with...)	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I have days off school because of not feeling well	0	1	2	3	4
5. I have days off school to go to the doctor or hospital	0	1	2	3	4

Appendix 6 Assessment form of core interviewing skills

Interview No.							Date:
Core skills	No Skill 1	Slight Skill 2	Fair Skill 3	Satisfactory Skill 4	Good Skill 5	Very Good Skill 6	Excellent skill 7
Greeting This takes place within room							Patient made welcome ? 'small talk' Introduce self. Time set
Opening phrase							Open invitation to talk
Establish rapport							With parent/s & child -collaborate approach -encourage 2-way exchange
Establish current scenario							1 st interview: story so far F/U: since last visit Include outline of study, goal of NT wgt maintenance
Minimal encouragers							Verbal utterances to encourage patient to talk
Verbal following Not using these							Repeat key words to convey That you are listening & encourage to talk
Paraphrasing							Reflect essence of <i>content</i> of patient talk –be tentative. Check for accuracy
Reflection <u>Children tend not to delve into emotional issues too much</u>							Reflect patient emotions –be tentative. Check for accuracy.
Use of open questions							Use of open questions to follow patient content
Sign posting Closed questions							Indicate need for series of detailed questions
Summarising							Use of summaries to check accuracy as interview progresses Use of summary towards end of interview to pull together. A start of F/U interview
Ending the interview							Making sure key elements have been summarised. Check for any concerns. Arrange next visit Check homework

Interview No.							Date:
Motivational Tools use	No Skill 1	Slight Skill 2	Fair Skill 3	Satisfactory Skill 4	Good Skill 5	Very Good Skill 6	Excellent skill 7
Information exchange (number of times used)							Ask permission Elicit-provide-elicit
Importance of change							Scaling question (0-10) <u>Not explore except through Pros & cons</u>
Confidence rating I							Scaling question (0-10)
Not formally exploring							
Explore Ambivalence							Pros/cons of change – Yes Pros/cons of no change – No
Problem solving							Identify barriers Generate patient solutions Explore options Select preferred option
Help with decision making							Emphasise: -patient choice -what others find helpful -‘you are the best judge’ Convey optimism & willingness to re-examine
Goal setting							SMART GOALS Assessing confidence for goals
Typical day							Elicit current behaviour Eating/activity
Establish support							Establish other sources of support
Agree on monitoring							Any homework/goals Arrange next appointment

Interview No.									Date:
OVERVIEW									Comments
Global rating (patient centeredness)									
Core conditions: -Empathy -Genuineness -Acceptance									
Guiding principles 1.Client responsibility 2. Social influence 3. Collaboration									
Affirmation									
PACE									

Interview No.	Date:
Comments:	

Appendix 7 Post pilot semi structured questionnaire, with parent and child answers

The answers from each parent and child are number and in the same order through out.

1. In general how did you feel about the programme – overall impression?

- a) Liked some – didn't like some
- b) Enjoyed it – enjoyed weight loss
- c) Good, relaxing atmosphere

2. Your expectations before the start

- a) Didn't know – expected it to be about child, as it happened
- b) Thought that he (child) would be told not to eat anything. Concerned he wouldn't loss weight. Sorry coming to an end.
- c) Sheet telling what to eat

3. How did it compare with your expectations? Worse or better?

- a) Didn't like coming as upset - better than jag
- b) Preferred treatment trial
- c) Better. Felt better, liked explanations, liked good versus bad.

4. How did you find the written materials?

- a) Quite enjoyed
- b) Liked written materials – good ideas. Not too childish, reasonable suggestions
- c) Liked balance sheet – easy to understand. Liked balance sheet.

5. Goal setting was it useful / difficult?

- a) Goal setting good as get reward
- b) Most useful – hard to set goals. Difficult to stick to.
- c) Good but hard – very useful. Helpful to give suggestions of ideas to families of things people will stick to.

6. Diary keeping was it helpful / easy to do?

- a) Found it upsetting. Sort of helpful, particularly 1 week as highlighted problem – after that boring
- b) Good to show what actually doing – didn't realise some activities /foods
- c) Good, helpful for changes. More emphasis on joint recording.

7. Did rewards help you to meet your goals?

- a) Yes
- b) Would have stuck to goals without rewards but rewards made it easier.
- c) Very helpful for child to keep to targets. Dad happy to give rewards.

8. Number of appointments, 2 week intervals – were they easy to attend / too many / too few?

- a) 2 weekly good. Child not too comfortable.
- b) Originally thought twice per week. Happy with frequency. More than 4 would be good – feel now left on own, worried about keeping up changes.
- c) Good length – 4 sessions not long enough.

Appendix 8a Standard care post study audit questionnaire

February 2005

Dear

Audit of standard dietetic care during SCOTT project

As part of the SCOTT project we would like to carry out a short audit on the type of advice given to patients by the dietitians who undertook the standard dietetic care.

Enclosed is a short questionnaire that we would be very grateful if you could take the time to fill out. We are interested in the typical care you gave to patients you saw during the SCOTT project and would ask you to answer the questions about your general advice.

Thank you in advance for your time.

Yours

Laura Stewart
Research Dietitian

Jan Chapple
Research Dietitian

Please tick or circle the appropriate answer (more than 1 can be indicated) and add any comments. Thank you.

How would you describe the dietary advice you gave

- ☐ General healthy eating
- ☐ Structured restrictions
- ☐ Categorising foods into good and bad
- ☐ Other

Comments

Did you discuss physical activity?

- ☐ Yes
- ☐ No

Comments

Did you make recommendations to change physical activity?

- ☐ Yes
- ☐ No

If yes could you briefly describe your general recommendations?

Comments

Did you discuss sedentary time (i.e. time spent on computers, watching TV)?

- ☐ Yes
- ☐ No

Comments

Did you make recommendations to change sedentary time?

- ☐ Yes
- ☐ No

If yes could you briefly describe your general recommendations?

Comments

Which printed information did you give the patients –

- ☐ SNDRi The Right Choice – Healthy lifestyle: primary school age
- ☐ SNDRi The Right Choice – Meal and snack suggestions
- ☐ SNDRi The Right Choice – A guide for you and our child on increasing activity
- ☐ SNDRi The Right Choice – Food labels
- ☐ SNDRi The Right Choice – Goal sheet
- ☐ SNDRi The Right Choice – Being young and overweight. Does it matter
- ☐ SNDRi The Right Choice – Asian evening meal suggestions
- ☐ Other leaflets – please state

Comments

Did you use goals/targets for change?

- ☐ Yes
- ☐ No

Comments

Who sets the goals?

- ☐ You
- ☐ The child
- ☐ The parents
- ☐ A combination

Comments

Did you set goals for changes in eating habits?

- ☐ Yes
- ☐ No

Comments

Did you set goals for changes in physical activity?

- ☐ Yes
- ☐ No

Comments

Did you set goals for changes in sedentary time?

- ☐ Yes
- ☐ No

Comments

Did you ask the child/families to keep a written record/diary of food intake/activity levels?

- ☐ Yes
- ☐ No

Comments

Did you use rewards/treats for the child meeting their goals?

- ☐ Yes
- ☐ No

Comments

In general do you think that you changed your 'typical' care during the SCOTT project?

- ☐ No
- ☐ Yes
- ☐ Sometimes

If yes please explain

In general do you think that standard dietetic weight management is effective?

- ☐ All of the time
- ☐ Most of the time

- ☐ Some of the time
- ☐ Never

Comments

Any other general comments

Thank you for taking the time to complete this audit. There is no need to put your name on this sheet but please do indicate your department.

- ☐ Edinburgh
- ☐ Glasgow
- ☐ Community

Please return to Laura Stewart, Dietitian, Royal Hospital for Sick Children,
Sciennes Rd, Edinburgh EH9 1LF

Feb 05

Appendix 8b Summary of answers to an audit of standard care dietitians' practice during the SCOTT project.

Number for each answer is given beside the question in bold. For some question more than one answer was given. Comments are given in full and the numbers correlate to the same dietitian though out.

How would you describe the dietary advice you gave

- ☐ General healthy eating **7**
- ☐ Structured restrictions **3**
- ☐ Categorising foods into good and bad
- ☐ Other

Comments

1. Depending on individual a combination of general healthy eating and structured restrictions/structured meal plan.

Did you discuss physical activity?

- ☐ Yes **7**
- ☐ No

Comments

1. Always encouraged regular/daily activity and try and suggest realistic goals depending on individuals.

Did you make recommendations to change physical activity?

- ☐ Yes **7**
- ☐ No

If yes could you briefly describe your general recommendations?

- 1.To try and be active daily e.g. walk to school/cycle, etc. I look at what doing at present and suggest ways to build on this.
2. Encouraged an increase and discussed examples.
- 3.Generally to increase physical activity but no information given about frequency/duration.
5. Include walking, dancing to music
6. Suggested more walking, cycling, dancing to music at home. Play with friends. PE participation (as some kids opt out of this more often than ideal).
7. Tried to identify activities enjoyed or could participate in and encouraged. Suggested whole family could do activities together.

Comments

5. General encouragement of any physical activity undertaken

Did you discuss sedentary time (i.e. time spent on computers, watching TV)?

- | | |
|------------------------------|----------|
| <input type="checkbox"/> Yes | 6 |
| <input type="checkbox"/> No | 1 |

Comments

1. Looked at how much time daily, I focus more on ways to increase activity rather than specifying time limit in sedentary activity.

Did you make recommendations to change sedentary time?

- | | |
|------------------------------|----------|
| <input type="checkbox"/> Yes | 5 |
| <input type="checkbox"/> No | 2 |

If yes could you briefly describe your general recommendations?

Comments

1. Focus on increasing activity.
4. To reduce the time spent watching TV/computer games. Didn't give information about maximum and minimum hours.
6. Reduce TV watching, computer games and exercise instead.
7. Tried to identify daily sedentary time and then suggest ways on how to reduce this.
5. Did not make specific recommendations about watching TV/computer but encouragement to make time for physical activity.

Which printed information did you give the patients –

- ☐ SNDRi The Right Choice – Healthy lifestyle: primary school age **7**
- ☐ SNDRi The Right Choice – Meal and snack suggestions **7**
- ☐ SNDRi The Right Choice – A guide for you and your child on increasing activity **7**
- ☐ SNDRi The Right Choice – Food labels **7**
- ☐ SNDRi The Right Choice – Goal sheet **7**
- ☐ SNDRi The Right Choice – Being young and overweight. Does it matter? **7**
- ☐ SNDRi The Right Choice – Asian evening meal suggestions **2**
- ☐ Other leaflets – please state

Comments

1. Used all but did not always give all to each patient – selected most appropriate.
4. Didn't always give the goal sheet.

Did you use goals/targets for change?

- ☐ Yes **7**
- ☐ No

Comments

1. Sometimes more structured than others but usually 2-4 targets.
4. Given summary sheet for areas covered in consult but not for every patient.

Who sets the goals?

- ☐ You **3**
- ☐ The child
- ☐ The parents **1**
- ☐ A combination **5**

Comments

1. If child/parent not forthcoming with targets I would suggest.
7. Initially I made suggestions but then got child/family agreement before setting.

Did you set goals for changes in eating habits?

- ☐ Yes **7**
- ☐ No

Comments

Did you set goals for changes in physical activity?

- ☐ Yes **4**
- ☐ No **3**

Comments

Did you set goals for changes in sedentary time?

- ☐ Yes **3**
- ☐ No **4**

Comments

1. (*Comment for both physical and sedentary*). Dependent on what child was doing to begin with, therefore not always set for each.
6. Just discussed it generally to decrease and increase exercise (*answered no*).
7. Not always – occasionally (*answered yes*)

Did you ask the child/families to keep a written record/diary of food intake/activity levels?

- ☐ Yes **3**
- ☐ No **4**

Comments

1. Again not for all. If child/parent very motivated may not ask them to.
2. Very occasionally. To prove to the families amount of foods consumed particularly treats. (*answered no*)
4. Generally not. (*answered no*)
5. Asked to keep record of food intake occasionally
7. Only if family were poor historians or child found it useful keeping record. (*answered yes*)

Did you use rewards/treats for the child meeting their goals?

- ☐ Yes **1**
- ☐ No **6**

Comments

1. Will sometime suggest rewards e.g. if save pocket money and not buying sweets then use for games, etc. (Not for food treats)
2. But I advised parents on changing treats and rewards from sweets etc to fruit, hair bobbles , socks, etc (*answered no*)
5. But may have come up in context of family member already offering 'something' – treat that is. (*answered no*)
7. Suggested a 'treat' day per week when for example chocolate or biscuit could be consumed or saving pocket money instead of buying confectionary to go to cinema or shopping.

In general do you think that you changed your 'typical' care during the SCOTT project?

- ☐ No **7**
- ☐ Yes
- ☐ Sometimes

If yes please explain

In general do you think that standard dietetic weight management is effective?

- ☐ All of the time
- ☐ Most of the time
- ☐ Some of the time **7**
- ☐ Never

Comments

1. Depends on the parent motivation.
2. Depends on child and parent level of motivation.
3. Depends on the support of the entire family and changing a family eating pattern can prove difficult.
4. Limited.
6. Depends on readiness to change (of the patient). Dietitians need training on psychological/counselling/?motivational

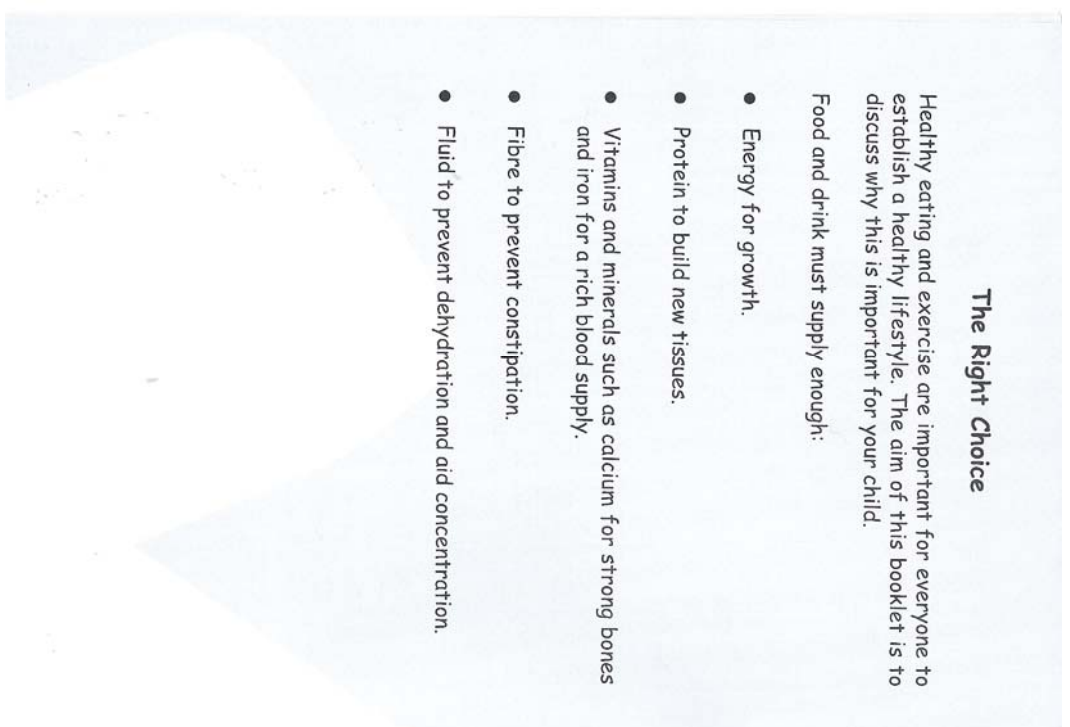
interviewing techniques to be more effective.

7. Depends on how motivated the child and family are. If advice given is taken on board weight loss will be achieved. Greater success during 'SCOTT' project. This could be families choose to be recruited.

Any other general comments

1. I don't have set ways of advising patients, will depend on individual. But probably have set questions initially.
2. Without being more specific about setting goals – not really surprised that no-one loses weight.

Appendix 9 Written materials used in standard care



Healthy eating means eating a variety of foods and in the right amount. This is important to ensure that children grow and keep well. The following diagram shows the five food groups. The size of each section gives a rough idea as to the amount of each food group that a child should eat daily.



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A Healthy Lifestyle

A healthy lifestyle also includes being active on a daily basis. Walking, swimming, cycling, dancing and playing football are all good ways of how to be active.

Can you think of things you and your child could do to be more active on a regular basis?

It is really important that the whole family is following the same healthy eating principles, and that support is given to the family member who is trying to make lifestyle changes.

To follow the healthy eating principles, here are some guidelines to help you:

- Eat regularly; it doesn't help to miss out meals. Breakfast is especially important.
- Drink plenty tap water or unflavoured bottled water.
- Include bread, pasta, cereals, rice, chapatti or potatoes at every meal.
- Eat fruit and vegetables daily; we should all be aiming for five portions per day.
- Include up to one pint of low fat milk per day.
- Cut down on foods and drinks high in sugar e.g. sweets, chocolate, fizzy drinks, cakes and biscuits.
- Cut down on the amount of high fat foods e.g. crisps, chips and pastries. Reduce in frequency and quantity.
- Avoid fried foods e.g. fried sausage, burgers and eggs.
- Look at your weekly shopping to see what changes you can make for the whole family.

To help reduce the energy content of popular, not so healthy food, here are some suggestions of lower energy alternatives:

High Energy Foods Sugar (white/brown)	Better Alternatives Sweetener if necessary e.g. Canderel, Sweet 'n' Low
Jam, marmalade, honey	Reduced sugar jam, marmalade
Sugary, diluting and fizzy juice	Sugar free drinks e.g. low calorie squash, fizzy drinks, water
Cakes, sweet pastries, chocolate biscuits and cream biscuits	Limit quantities (see snack sheet) Plain biscuits e.g. digestive, crackers, crispbreads Fruit teacakes, scones, crumpets, pancakes, with low fat spread
Tinned fruit in syrup	Tinned fruit in natural juice and all fresh fruit
Thick 'n' Creamy or custard style yoghurt, fromage frais with sugar	Low fat yoghurt or fromage frais
Sugar coated breakfast cereals e.g. Frosties, Coco Pops, Frosted Shreddies	Plain cereals e.g. Cornflakes, Rice Krispies, Shreddies
Fried Foods	Grill, bake, boil, steam or microwave
Crisps & nuts, sweets and chocolate	Best to limit total quantities. (see snack sheet for alternatives)

Healthy eating means eating a variety of foods and in the right amount. This is important to ensure your child grows and keeps well. How can this be achieved?

Breakfast:	Fruit or unsweetened fruit juice Plain cereal and low fat milk
Or	Toast and low fat spread Glass of low fat milk
Mid Morning:	Fruit Carton of milk/water/low calorie drink
Lunch:	Baked potato & baked beans
Or	Cheese & tomato sandwich Low fat/low sugar yoghurt Apple/banana/raisins/kiwi-fruit Water/low calorie drink
Mid Afternoon:	1 plain biscuit/fruit/slice of toast Water/low calorie drink
Evening Meal:	Chicken/meat/fish/pulses/eggs/vegetarian Vegetables/salad Jacket/Boiled potatoes/rice/pasta/ chapatti/bread Fruit e.g. tinned pineapple in natural juice Low fat yoghurt/custard Water/low calorie drink
Before Bed:	Glass of low fat milk Plain breakfast cereal and low fat milk
Or	Slice of toast, with low fat spread

Top Ten Tips for You and Your Child

- Remember children learn best by example: be a good role model by adopting healthy eating and exercise behaviours for yourself.
- Ask friends and family members to support your child's efforts to have a healthy lifestyle. Everyone should be consistent in their approach to your child's healthy eating plan.
- Encourage your child to be active and limit their time watching TV, playing on the computer or playing video games.
- Avoid calling foods good or bad: offer healthy options. Don't buy the foods you know your child should be avoiding but agree on one to two treats a week for the whole family.
- Instead of rewarding your child with food, try one of the following:
 - going to the cinema, ten pin bowling, or ice skating.
 - a new book/toy/magazine.
 - having a friend stay overnight.
- Praise efforts made by your child to be healthy instead of dwelling on bad habits.
- Encourage your child to decide whether they really are hungry when they ask for food.
- Separate eating from other activities such as watching TV or doing school work.
- Provide meals and snacks at regular times instead of allowing your child to "graze" all day long.
- Comfort your child with attention, listening and hugs instead of food.

Notes

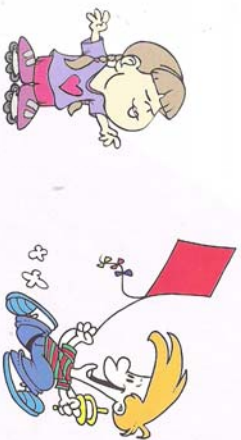
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A Guide for You and Your Child on Increasing Activity



Fast Track to an Active Life

As part of a healthy lifestyle, it is important that your child also increases their level of activity. This is ideal for family and group involvement. The following are some suggestions:

Plan family and group activities such as:

- Walks
- Visits to parks and playgrounds
- Walking your dog/neighbour's dog
- Using community sports/leisure centres. Contact your local council leisure department for information on facilities in your area



- Swimming
- Cycling

Encourage individual or team activities that children enjoy such as:

- Football
- Swimming
- Cycling
- Dancing
- Rollerblading
- Brownies/Cubs & Guides/Scouts
- Attending PE lessons/outdoor education



Notes

Encourage your child to try these easy activities which can be done indoors or outdoors:

- Skipping
- Dancing to favourite music
- Running/Jumping on the spot
- Hopscotch
- Helping with the housework



Encourage your child to be more active - take the stairs instead of the escalators or lift.

Leave the car at home and plan time to walk or cycle to school, nearby shops or friends' homes.

Remember that these activities should be fun! Do encourage your child but do not push too hard. Your child is more likely to join in a new activity if a friend is going too.

Limit the amount of time your child spends watching TV or playing video/computer games.



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Meal Suggestions

Between Meal Snacks

Many between meal snacks available in the shops e.g. biscuits, yoghurts, are advertised as being low in fat, but often have extra sugar added. This can be misleading, as they are not lower in energy. The following are the most suitable to have:

Fruit: Fresh, dried, tinned in juice. Examples include melons, apricots, peaches, kiwis, satsumas, strawberries, grapes, apples, pineapples, dates, sultanas, prunes.

For a change: Chop, slice or grate, or make fruit salad using a mixture of fresh, tinned and dried fruits. Freeze fruit juice in ice pole bags or lolly moulds.

Raw Vegetables: Examples include celery, carrot, peppers, cherry tomatoes, cucumber, cauliflower florets, baby sweetcorn.

For a change: Dip into low fat cheese or salsa tomato sauces or yoghurt or fromage frais (diet or natural).

Sugar-free jelly:

For a change: Mix (before set) with a low fat yoghurt or low fat fromage frais.

Popcorn: Choose plain type.

Vegetable Soup: Home-made using stock cubes and a variety of fresh or frozen vegetables such as carrot, turnip, parsnip, onions, celery, tomato, and mushrooms. This can be liquidised to give a smooth texture if preferred.

Breakfast Cereal: Choose plain ones like Weetabix, Fruit & Fibre, Rice Krispies, etc. with low fat milk.

Plain Biscuits: Choose one plain biscuit e.g. digestive, rich tea or one savoury biscuit e.g. crackers, water biscuits, rice cakes with a scrape of spread.

Breakfast

Fruit juice or fruit
Cereal with low fat milk

Cereal: choose ones like Weetabix, Shreddies, Fruit & Fibre, Cheerios, Fruitbix, Rice Krispies, Puffed Wheat.

Fruit juice or fruit
Porridge/Ready Brek

Fruit: try different types like bananas, kiwis, strawberries, raisins, apples.

Fruit juice or fruit
Toast with spread
Low fat yoghurt/milk

Spreads: try lower fat cheese spread, low fat butter, low fat margarine, low sugar jam, low sugar marmalade or yeast spread.

Fruit juice or fruit
Plain biscuits with spread
Low fat yoghurt/milk

Biscuits: choose ones like oatcakes, rice cakes, water biscuits or crackers.

Fruit juice or fruit
Crusty bread, roll or crumpet
Low sugar jam
Low fat yoghurt/milk

Breads and Rolls: try different varieties like granary, wholemeal, high fibre white, or bagels.



Snack Meals/Packed Lunches

Corned beef & tomato sandwich
Low fat fromage fraise
Fruit

Fillings: The following are ideas for sandwiches, rolls and baked potatoes.

Ham and low calorie coleslaw
tortilla wrap

Cold meats: such as ham, turkey, chicken, or beef.

Low fat yoghurt
Fruit

Cheese: low fat varieties, including low fat cheese spread.

Lentil/vegetable soup (home-made, low calorie, timed or cup-a-soup)
Bread roll
Low fat rice pudding pot
Fruit

Egg/fish: scrambled or boiled egg, timed tuna, salmon or mackerel.

Pitta bread with low fat cheddar cheese, lettuce
Small packet raisins

For a change:
To grated cheese, add raisins, grated carrot, chopped pineapple.

Slice of pizza
Mixed salad leaves
Cherry tomatoes
Fruit

To cottage cheese, add chopped peppers, grapes.

Grilled bacon, lettuce, tomato roll
Low fat custard pot, fruit

To tuna fish, add sliced or spring onion, sweet corn and mix with a small amount of tomato ketchup.



Main Meals

Minestrone Soup
Grilled fish fingers/fishcake with peas or baked beans
Jacket potato

Stir-fry chicken with vegetables (peppers, mushrooms, bean sprouts)

Sweet & sour or black bean sauce
Boiled noodles

Low fat fromage fraise

Beef curry with added vegetables (e.g. carrots, green beans)

Boiled rice

Fresh fruit salad and 1 scoop ice-cream

Lentil soup

Grilled lean pork chop with vegetables such as broccoli & cauliflower

Boiled savoury rice

Grilled sausage with baked beans
Jacket potato

Low fat rice pot or low fat timed rice with peaches in juice

Lean minced meat with carrots & turnip
Mashed potato
Sugar free fruit jelly (made with fresh fruit or fruit timed in juice)

Tuna pasta bake with sweetcorn and peas
Baked apple and low fat custard

Pasta shapes with tomato pasta sauce mixed with cooked mushrooms, peas (ham optional)
Timed fruit in juice e.g. fruit cocktail


Vegetable chilli with beans with pitta bread or tortilla wrap
Low fat fruit mousse

Vegetable soup
Macaroni cheese with a side salad of lettuce, beetroot, spring onion

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Asian Evening Meals


Mince and chick-pea curry (Channa-Keema) Boiled Rice Salad Natural yoghurt	Chana daal with tinds 2 small chapattis
Lentil daal (massar) Potato and mixed vegetable curry 2 small chapattis Diet fromage frais	Aloo Ghobi 2 small chapattis Low-fat custard
Tandoori chicken Boiled rice Fresh fruit salad and 1 scoop ice-cream	Quorn curry Boiled rice Timed fruit salad in juice
Spicy baked fish and peppers Boiled Rice Salad	Chilli con carne or kidney beans curry 2 small pitta breads Shredded cabbage and onions
Two egg curry with peas 2 small chapattis Low-fat rice pot or timed peaches in juice	

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A plan to help you to achieve a healthy lifestyle.
Below is a list of the goals you agreed to. Try and follow as
many of them as you can!

1)

2)

3)


4)

5)

6)

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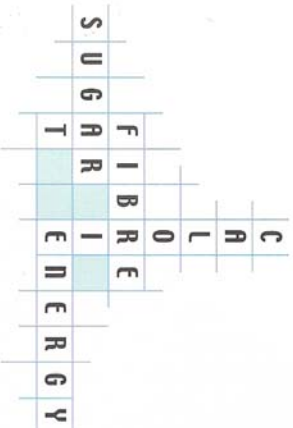
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Food Labels



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Introduction

With so many food products available, and with so many manufacturers making claims concerning their food products, it can be a difficult task deciding whether a food is suitable or not.

Food labels give us information about foods and products so that we can make the 'right choice'. This information leaflet looks at nutrition information that you are likely to read on the labels of familiar products. It gives some guidelines that will help you to make a decision on whether or not to include these products in your eating plan.

Certain low-fat products, such as yoghurts and biscuits, may contain high levels of sugar. So, although they do have less fat, the added sugar means that their energy value is similar to that of non-low fat foods. In general, these products are also more expensive.

The Ingredients List

When you look at a list of ingredients on a food product label, they must, by law, be listed in order - with the greatest amount first, and the least amount last. So if sugar appears first on the list, it is in the greatest amount.

What to look out for on a label when you go shopping?

- total amount of energy
- total amount of fat
- total amount of sugar
- total amount of fibre

Fat contains over twice the amount of energy compared to sugar (weight for weight) and, therefore, the more you eat, the more likely you are to put on weight!

Sugar does not contain any vitamins or minerals, and eating too much can cause weight gain and tooth decay.

Fibre adds bulk to your diet, giving you a feeling of fullness and also helps prevent constipation.

How can Nutrition Labels help us to make the Right Choice?

They give us information on the amount of fat, in grams, and the energy content, in calories, per 100g. (Remember that a serving may contain more or less than 100g, so always check the packet or portion size!)

To help you, in a 100g portion:

A lot	A little
10g sugar	2g sugar
20g fat	3g fat

Look at the difference in the fat and calorie content of these foods - per 100g portion:

Which one is the 'Right Choice'?

Fried home made chips	Low fat oven chips	Boiled potato
7g fat	5g fat	0.1g fat
190 calories(kcal)	167 calories(kcal)	72 calories(kcal)

Which one would you choose?

Creamy yoghurt, 110g pot	Lite yoghurt, 110g pot
3.5g fat	0.1g fat
123 calories(kcal)	58 calories(kcal)

Look at the difference in the packet size of the following, then the fat and calorie content:

Does this help you to make the 'Right Choice'?

Crisps (34g)	Lite crisps (28g)	Potato snacks (22g)
11g fat	6g fat	4g fat
181 calories(kcal)	132 calories(kcal)	95 calories(kcal)



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Appendix 10 Summary of data distribution and statistical tests performed for all statistical data presented in thesis

Table 1: BMI SD score and change in BMI SD score over time

Data	Group and period (number)	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
BMI SD score	NT baseline (n=69)	3.15 (0.56)	3.17 (2.68, 3.57)	>0.100
	six months (n=49)	2.94 (0.59)	2.95 (2.49, 3.40)	>0.100
	12 months (n=45)	2.88 (0.62)	2.83 (2.41, 3.36)	>0.100
	SC baseline (n=65)	3.26 (0.62)	3.29 (2.85, 3.64)	>0.100
	six months (n=48)	3.16 (0.66)	3.17 (2.72, 3.52)	>0.100
	12 months (n=41)	3.10 (0.67)	3.10 (2.70, 3.49)	>0.100
Changes in BMI SD score	NT 6-0 months (n=49)	-0.12 (0.21)	-0.10 (-0.24, -0.02)	0.037
	12-0 months (n=45)	-0.17 (0.34)	-0.07 (-0.32, 0.04)	<0.010
	SC 6-0 months (n=48)	-0.11 (0.21)	-0.06 (-0.22, 0.05)	0.072
	12-0 months (n=41)	-0.18 (0.28)	-0.19 (-0.31, 0.02)	>0.100

Table 2: BMI centile and change in BMI centile over time

Data	Group and period (number)	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
BMI centiles	NT baseline (n=69)	99.75 (0.34)	99.93 (99.62, 99.98)	<0.010
	six months (n=49)	99.44 (1.09)	99.84 (99.36, 99.97)	<0.010
	12 months (n=45)	99.24 (2.19)	99.77 (99.20, 99.96)	<0.010
	SC baseline (n=65)	99.78 (0.36)	99.95 (99.78, 99.99)	<0.010
	six months (n=48)	99.68 (0.61)	99.92 (99.67, 99.98)	<0.010
	12 months (n=41)	99.56 (0.75)	99.90 (99.66, 99.98)	<0.010
Changes in BMI centiles	NT 6-0 months (n=49)	-0.25 (0.88)	-0.03 (-0.09, <0.00)	<0.010
	12-0 months (n=45)	-0.47 (2.08)	-0.01 (-0.18, 0.01)	<0.010
	SC 6-0 months (n=48)	-0.12 (0.41)	-0.01 (-0.06, <0.00)	<0.010
	12-0 months (n=41)	-0.23 (0.54)	-0.02 (-0.13, <0.00)	<0.010

Table 3: Weight SD score and change in weight SD score over time

Data	Group and period (number)	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
Weight SD	NT baseline (n=69)	2.85 (0.70)	2.85 (2.29, 3.28)	>0.100
	six months(n=49)	2.64 (0.70)	2.63 (2.09, 3.04)	>0.100
	12 months(n=45)	2.60 (0.72)	2.59 (2.13, 3.08)	>0.100
	SC baseline (n=65)	2.98 (0.70)	2.97 (2.48, 3.43)	>0.100
	six months (n=48)	2.90 (0.77)	2.91 (2.52, 3.43)	>0.100
	12 months (n=41)	2.85 (0.79)	2.90 (2.28, 3.42)	>0.100
Changes in Weight SD	NT 6-0 months (n=49)	-0.12 (0.19)	-0.08 (-0.24, 0.01)	0.065
	12-0 months (n=45)	-0.11 (0.35)	-0.04 (-0.27, 0.10)	<0.010
	SC 6-0 months (n=48)	-0.06 (0.22)	-0.02 (-0.17, 0.06)	0.035
	12-0 months(n=41)	-0.10 (0.30)	-0.10 (-0.26, 0.08)	>0.100

Table 4: weight and weight change over time

Data	Group and period (number)	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
Weight	NT baseline (n= 69)	54.0 (13.7)	52.6 (43.8, 61.2)	>0.100
	six months (n=49)	55.7 (13.7)	54.8 (46.8, 62.3)	0.083
	12 months (n=45)	58.9 (13.8)	58.1 (52.1, 64.5)	0.086
	SC baseline (n=65)	52.1 (15.2)	49.0 (41.2, 61.7)	>0.100
	six months (n=48)	55.6 (16.0)	53.0 (43.2, 66.4)	>0.100
	12 months (n=41)	57.3 (16.3)	53.9 (46.8, 66.0)	0.043
Changes in Weight	NT 6-0 months (n= 49)	2.9 (3.1)	3.2 (1.3, 4.2)	<0.01
	12-0 months (n=45)	6.2 (4.8)	7.0 (3.9, 9.0)	<0.01
	SC 6-0 months (n=48)	3.4 (3.0)	4.0 (2.6, 5.5)	0.016
	12-0 months (n=41)	6.6 (4.2)	7.2 (4.5, 8.5)	>0.10

Table 5: Waist and change in waist over time

Data	Group and period (number)	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
Waist	NT baseline (n=67)	82.8 (9.5)	83.0 (77.2, 88.5)	>0.100
	six months (n=49)	81.8 (9.3)	82.5 (73.5, 86.8)	>0.100
	12 months (n=45)	82.6 (8.6)	82.5 (75.8, 87.7)	>0.100
	SC baseline (n=64)	81.4 (10.5)	81.0 (73.3 89.1)	>0.100
	six months (n=45)	81.9 (10.2)	80.9 (74.7, 91.0)	>0.100
	12 months (n=41)	82.6 (10.5)	80.8 (75.0, 91.5)	>0.100
Changes in Waist	NT 6-0 months (n=48)	-0.4 (3.6)	-0.2 (-1.9, 1.6)	<0.010
	12-0 months (n=44)	0.2 (6.0)	0.9 (-2.5, 5.4)	<0.010
	SC 6-0 months (n=45)	-0.04 (3.9)	0.5 (-2.4, 2.4)	>0.100
	12-0 months (n=41)	1.7 (4.6)	2.1 (-0.7, 4.7)	>0.100

Appendix table 6: Waist SD score and waist SD score changes over time

Data	Group and period (number)	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
Waist SD	NT baseline (n=67)	3.28 (0.53)	3.32 (2.91, 3.56)	>0.100
	six months (n=49)	3.01 (0.52)	3.08 (2.62, 3.40)	>0.100
	12 months (n=45)	2.95 (0.56)	3.05 (2.46, 3.40)	0.100
	SC baseline (n=64)	3.29 (0.63)	3.30 (2.90, 3.69)	>0.100
	six months (n=45)	3.11 (0.61)	3.06 (2.75, 3.64)	>0.100
	12 months (n=41)	3.14 (0.70)	3.25 (2.67, 3.62)	>0.100
Changes in Waist SD	NT 6-0 months (n=47)	-0.20 (0.24)	-0.18 (-0.33, -0.06)	0.024
	12-0 months (n=45)	-0.26 (0.43)	-0.20 (-0.46, -0.04)	<0.010
	SC 6-0 months (n=45)	-0.16 (0.34)	-0.10 (-0.33, -0.01)	0.013
	12-0 months (n=41)	-0.19 (0.35)	-0.16 (-0.40, 0.05)	>0.100

Table 7: Waist centiles over time

Data	Group and period (number)	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
Waist centile	NT baseline (n=67)	99.80 (0.62)	99.95 (99.82, 99.98)	<0.01
	six months (n=49)	99.63 (0.67)	99.90 (99.56, 99.96)	<0.01
	12 months (n=45)	99.38 (1.77)	99.89 (99.30, 99.97)	<0.01
	SC baseline (n=64)	99.65 (1.25)	99.95 (99.81, 99.99)	<0.01
	six months (n=45)	99.49 (1.62)	99.89 (99.70, 99.99)	<0.01
	12 months (n=41)	99.46 (1.36)	99.94 (99.62, 99.98)	<0.01

Table 8: Habitual physical activity over time

Data	Group and period (number)	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
Mean cpm	NT baseline (n=60)	642 (202)	649 (508, 749)	0.037
	SC baseline (n=57)	686 (229)	645 (526, 821)	>0.10
% Sed time	NT baseline	81.1 (7.0)	81.2 (76.5, 86.4)	>0.10
	SC baseline	79.6 (7.1)	80.7 (75.4, 84.9)	<0.01
% Light	NT baseline	15.6 (5.4)	15.8 (11.4, 19.4)	0.092
	SC baseline	16.8 (5.1)	16.5 (13.3, 20.3)	>0.10
% MVPA	NT baseline	3.2 (2.7)	2.3 (1.8, 4.1)	>0.10
	SC baseline	3.6 (2.7)	2.6 (1.8, 4.5)	<0.01
Mean cpm	NT six months (n=34)	635 (192)	626 (490, 716)	0.057
	SC six months (n=33)	568 (157)	538 (458, 626)	0.049
% Sed time	NT six months	81.9 (5.8)	81.8 (78.4, 86.4)	>0.10
	SC six months	83.9 (4.6)	84.4 (81.5, 86.9)	>0.10
% Light	NT six months	14.6 (3.9)	14.5 (12.0, 17.5)	>0.10
	SC six months	13.3 (3.8)	13.0 (11.1, 15.2)	>0.10
% MVPA	NT six months	3.5 (2.8)	3.0 (1.7, 4.3)	<0.01
	SC six months	2.8 (1.7)	2.3 (1.3, 3.8)	<0.01

cpm –counts per minute % sed time – percentage sedentary time

%light – percentage light activity %MVPA – percentage moderate-vigorous physical activity

Table 9: Changes in habitual physical activity over time

Data	Group and period (number)	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
Mean cpm	NT 0-6 months (n=33)	18 (163)	21 (-129, 157)	>0.10
	SC 0-6 months (n=33)	-98 (165)	-115 (-194, 1.5)	>0.10
% Sed time	NT 0-6 months	0.1 (5.6)	0.05 (-4.8, 3.8)	>0.10
	SC 0-6 months	3.8 (5.3)	4.5 (0.02, 6.2)	>0.10
% Light	NT 0-6 months	-0.6 (4.6)	-0.5 (-3.5, 2.6)	>0.10
	SC 0-6 months	-3.3 (4.1)	-3.8 (-5.2, -0.6)	>0.10
% MVPA	NT 0-6 months	0.5 (2.1)	0.2 (-0.8, 1.4)	0.087
	SC 0-6 months	-0.4 (1.8)	-0.7 (-1.8, 1.0)	>0.10

cpm –counts per minute % sed time – percentage sedentary time
 %light – percentage light activity %MVPA – percentage moderate-vigorous
 physical activity

Table 10: Changes in height over time

Data	Group and period	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
Changes in height	NT 6-0 months (n=49)	3.3 (0.9)	3.2 (2.8, 4.0)	0.023
	12-0 months (n=45)	6.4 (1.2)	6.4 (5.8, 7.0)	>0.10
	SC 6-0 months (n=48)	3.7 (1.0)	3.6 (3.0, 4.3)	>0.10
	12-0 months (n=41)	6.8 (1.4)	7.0 (6.0, 7.6)	>0.10

Appendix table 11: Total score for parental quality of life questionnaire and changes in parental scores over time

Data	Group and period	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
Parental scores	NT baseline (n=67)	66.6 (14.5)	66.3 (58.7, 76.3)	>0.100
	six months (n=47)	70.6 (15.7)	70.6 (60.9, 83.7)	>0.100
	12 months (n=43)	69.1 (15.9)	70.6 (57.6, 81.5)	>0.100
	SC baseline (n=61)	66.5 (14.8)	65.2 (54.9, 78.3)	>0.100
	six months (n=45)	70.8 (12.8)	69.6 (60.9, 81.7)	>0.100
	12 months (n=38)	71.1 (16.2)	73.9 (55.2, 82.9)	>0.100
Changes in Parental scores	NT 6-0 months (n=47)	3.3 (9.1)	3.3 (-2.2, 10.3)	>0.100
	12-0 months (n=43)	2.7 (8.0)	3.1 (-3.3, 8.7)	>0.100
	SC 6-0 months (n=44)	5.2 (9.8)	6.0 (-2.0, 12.8)	>0.100
	12-0 months (n=37)	4.8 (11.3)	4.3 (-3.3, 14.1)	>0.100

Appendix table 12: Total score for child quality of life questionnaire and changes in child scores over time

Data	Group and period	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
Child scores	NT baseline (n=69)	72.9 (16.4)	75.0 (63.6, 85.9)	0.082
	six months (n=49)	76.8 (14.2)	81.5 (64.7, 87.5)	0.022
	12 months (n=45)	81.3 (13.6)	85.2 (69.6, 92.4)	0.046
	SC baseline (n=57)	70.1 (16.5)	72.8 (60.9, 80.4)	<0.01
	six months (n=43)	75.2 (15.6)	78.3 (65.2, 85.2)	<0.01
	12 months (n=38)	75.7 (12.8)	78.3 (67.4, 84.0)	>0.10
Changes in	NT 6-0 months (n=49)	3.7 (12.6)	2.2 (-4.9, 10.9)	>0.10
	12-0 months (n=45)	7.4 (14.6)	10.9 (-3.9, 17.4)	>0.10
Child scores	SC 6-0 months (n=43)	6.9 (13.5)	6.5 (<0.001, 13.5)	>0.10
	12-0 months (n=37)	8.0 (16.8)	8.7 (<0.001, 19.6)	>0.10

Appendix table 13: Compliance BMI SD scores and changes in BMI SD scores

Data	Group and period	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
BMI SD score	NT baseline (n=39)	3.1 (0.6)	3.1 (2.5, 3.6)	>0.100
	six months (n=39)	2.9 (0.6)	3.0 (2.5, 3.4)	>0.100
	12 months (n=36)	2.9 (0.7)	2.8 (2.3, 3.4)	>0.100
	SC baseline (n=41)	3.2 (0.6)	3.2 (2.9, 3.6)	0.075
	six months (n=38)	3.1 (0.6)	3.2 (2.6, 3.5)	>0.100
	12 months (n=35)	3.0 (0.6)	3.1 (2.3, 3.4)	>0.100
Changes in BMI SD score	NT 6-0 months (n=39)	-0.16 (0.20)	-0.12 (-0.27, -0.03)	<0.01
	12-0 months (n=36)	-0.20 (0.36)	-0.09 (-0.36, 0.02)	<0.01
	SC 6-0 months (n=38)	-0.13 (0.22)	-0.08 (-0.26, 0.02)	>0.100
	12-0 months (n=35)	-0.18 (0.28)	-0.16 (-0.30, 0.02)	>0.100

Table 14: Compliance weight and changes in weight

Data	Group and period	Mean (SD)	Median (IQ range)	Ryan Joiner p-value
Weight	NT baseline (n=39)	53.7 (12.5)	52.6 (45.4, 60.6)	>0.100
	six months (n=39)	56.1 (13.1)	55.2 (48.0, 64.6)	>0.100
	12 months (n=36)	60.3 (14.6)	59.2 (52.6, 68.6)	>0.100
	SC baseline (n=41)	52.0 (15.6)	48.1 (40.0, 60.4)	0.079
	six months (n=38)	55.4 (16.6)	52.3 (42.7, 66.9)	>0.100
	12 months (n=35)	58.0 (16.4)	53.9 (46.8, 67.8)	0.021
Changes in Weight	NT 6-0 months (n=39)	2.4 (2.6)	3.0 (1.0, 4.0)	0.050
	12-0 months (n=36)	5.9 (5.3)	7.0 (3.6, 9.1)	0.02
	SC 6-0 months (n=38)	3.1 (3.2)	4.0 (1.9, 5.4)	0.041
	12-0 months (n=35)	6.5 (4.4)	7.1 (4.4, 8.0)	>0.100

Appendix 11 Figures showing boxplots of data distribution over time

Figure 11.1: Boxplot of BMI SD over time – Standard Care

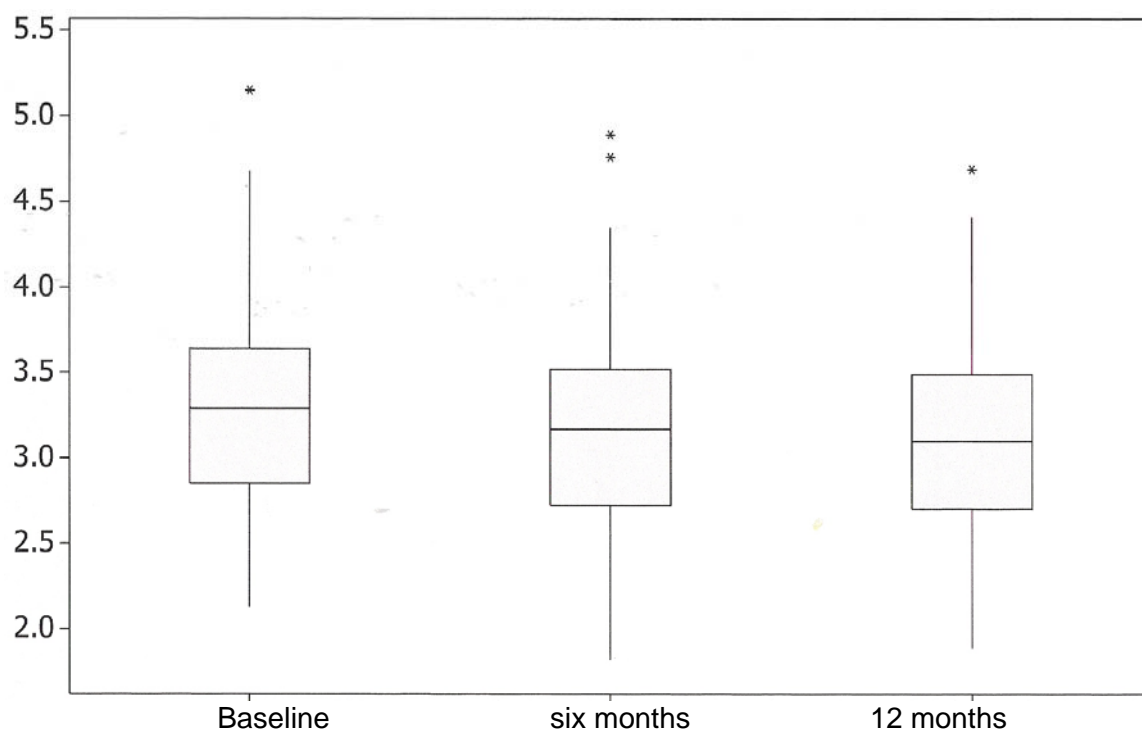


Figure 11.2: Boxplot of BMI SD over time – Novel Treatment

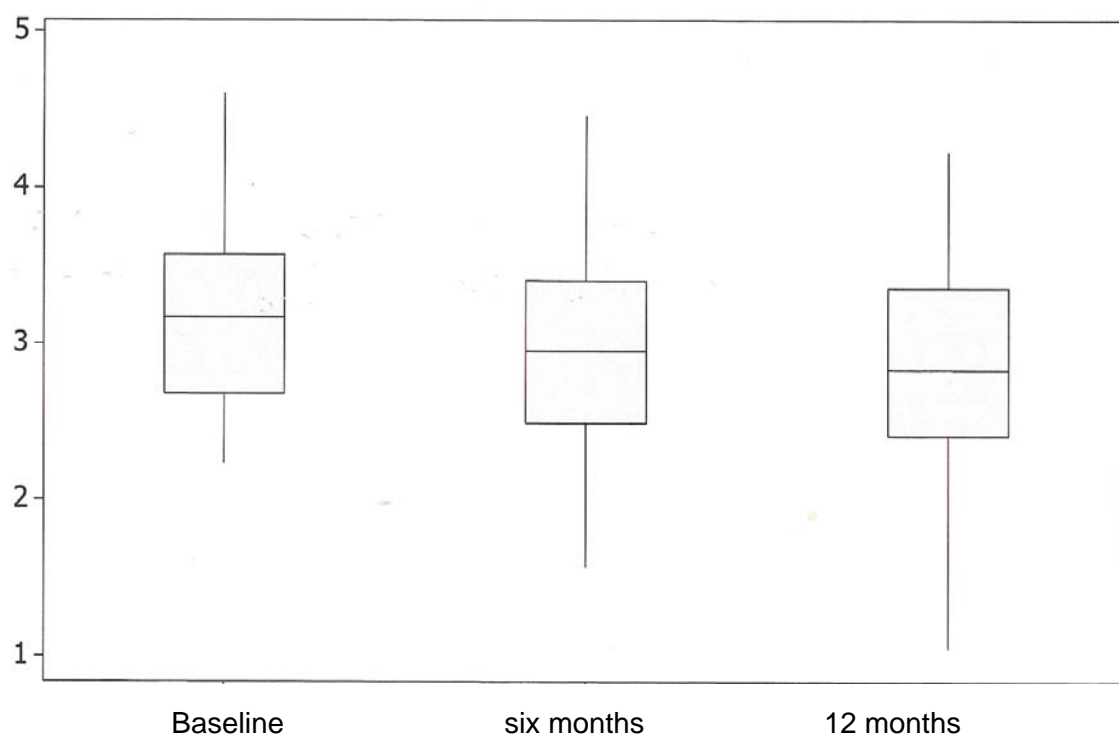


Figure 11.3: Boxplot of BMI centiles over time – Standard Care

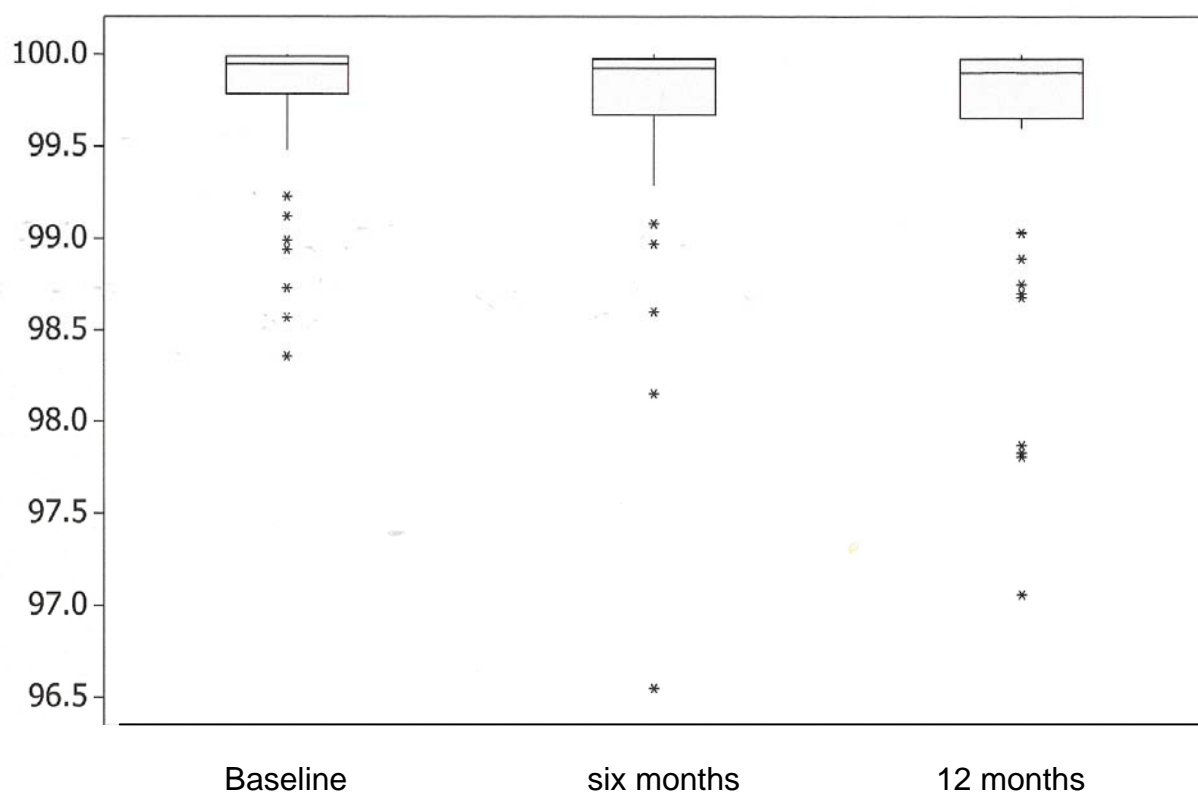


Figure 11.4: Boxplot of BMI centiles over time – Novel Treatment

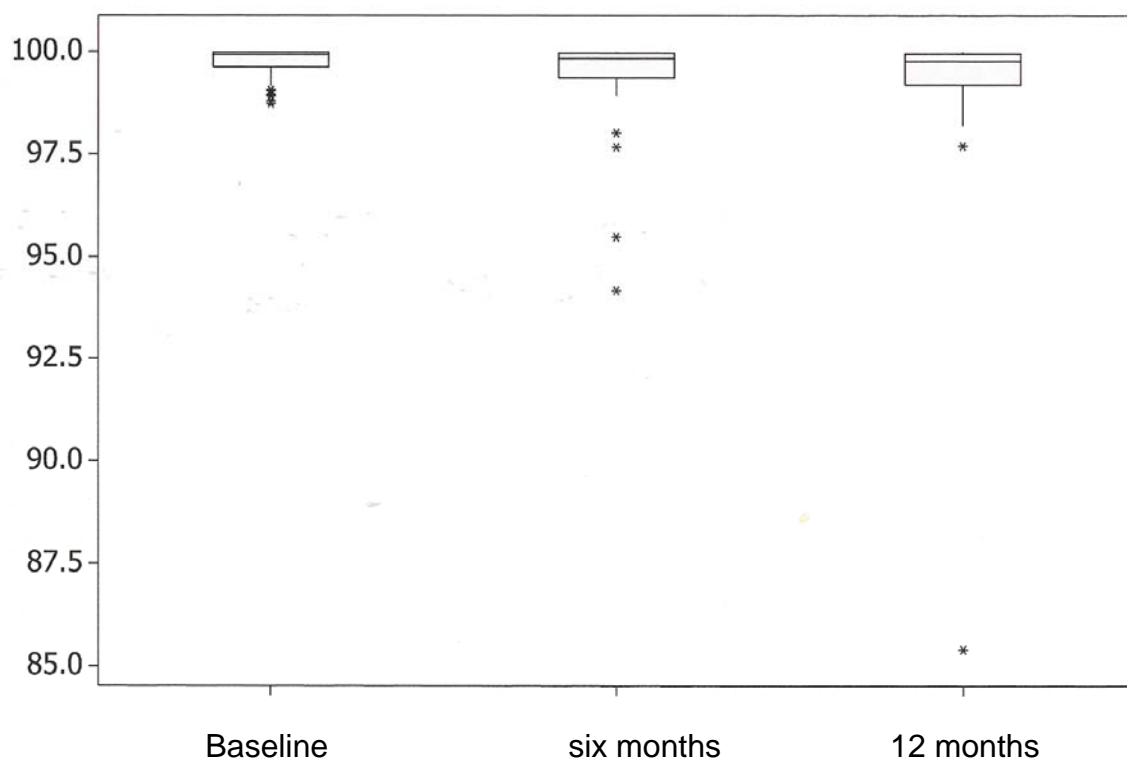


Figure 11.5: Boxplot of weight over time – Standard Care

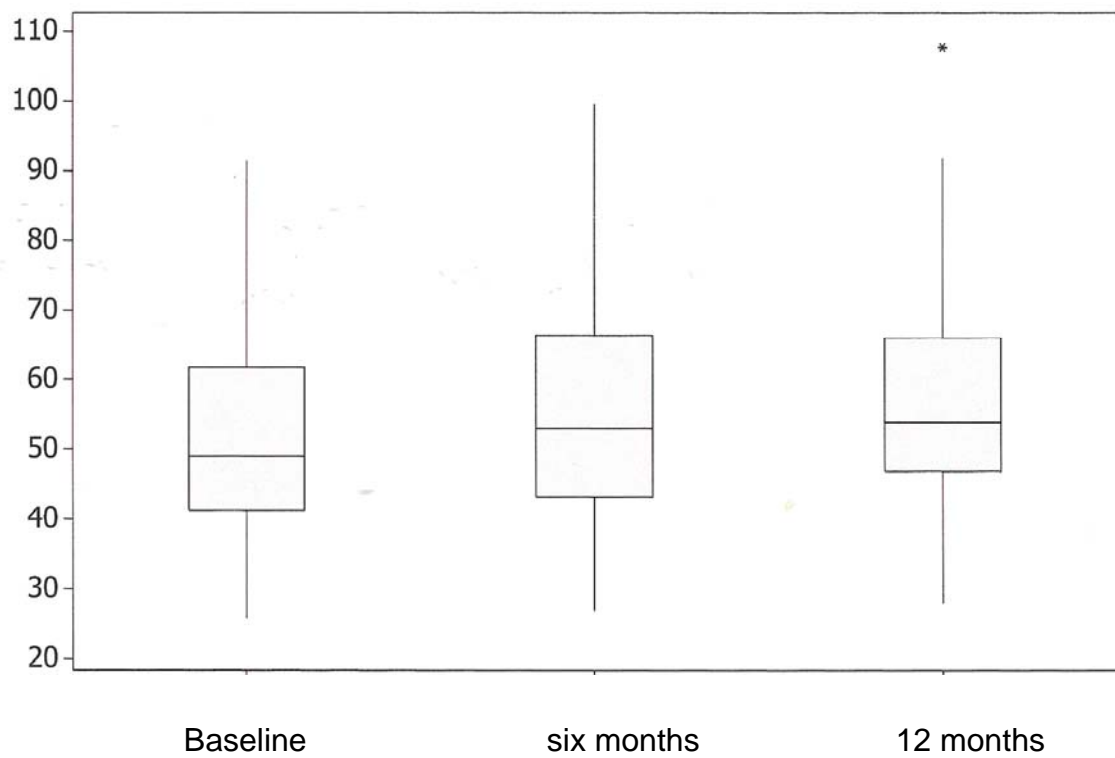


Figure 11.6: Boxplot of weight over time – Novel Treatment

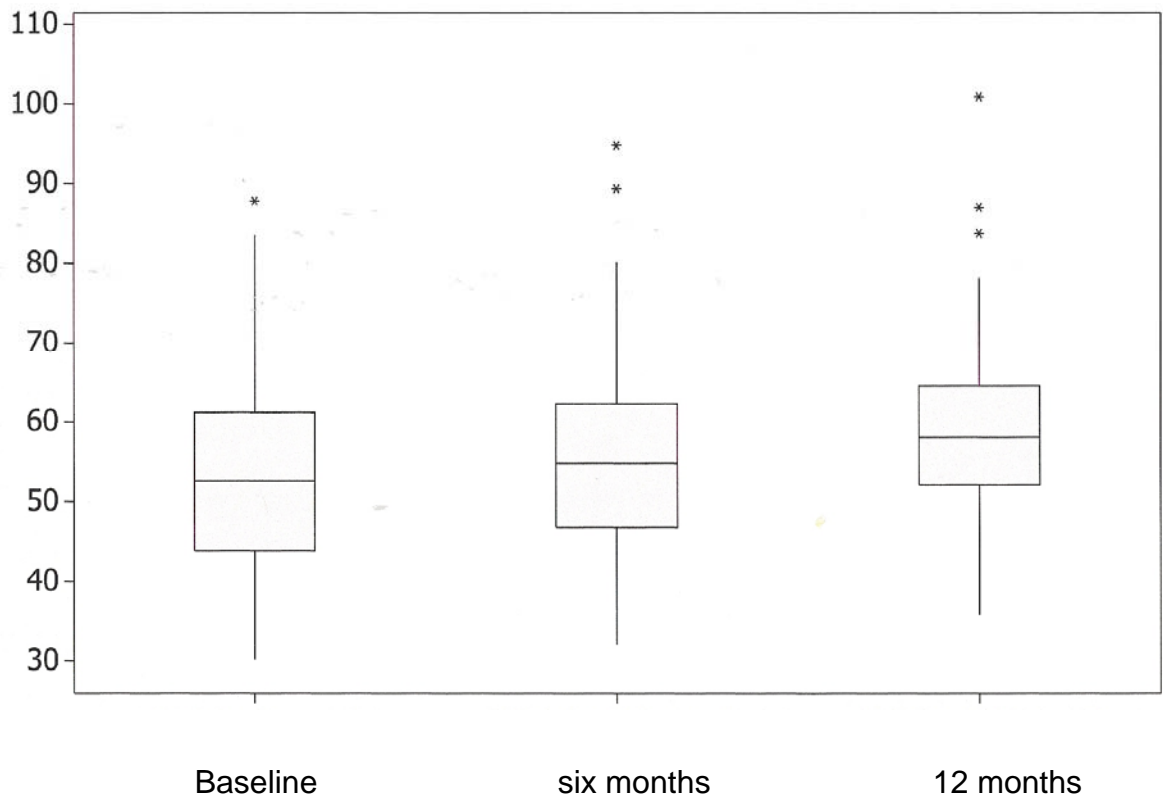


Figure 11.7: Boxplot of weight SD score over time – Standard Care

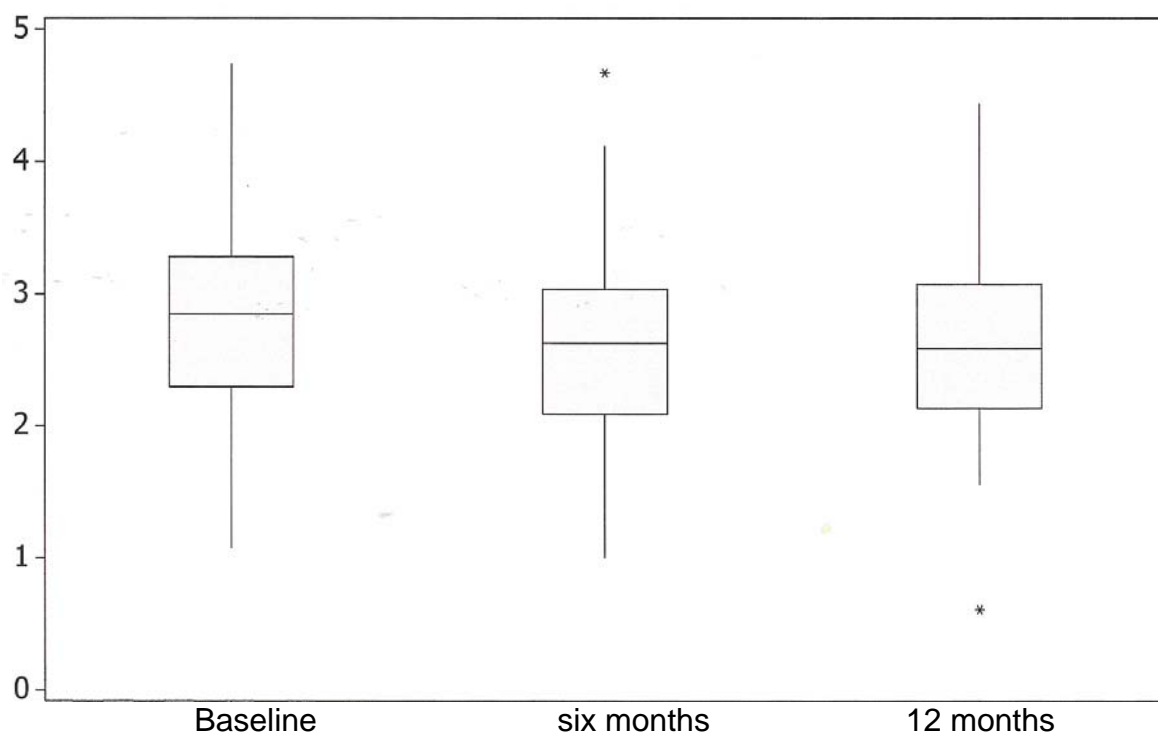


Figure 11.8: Boxplot of weight SD score over time – Novel Treatment

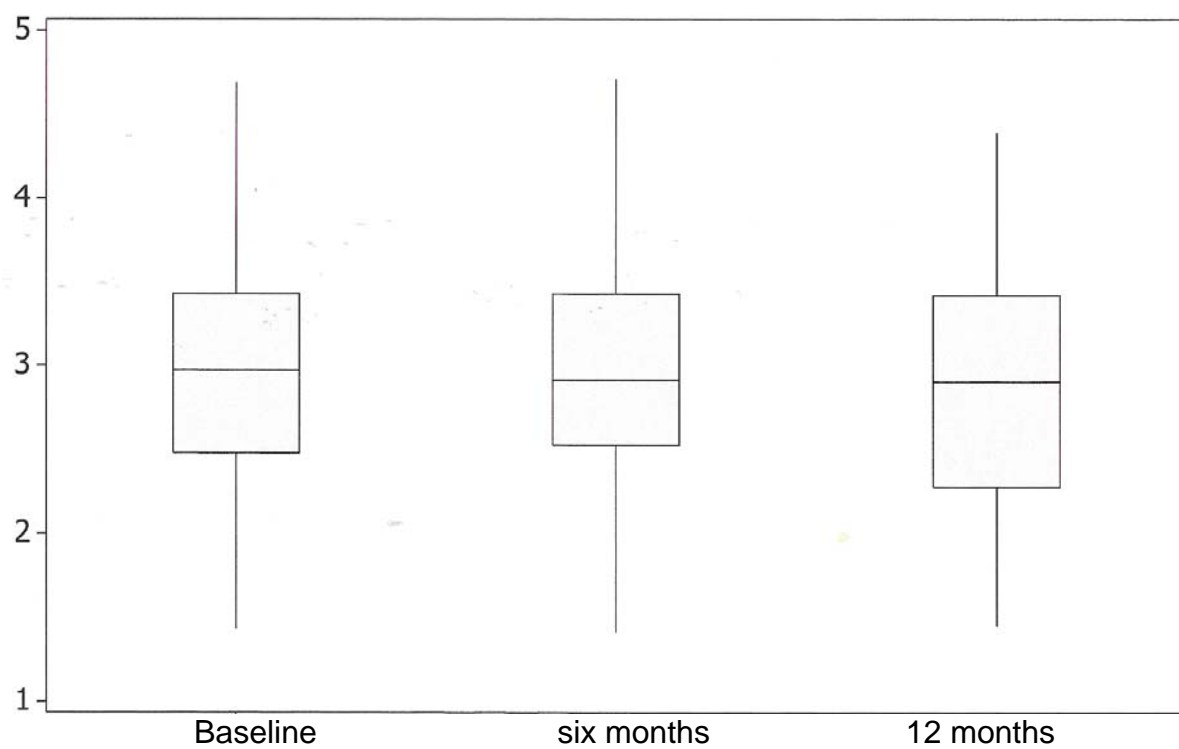


Figure 11.9: Boxplot of waist measurement over time – Standard Care

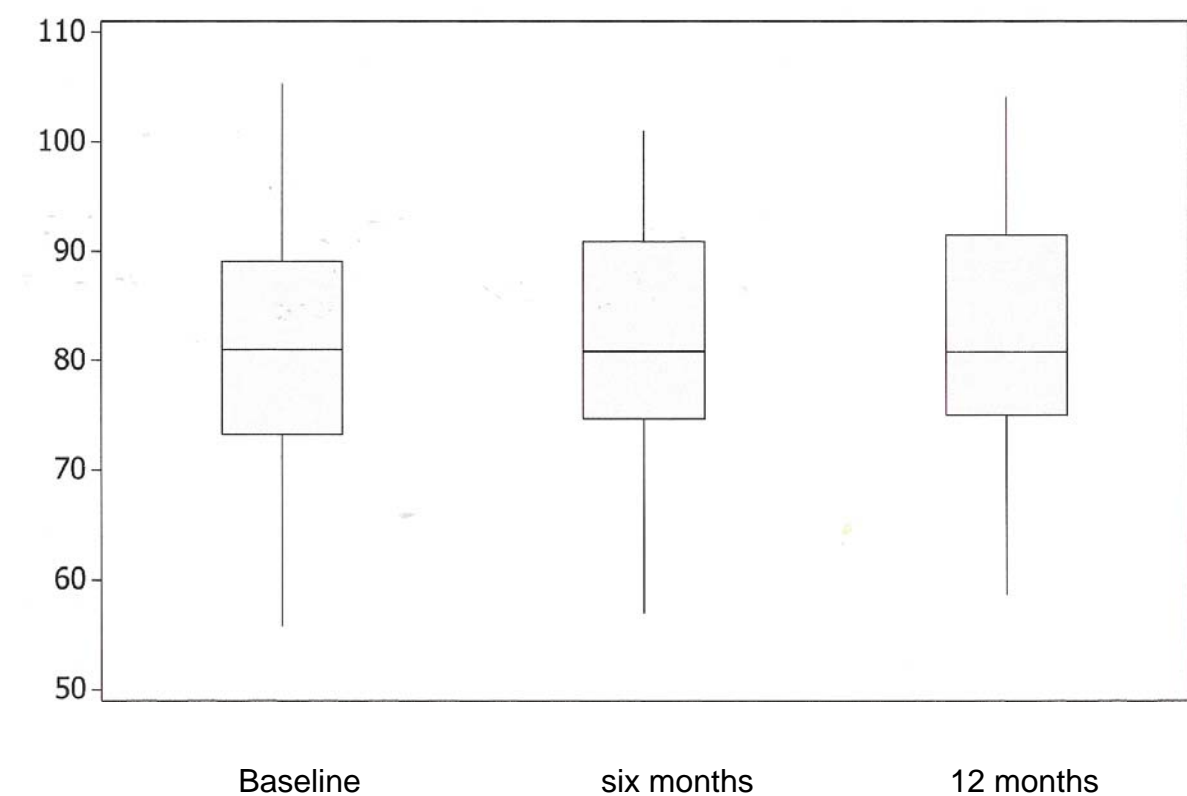


Figure 11.10: Boxplot of waist measurement over time – Novel Treatment

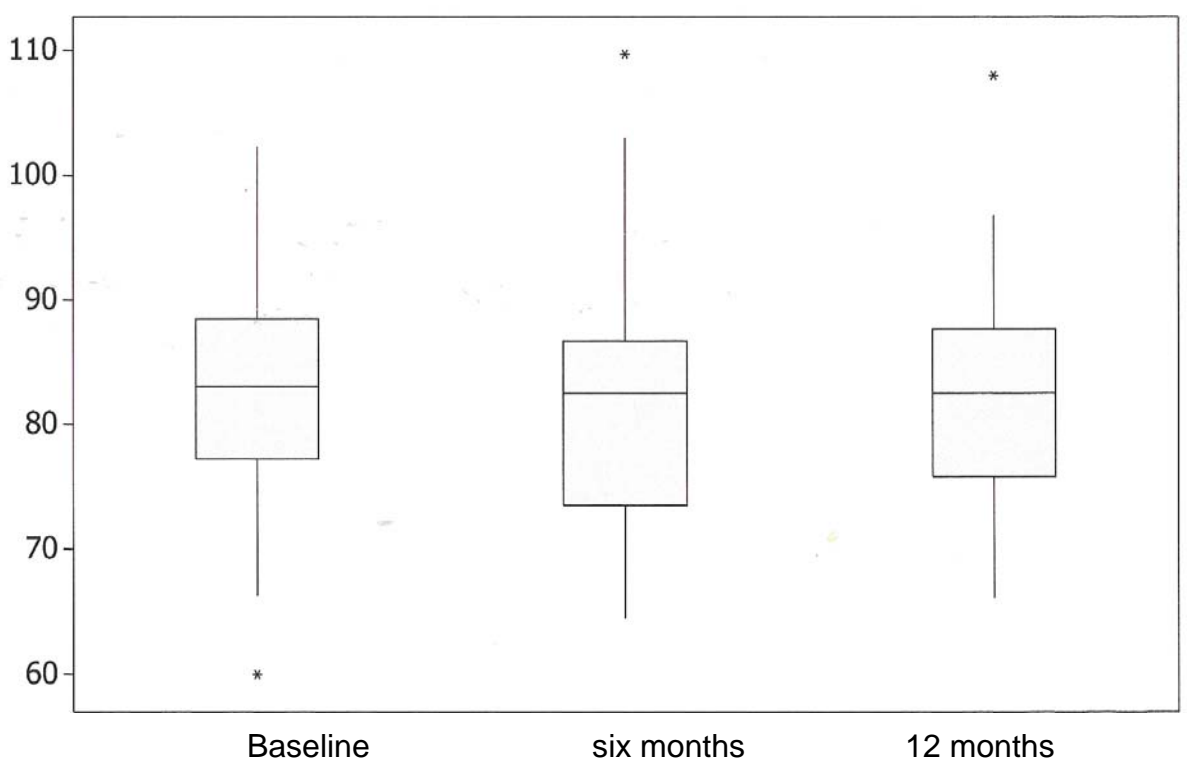


Figure 11.11: Boxplot of waist measurement SD score over time – Standard Care

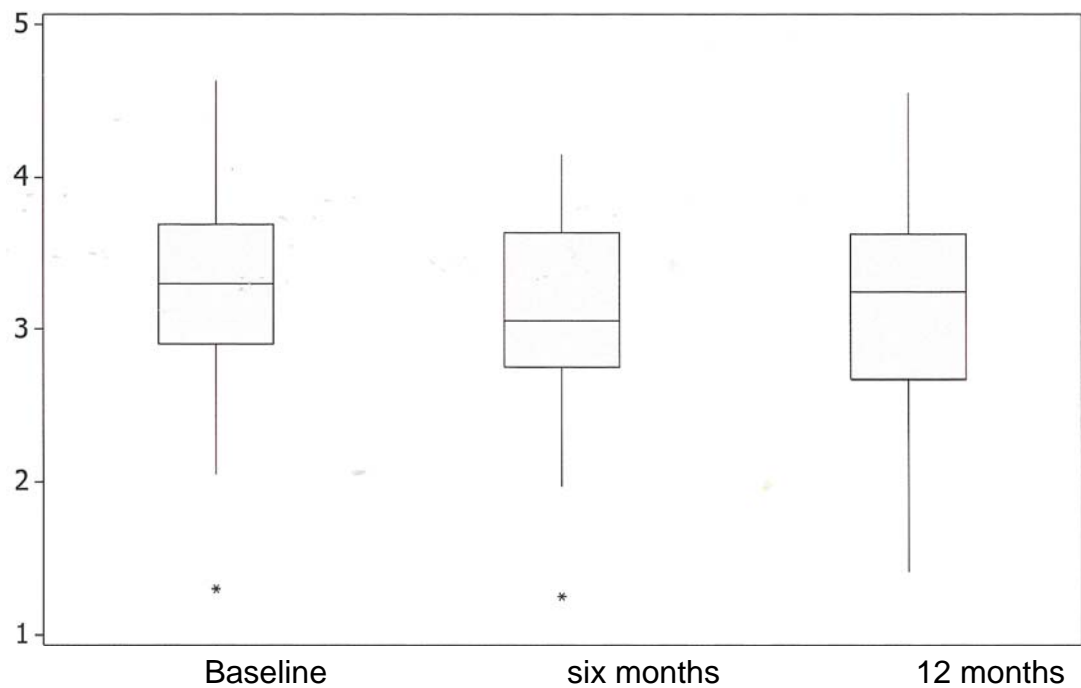


Figure 11.12: Boxplot of waist measurement SD score over time – Novel Treatment

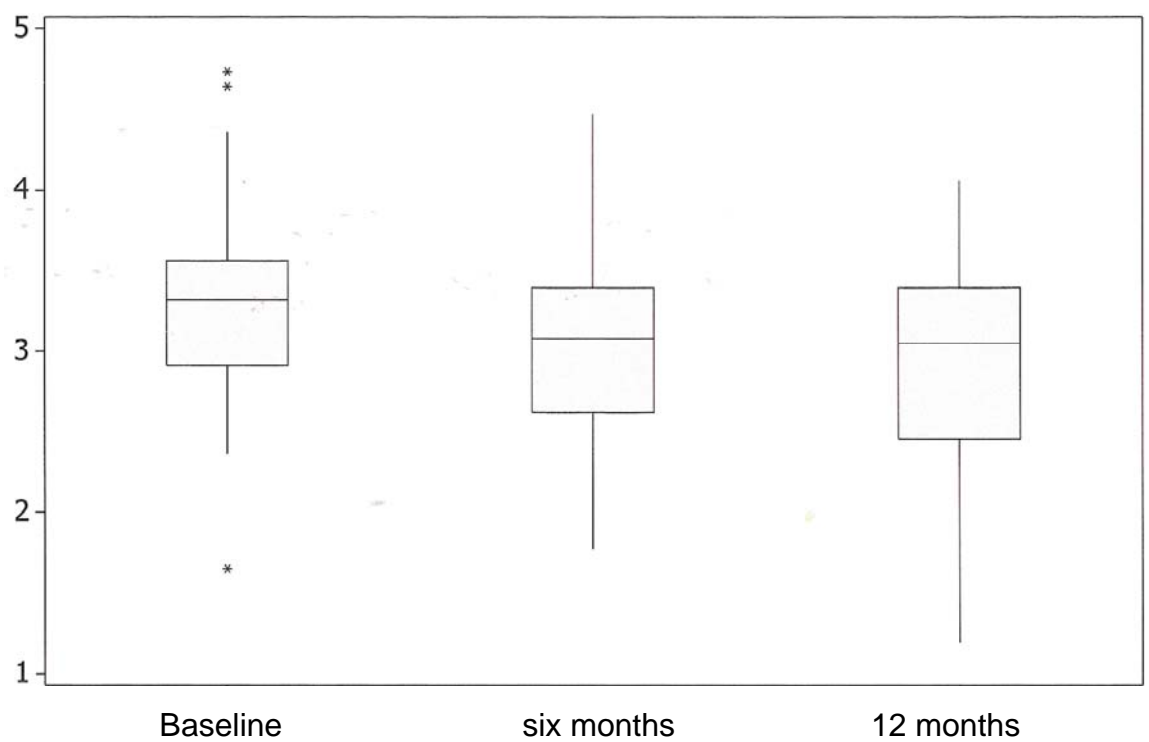


Figure 11.13 Boxplot of mean Counts Per Minute (CPM) over time - Standard Care and Novel treatment

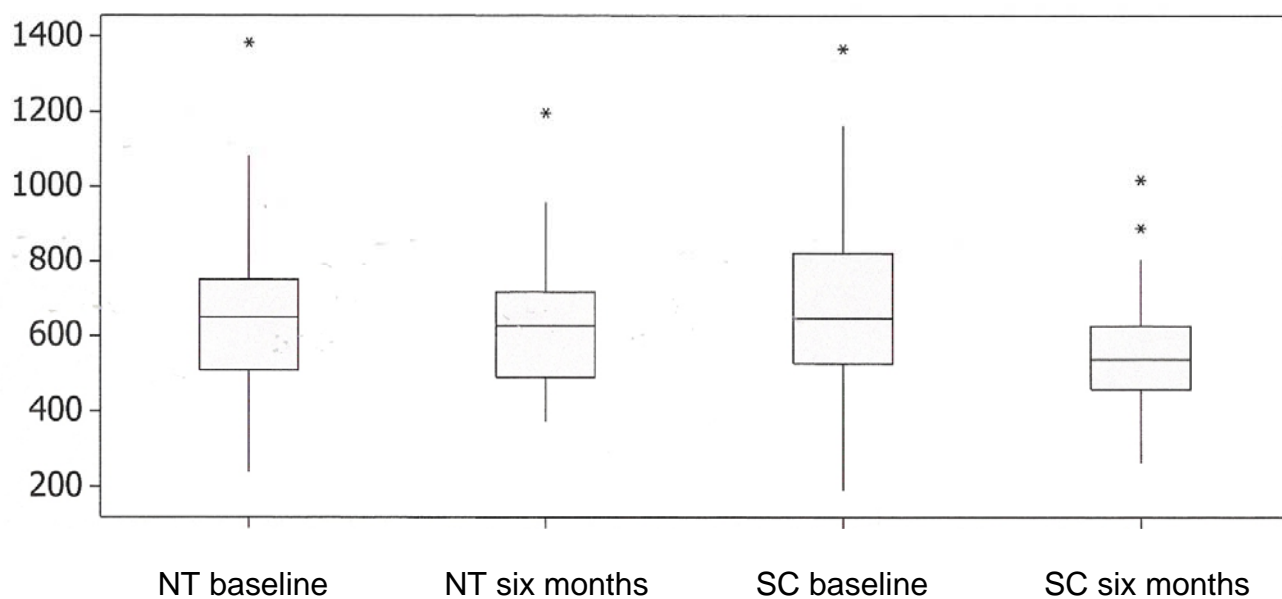


Figure 11.14: Boxplot of percentage sedentary behaviour over time – Standard Care and Novel treatment Group

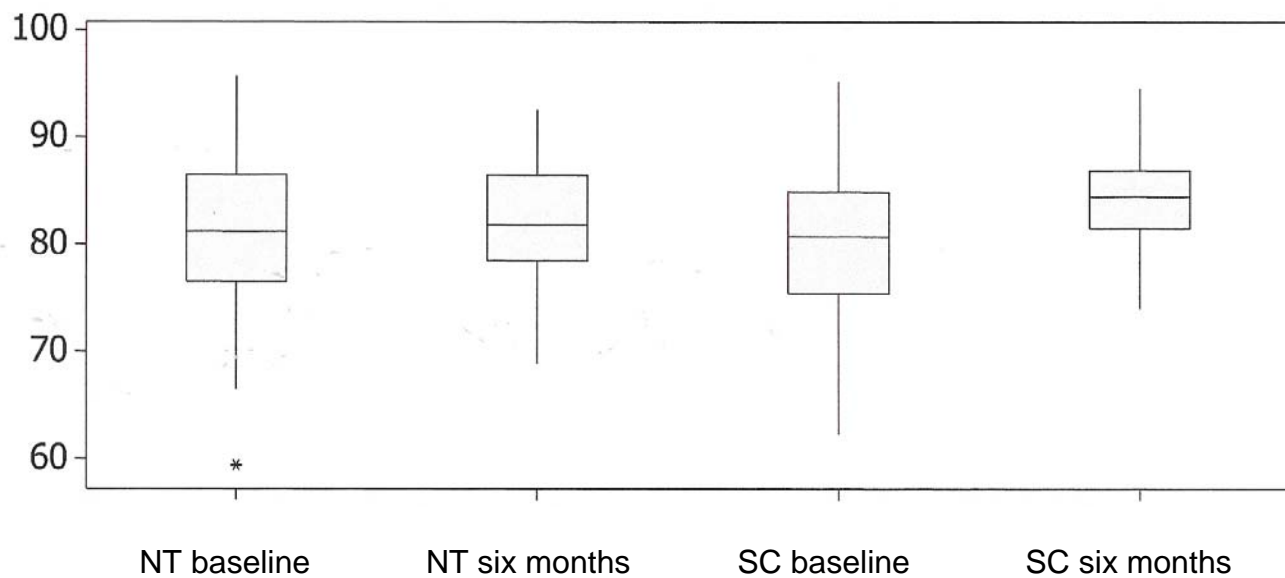


Figure 11.15 Boxplot of percentage light physical activity over time – Standard Care and Novel Treatment

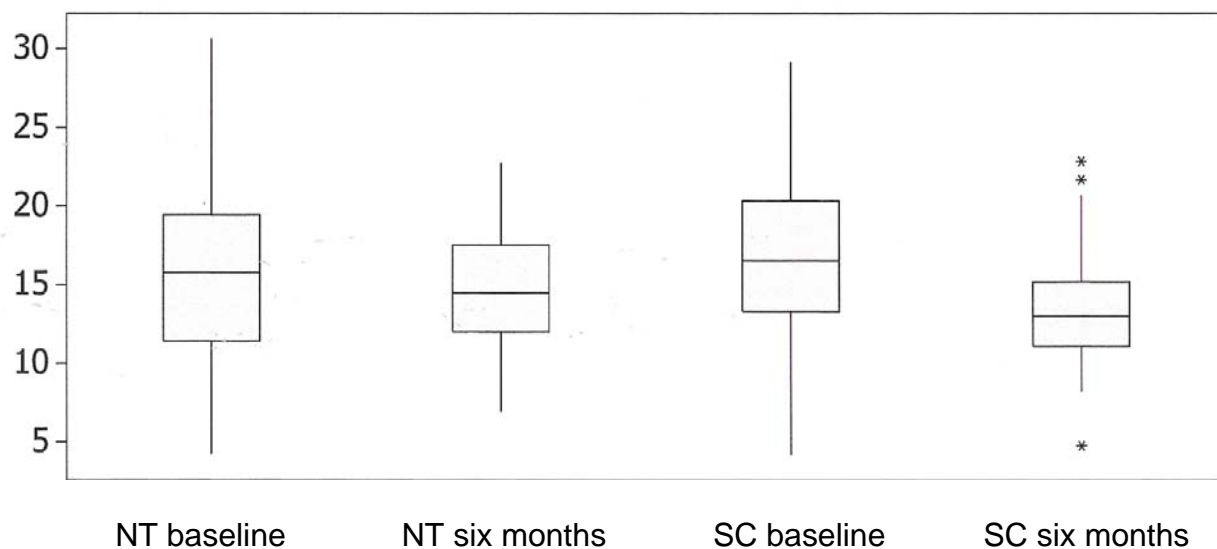


Figure 11.16: Boxplot of percentage Moderate to Vigorous Physical Activity (MVPA) – Standard Care and Novel Treatment

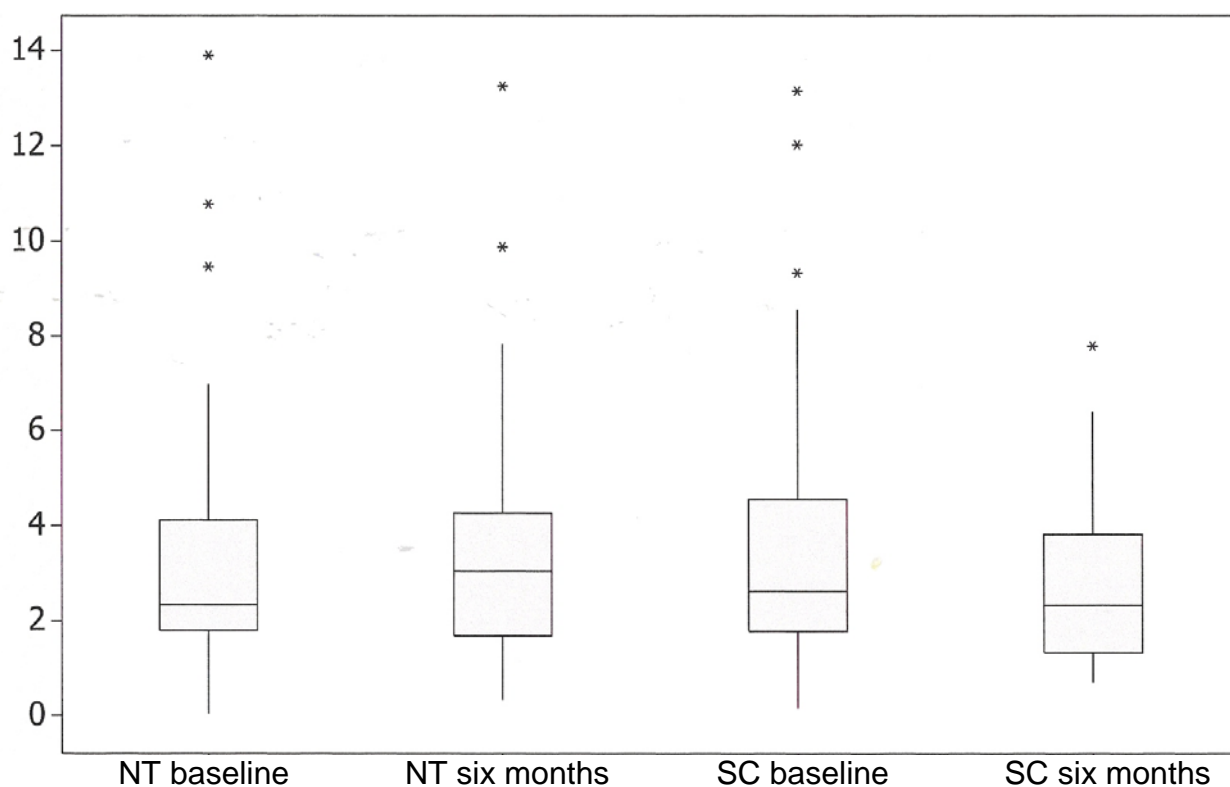


Figure 11.17: Boxplot of height over time – Standard Care

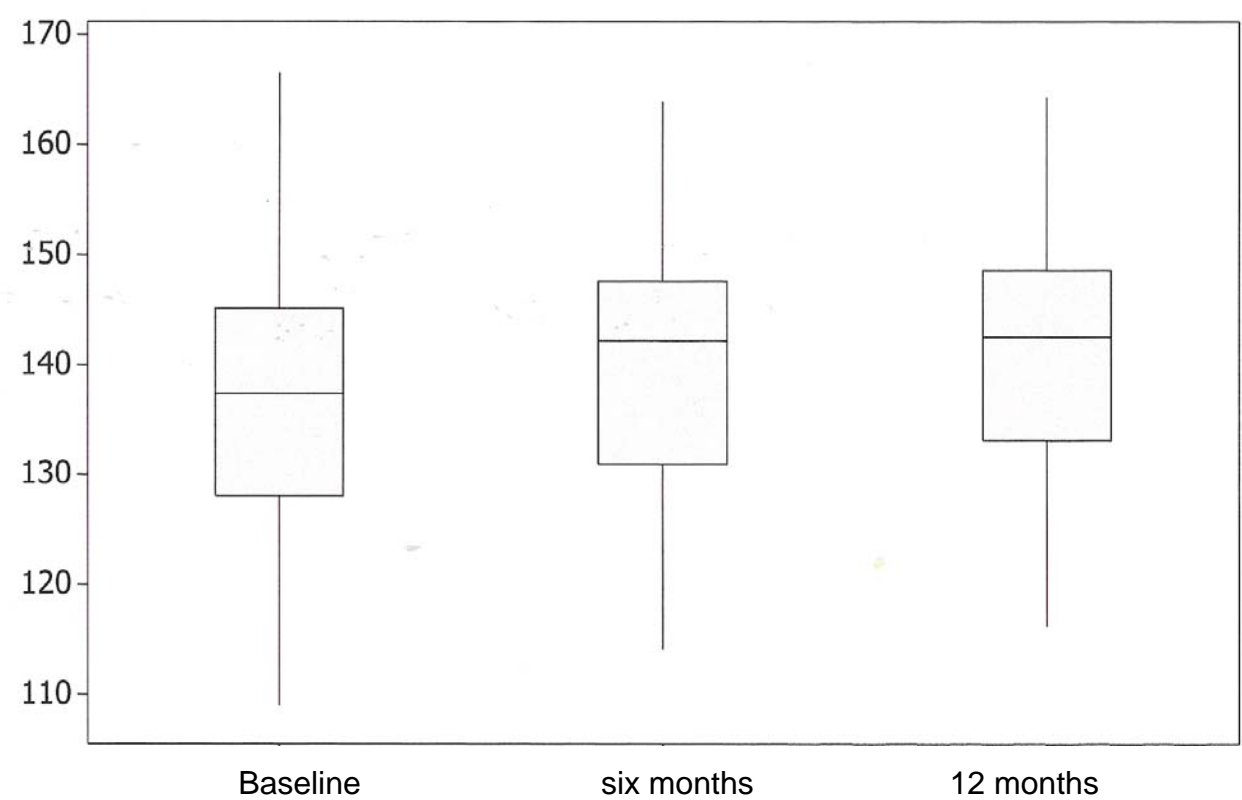


Figure 11.18: Boxplot of height over time – Novel Treatment

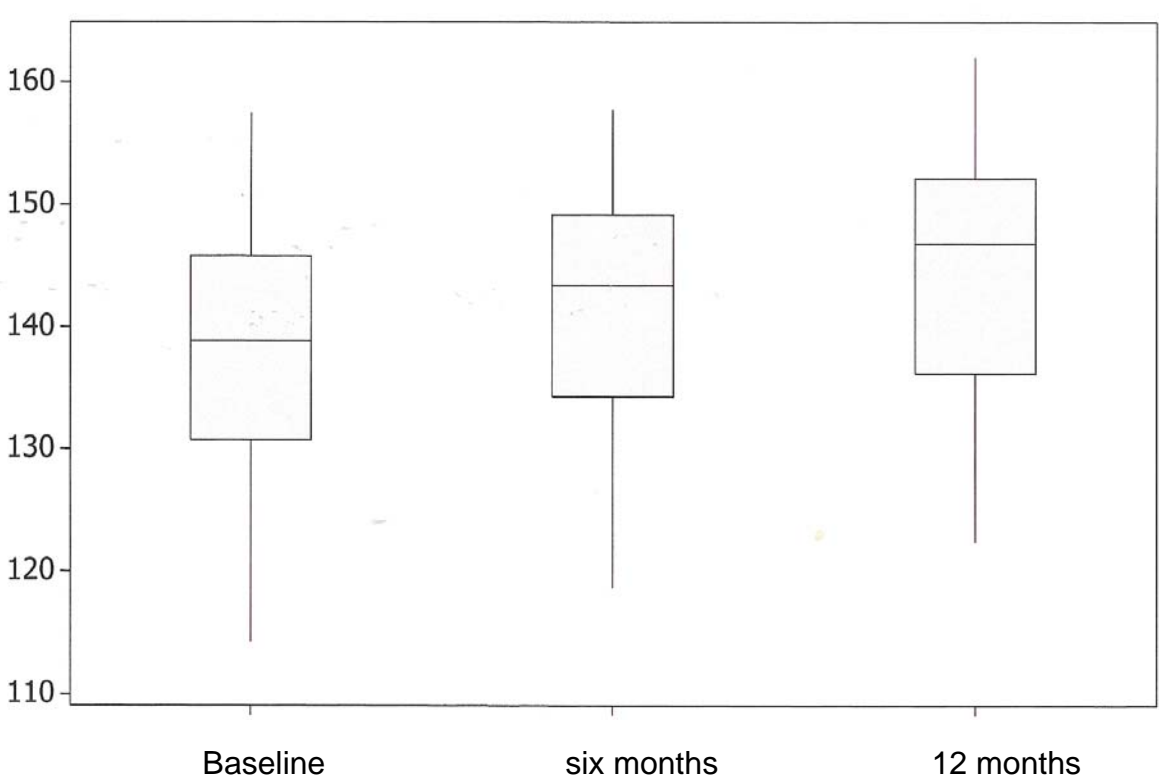


Figure 11.19: Boxplot of Quality of Life Total Score over time – Standard Care children

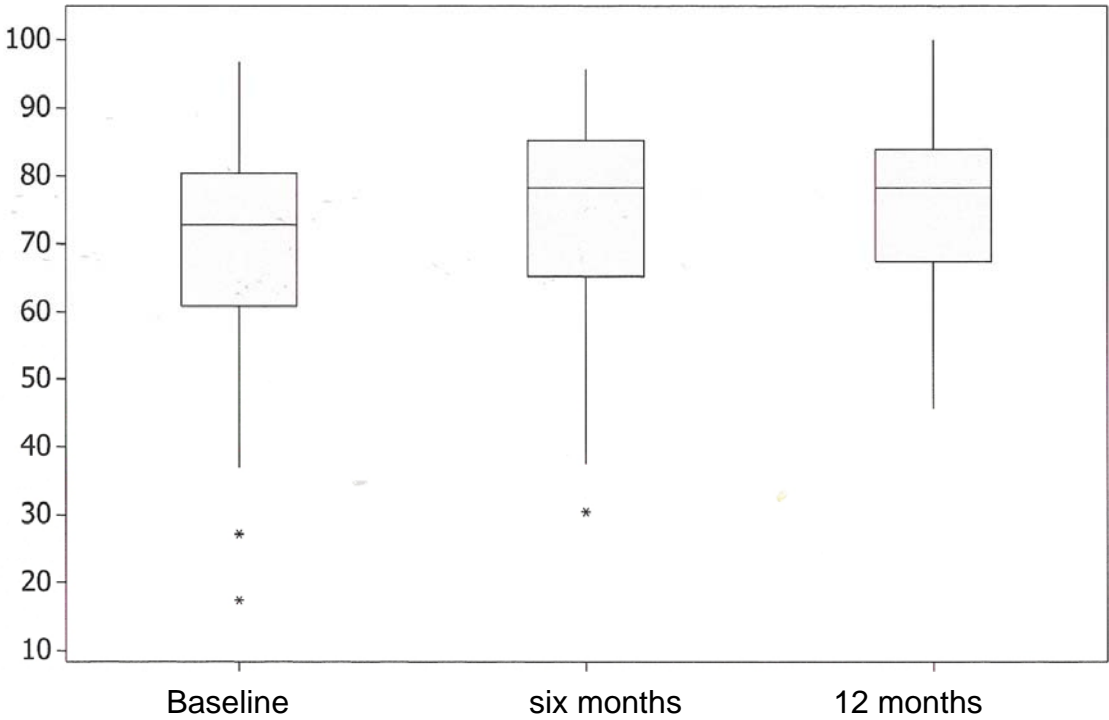


Figure 11.20: Boxplot of Quality of Life Total Score over time – Novel Treatment children

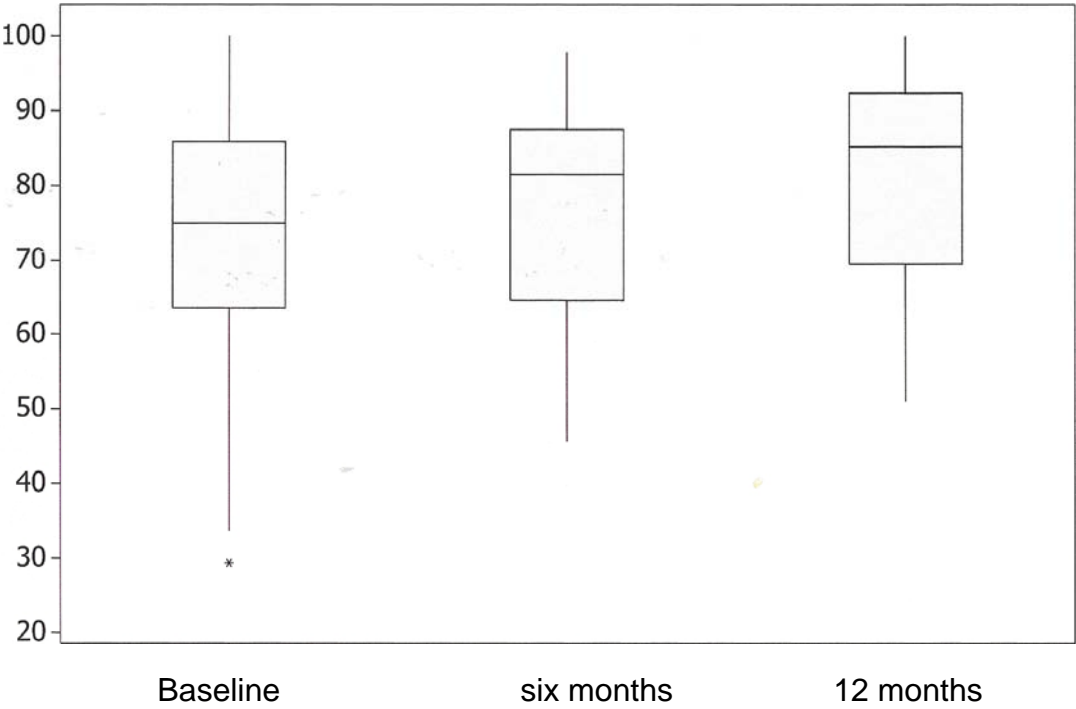


Figure 11.21: Boxplot of Quality of Life Total Score over time – Standard Care parents

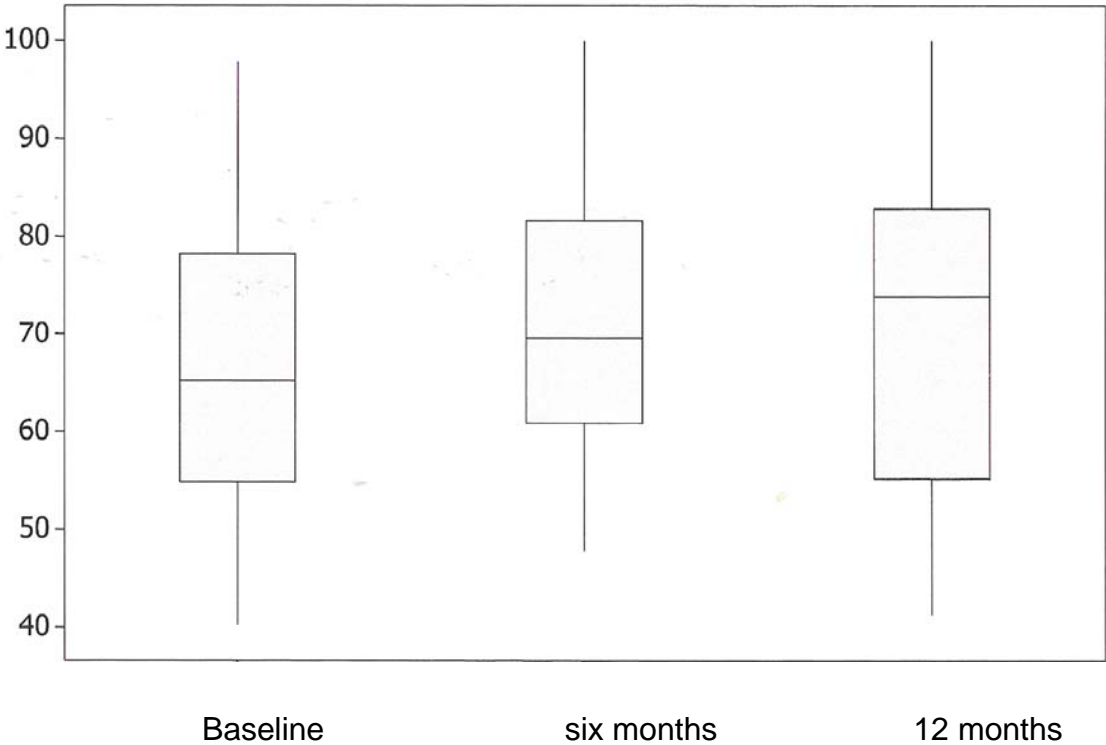
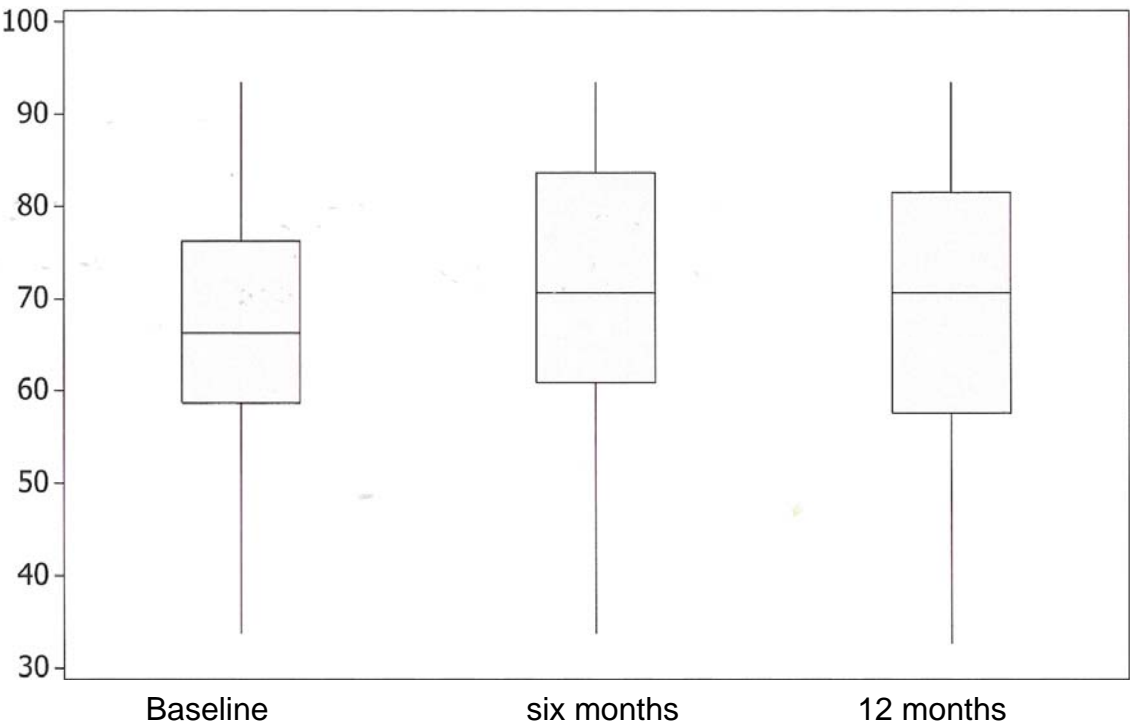


Figure 11.22: Boxplot of Quality of Life Total Score over time – Novel Treatment parents



Appendix 12 Sample edited matrix chart

Subject	Pre treatment	During treatment	Post treatment	Summary
SC 2	Mum noticed weight gain and was 'panicky' Went to doctor (65-66) (213-214)	Not many changes made/suggested (90-91) Whole nucleus family supportive, made changes (93-114) Spoke about with dad Siblings joined in (189-208) Focus on where to go and what to do. Dietitians advice was basic but helpful (146-147)	Weight going up Weight expectations not met (ambivalent) (222-232) Kept going would have been beneficial for child (246-250) Positive experience (266-270) Everyone spot on /well treated (299-314)	Satisfied with treatment Ambivalent about weight Positive experience Supportive nucleus
SC1	Didn't realise so overweight. Shocked when doctor told her weight and needed to do something (139-155) Hoped coming to the dietitian might wake up the child, realised needed to make an effort (176) Knew what to do (273)	Child didn't like attention drawn to weight (2160) No support from dietitian(9-62) No support from family (92, 117) Gran (2390 Parents responsibility (220-222) Fighting (241-260)	Negative, didn't enjoy (326-332) Not a success due to relationship with dietitian (208, 210-212) My lose weight when older (96, 112) Doesn't see himself as huge or obese (326-332)	Not satisfied with treatment Ambivalent to weight Negative experience Poor relationship with dietitian No support

Subject	Pre treatment	During treatment	Post treatment	Summary
NT2	GP referred due to weight concerns. Dad already making changes after referral (37)	No support from outside nucleus – including ex-wife (43-58) Helped focused child (70-75)	Worthwhile for both dad and child (33) Positive experience (303)	Treatment successful Weight success/ambivalent Positive experience No support outside nucleus
NT1	Mum noticed overweight and went to GP. People calling child names, hadn't discussed with child (147)	Dietitian helped with motivation when parent had previously struggled (30) Sister supportive (65) Husband supportive-ish (113)	Very positive experience Best thing to do (159)	Treatment successful Happy with weight Positive experience Support from dietitian and family

Appendix 13 Summary of questions for critically appraising qualitative research

Area	Criteria/question
Scope and purpose	<p>Explicitly stated aims/objectives of the research</p> <p>Relevance/importance of need for investigation</p> <p>Clarity about context of study</p> <p>Clarity about phenomena under study</p>
Design	<p>Appropriate use of qualitative methods</p> <p>Clarity about tradition/approach being used</p> <p>Appropriate design to meet study objective</p> <p>Need for staged/phased/longitudinal research explained</p> <p>Clarity about basis/appraisal criteria of evaluation research</p>
Timescale	Manageable within timeframe/resources
Researcher	<p>Understanding of researcher's connection to research study and subject manner</p> <p>Clarity about philosophical orientation</p> <p>Does researcher have appropriate skills/experience to conduct the research</p>
Sample	<p>Appropriate for qualitative research</p> <p>Appropriate for aims of study</p> <p>Clarity about selection of setting</p> <p>Clarity about coverage of sample</p> <p>Comprehensive</p> <p>Appropriate sample frame for aims of study</p>

Area	Criteria/question
Data collection	<p>Appropriate to study's question</p> <p>Rigorous/systematically conducted</p> <p>Role of researcher explained</p>
Analysis	<p>Appropriate for qualitative research study aims</p> <p>Clarity about analytic process</p> <p>Comprehensive</p>
Audit trail	<p>Sufficient information for research process to be 'audited' by others</p>
Reflexivity	<p>Reflections on the researcher's impacts on data and its interpretation</p> <p>Reflections on research conduct and process</p>
Ethical issues	<p>Evidence of consideration of ethical issues</p>
Visibility of origins and logic of evidence	<p>Clarity about how evidence and conclusions derived</p> <p>Conveys subjective meanings of participants</p> <p>Display of diversity</p> <p>Display of context</p> <p>Texts of validity used/efforts made to assess validity</p>
Confirmability/ reliability/ consistency	<p>Efforts made to assess consistency/reliability of results</p>

Area	Criteria/questions
Generalisability/ transferability	Clarity about extent to which any evidence can be generalised beyond settings/participants of study
Credibility/ Integrity/plausibility	Provides credible evidence/meaningful illuminations of the lives and contexts being researched
Contribution/value	Documentation of how evidence relates to existing knowledge Makes a contribution to field of study
Clarity	Coherently presented

Taken from - Spencer L, Ritchie J, Lewis J, Dillon L. Quality in Qualitative Evaluation: A framework for assessing research evidence. Government's Chief Social Researcher's Office, Cabinet Office, 2003.

Appendix 14 Information sheets for qualitative study

April 2005

Parents views of the dietetic treatment their child received in the Scottish Childhood Overweight Treatment Trial (SCOTT)

Dear

Many thanks to you and your child for taking part in the SCOTT study. We would like to invite you to take part in a new research project. We would like to find out your views on the dietetic treatment and lifestyle advice your child received in the SCOTT study. We will do this by inviting one or both parents/guardians to take part in one interview lasting approximately 60 – 90 minutes in a quiet room in the Royal Hospital for Sick Children.

Enclosed with this letter is a Parent/Guardian Information Sheet to provide you with further information about the study, please read this carefully and take your time to decide whether or not you wish to part. **Please understand that taking part in this study is entirely voluntary.** You can decline to take part or withdraw from the study at any time without giving a reason. If you do decide to participate, please sign the **Parent Consent Form** and return this sheet in the stamped addressed envelope provided. A researcher will then contact you to arrange a convenient time to attend the interview.

Should you have any questions regarding this study, please contact Dr Adrienne Hughes on 0141 201 9341. We will be happy to answer any queries you may have regarding the study.

Thank you for taking the time to read this.

Yours sincerely,

Dr Adrienne Hughes (Researcher)

November 2004 version 2



Parent/Guardian Information Sheet

Study title

Parents views of the dietetic treatment their child received in the Scottish
Childhood Overweight Treatment Trial (SCOTT).

Invitation

You are being invited to take part in a research study. It is important for you to understand why the research is being done and what it will involve before you decide to participate. Please read the following information carefully and discuss it with others if you wish. If there is something you do not understand or if you would like more information about the study, please ask us. Please take time to decide whether or not you wish to take part.

What is the purpose of the study?

We would like to find out the parents/guardians views on the dietetic treatment their child received in the SCOTT study. This information will help us to understand how the families responded to the treatment used in SCOTT and which features of the treatment worked best. This will help us to improve the dietetic treatment of overweight children in the future. The entire study will take us 10 months to complete.

Why have I been invited?

You have been invited as your child took part in the SCOTT research project. We would like to interview 32 parents/guardians in total and are inviting parents of children from both treatment groups in the SCOTT project, both sexes, a range of ages and from different areas.

Do I have to take part?

It is up to you to decide whether or not you want to take part. You can decline to take part or withdraw from the study at any time without giving a reason. If you do decide to take part, you will be given this information sheet to keep and will 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. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you or your child receive.

What will happen to me if I take part?

We will ask one or both parents/guardians to take part in one interview lasting approximately 60 – 90 minutes in a quiet room in the Royal Hospital for Sick Children. You will be given your travel expenses for the attending the interview.

The interview will be carried out by a trained researcher. You will be asked to discuss your thoughts and views about the dietary treatment and lifestyle advice your child received in the SCOTT study. For example what is your view on the duration and number of appointments with the dietitian? The questions have no correct answer. There will also be an opportunity for you to discuss views that are important to you. The interview will be recorded on a tape recorder. Recording the interview means that you do not have to wait in between questions while your answer is written down and nothing you say will be missed out. Thus, it should help the conversation run more smoothly. The interview will be replayed and your answers will be written down later on. We will compare all of the answers collected from the parents/guardians. The tape and paper copy of your interview will be identified by a study code and not personal details. Both the tape and paper copy of the interview will be kept in a locked filing cabinet separately from any of your personal information. Any names you may mention on the tape will be deleted from the paper copy.

What do I have to do?

Apart from taking part in the one interview you will not have to do anything else.

What are the possible disadvantages of taking part?

A possible disadvantage is the time to travel to the hospital and time spent in the interview. However, we will try to arrange the interview around work and family commitments.

What are the possible benefits of taking part?

There are no direct benefits to you from taking part in the study. However, we hope that the information from this study can help us to improve the treatment of other patients in the future. This study may help us to understand the concerns that parents of overweight children may have about the treatment and lifestyle advice given in the SCOTT project.

What happens when the research study stops?

As your child has already completed their treatment in the SCOTT project this study finishing will not affect you or your child's care.

What happens if something goes wrong?

If you become uncomfortable about anything during the interview please tell the researcher who will stop the interview immediately. If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. 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, the normal National Health Service complaints mechanisms should be available to you

Will my taking part in the study be kept confidential?

Yes, all information collected from you will be kept strictly confidential. Your name and any details by which you or your child could be identified will not be used and

we do not need to look at your child's medical records. All names mentioned on the tape will be deleted from the paper copy of the interview. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

The comments from all the parents who take part will be looked at together. We believe the results will be useful to other health professionals working with overweight children and it may be presented at scientific meetings or published in scientific journals. If this happens neither you nor your child's identity will be disclosed and total confidentiality will be maintained. If you decide to withdraw from the study after being interviewed, we will not use your interview in the final results.

Who is organising and funding the research?

The research is organised by the Department of Human Nutrition at the University of Glasgow and has been funded by the Scottish Executive Health Department in Edinburgh.

Who has reviewed the study?

The study has been reviewed and approved by the Yorkhill and Lothian Research Ethics Committees, and the Multi-Centre Research Ethics Committee for Scotland, Committee B.

Contact for further information

For further information on the study, contact Dr Adrienne Hughes on 0141 201 9341.

Thank you for reading this information sheet.

If you agree to take part in the study you will be given a copy of this information sheet and a copy of your signed consent form to keep.

November 2004/version 2



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GLASGOW

Appendix 15 Consent form for qualitative study

Number:

Number:

Centre

Study

Parent/Guardian Consent Form

Parents views of the dietetic treatment their child received in the Scottish Childhood Overweight Treatment Trial (SCOTT)

Name of Researcher:

Please initial box

1. I confirm that I have read and understand the information sheet
dated ☐ (version) for the above study and have had
the opportunity to ask questions.
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.
3. I agree to take part in the above study. ☐

Name of Patient

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

September 2004 version 1

CXXIX

Appendix 16 Themes used for coding data in Nvivo - based on initial 4-5 interviews

Nodes	Tree	Child	Child	Child
Appointments	Location	place		
		distance		
		travel		
		frequency		
		length		
	Timing			
	Content	reinforcement		
	Follow Up			
	Attendance			
Pre-appointments	Preconceptions	information		
		knowledge		
	Apprehensions			
	Anticipation			
	Weight perception	knowledge		
		self esteem		
		self awareness		
		parental		
		awareness		
		expectations		
		body image		
		motivation		

Nodes	Tree	Child	Child	Child
During sessions	Emotions	guilt	parent	
			child	
		motivation	Parent	targets
				rewards
			child	goals – control
				targets
		monitoring		rewards
			parent	goals – control
				awareness
			child	reinforcement
		weight perception		awareness
			parent	reinforcement
				body image
			child	expectations
		self esteem		body image
				expectations
			denial	self image
			stigma	
			peers	

Nodes	Tree	Child	Child	Child
During sessions	Parenting	involvement	mum	
			dad	
		commitment	mum	
			dad	
		support	mum	
			dad	
		motivation	mum	
			dad	
		cooking menu planning	skills shopping	
		sharing information	introducing food child others	expanding food
Relationships	Dietitian	support		
		rapport		
		encouragement		
		information		
	Family	support	mum	commitment
				encouragement
				sharing info
			dad	commitment
				encouragement
				sharing info
			others	commitment
				encouragement
				sharing info
		barriers	holidays Xmas objections	

Nodes	Tree	Child	Child	Child
Relationships	School	involvement support	permission	
Research	Pedometer CSA Measurements results	self awareness self esteem peers stigma self awareness self esteem peers stigma feedback		
Outcomes	Weight perceptions Emotions Changes Continuing	child parent lifestyle diet activity sedentary behavioural change compliance	general child family	
Reasons	Lifestyle Media Society	activity inactivity food unknown		

Appendix 17 Evidence table for studies discussed in chapter 6

Study	Population	Study's stated Objectives
Carnell et al 2005	564 parents of 3-5 year olds London, UK	To assess parents' awareness of child's weight status using a questionnaire. Child's weight measured by researchers.
Jeffery et al (2005)	277 parents Mean age of children 7.4 years Plymouth, UK	To explore parents' awareness of child's weight status using a questionnaire. Child's weight measured by researchers.
Jain et al (2001)	18 low income mothers of pre school children (mean age 44 months) Cincinnati, Ohio, USA	To explore parents perceptions on when to classify a child as overweight, how a child becomes overweight and barriers to managing childhood obesity. Focus groups.
Etelson et al (2003)	83 parents of 4-8 year old children. Westchester County, New York, USA	To examine parents understanding of excess weight as a healthy risk, their knowledge of healthy eating and recognition of overweight in their own child. Child's weight obtained from routine clinic visit medical notes.
Baur (2005)		Editorial discussing implications of Carnell et al (2005) paper.

Study	Population	Study's stated objectives
Murtagh et al (2006)	20 children (aged 7-15 years) who had attended the WATCH IT programme. Leeds, UK	To identify the levers and barriers to weight loss experienced by the children. Interviews and focus groups.
Dixey et al (2006)	24 parents of children who took part in the WATCH IT programme Leeds, UK	Parent focus groups to explore parents perception of the treatment programme and their role in their children's weight management
Edmonds (2005)	40 parents of children aged (4-15 years) who had concerns about their child's weight. Central and south-west England, UK	To explore the parents' perceptions o seeking help from health professional for their child's weight. Semi structured in-depth interviews.
Latner and Stunkard (2003)	458 10-11 year old children Central and northern New Jersey, USA	To replica a 1961 study of stigma in childhood obesity and to see what affect the present day increased prevalence of obesity had on this stigma.
Rhee et al (2006)	872 parents of children aged 54 months. Cohort study in 10 centres across USA	To determine the relationship between the 4 parenting styles (authoritative, authoritarian, permissive and neglectful) and overweight in the first grade.
Dietz and Robinson (2005)		Case vignette, review of evidence and clinical recommendations

Study	Population	Study's stated objectives
Golan (2006)		Description of weight management programme with parents as the main agents of change.
Barlow and Ohlemeyer (2006)	43 families who failed to completed a weight management programme. St Louis, USA	Questionnaire used to determine reasons for non return to clinic

Dietetic Management of Pediatric Overweight: Development and Description of a Practical and Evidence-Based Behavioral Approach

Laura Stewart, SRD; Jan Houghton, SRD; Adrienne R. Hughes, PhD; Dymphna Pearson, SRD; John J. Reilly, PhD

here is great uncertainty over how to treat childhood overweight. Recent systematic reviews provide a consensus on the most promising elements of treatment, but no successful, generalizable, evidence-based treatment model is currently available. We describe a novel approach to treatment that is evidence-based, putting recommendations of recent systematic reviews into practice. The novel treatment uses a client-centered approach

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and behavioral change techniques to increase and maintain motivation for lifestyle change. It focuses on increasing physical activity, reducing sedentary behavior, and changing diet in children who are overweight (body mass index >98th percentile) and of elementary school age. Treatment lasts for 6 months and requires 5 to 6 hours of a dietetics professional's time per patient (in contrast to more traditional, less intensive approaches in the United Kingdom, which invest approximately 1.5 hours per patient). Preliminary assessment of the program suggests that it is practical, and patient dropout is low. Formal evaluation of efficacy will not be available until completion of a randomized, controlled trial in 2006. This description of our novel treatment will enhance generalizability of the program if it is successful, and a detailed description will assist in development of other treatments even if it is unsuccessful.

Childhood overweight is now very common and is still increasing across the world (1). There is clear evidence that overweight in childhood is associated with adverse health outcomes in both childhood and adulthood (2,3). Despite the combination of high and increasing prevalence, adverse consequences, and increasing public concern, treatment programs for childhood overweight are not widely available. In addition, systematic reviews have concluded that there are currently no successful treatment models that are evidence-based and generalizable (2,4). Treatment offered by many centers is unsuccessful and is characterized by high patient dropout and continued patient weight gain (5).

Recent systematic reviews have con-

cluded that the most promising treatments are the intensive behavioral programs offered by Epstein and colleagues in the United States (2,4,6,7). Robinson concluded that a behavioral approach to treatment was "state of the art" (7). However, Epstein's treatments have not been described in detail or widely distributed, so they cannot be easily replicated. In addition, the Epstein program is not readily generalizable to settings in which resources for treatment are limited, because it requires access to large numbers of specialist health professionals for long periods of time (2,4,6,8).

This report describes a simpler but evidence-based behavioral treatment program for overweight in elementary school-aged children. Because the treatment is being evaluated rigorously in an ongoing randomized, controlled trial (Scottish Childhood Obesity Treatment Trial), a detailed description of the program will be necessary if it is successful, or may help to provide an explanation of reasons for failure if unsuccessful.

The novel treatment uses behavioral change techniques, and describing the development of our approach should be helpful for dietetics professionals who are considering how to make their consultations in chronic disease management more behavioral in nature. There is increasing awareness that a more behavioral approach may be beneficial in bringing about lifestyle changes and encouraging adherence to prescribed treatments, including dietary change (9).

BACKGROUND: THE EVIDENCE BASE

Recent systematic reviews of childhood obesity and expert committee

Red foods ^a	Amber foods ^b	Green foods ^c
<ul style="list-style-type: none"> ● Fried foods ● Potato chips ● Pies, pastries ● Take-out meals ● Fries and burgers ● Sugar ● Sweets ● Chocolate ● Chocolate biscuits ● Fancy biscuits ● Cakes ● Sugar-sweetened drinks ● Desserts ● Sugar- or honey-coated breakfast cereals 	<ul style="list-style-type: none"> ● Lamb, pork, beef ● Sausages and burgers ● Chicken and turkey ● Fish ● Eggs and cheese ● Vegetarian meals ● Bread/chapati ● Potatoes ● Rice ● Pasta ● Plain breakfast cereals <p>Low-fat alternatives of</p> <ul style="list-style-type: none"> ● Milk ● Butter/margarine ● Yogurts 	<ul style="list-style-type: none"> ● Fresh/dried fruit ● Tinned fruit in fruit juice ● Vegetables/salad ● Homemade/tinned vegetable soup ● Sugar-free gelatin ● Plain breakfast cereals and low-fat milk ● Plain popcorn, breadsticks ● Sugar-free lollies ● Diet or sugar-free drinks
^a Long-term aim to be restricted to one per day. ^b Recommended to be restricted to meal times. ^c To be taken freely and substituted for red foods.		

Figure 1. Summary of the modified traffic light diet used in a behavioral treatment program for overweight in elementary school-aged children in Scotland.

recommendations (2,4,6,8,10,11) have consistently recommended that treatment:

1. be directed at motivated families (in which the child and/or parents perceive obesity as a problem and appear willing to make lifestyle changes);
2. be directed at the entire family rather than just the obese child;
3. aim for weight maintenance (rather than weight loss);
4. be more intensive than has been the norm (more frequent and longer appointments); and
5. should combine changes in diet plus changes in physical activity and/or reduction in sedentary behavior (eg, television viewing).

We have incorporated these recommendations in our novel treatment program. However, the precise approach taken to achieve these lifestyle changes has not been clearly recommended in any reviews or guidelines and so practical guidance as to dietetic implementation of these recommendations is lacking.

THE SCOTTISH CHILDHOOD OBESITY TREATMENT TRIAL NOVEL TREATMENT Dietary Changes

The dietary advice given in our novel treatment is a simplified version of

the “traffic light” diet concept used by Epstein and colleagues (12). Our modified traffic light diet is intended to be easier for children and parents to follow by reducing complexity and abandoning the need to “calorie count,” as in the Epstein regimen. The traffic light method categorizes food into “good” and “bad” (green and red) foods and the child is actively encouraged to count and reduce the number of red foods he or she eats. The long-term (6-month) aim of our program is for the child to restrict his or her intake to one red food per day. Figure 1 outlines the traffic light food categories.

Changes in Physical Activity and Sedentary Behavior

Consistent with recent evidence-based guidelines, systematic reviews, and Epstein’s pioneering work (2,4,12-14), our program takes a two-pronged approach, with advice given to both increase physical activity and decrease sedentary behavior. These are now widely regarded as separate constructs (15), but in UK dietetics, emphasis on modifying sedentary behavior as part of dietetic treatment is uncommon. In our program, the children are encouraged to increase their physical activity initially to 30 minutes of moderate to vigorous activity at least five times per week, increasing to a long-term goal of 60 minutes

at least five times per week (in conjunction with UK recommendations for all children) (2). The children are also encouraged to restrict their sedentary time, as is widely recommended, to no more than 2 hours per day or the equivalent of 14 hours per week. Written materials describing these lifestyle changes are handed out at the first appointment.

DESCRIPTION OF THE TREATMENT PROGRAM

The treatment program is a structured intervention with the outline of each interview defined in advance. It involves eight appointments over 26 weeks. The Table outlines the appointment structure with a brief summary of content. The need for parental and family support is fundamental and is emphasized throughout the program (2,7,10). Because the emphasis of the program is on behavior change rather than weight change, the children are only weighed three times during the 6-month intervention.

Behavioral Change Techniques Employed

A key element of the intervention is that the approach is client-centered and employs behavioral change techniques: the client (in this case the child) takes control of his or her own lifestyle changes. Various behavioral

OF PROFESSIONAL INTEREST

Table. Summary of the novel treatment program: Timing and duration of appointments, and behavioral strategies and materials used

Appointment	Approximate duration (min)	Materials used (behavioral strategies used)	Timetable (weeks)
1	60	Energy balance Importance (assessing readiness to change) Making your mind up (exploring importance of change, problem solving, exploring barriers to change) Typical day Healthy eating plan Be active! Don't just sit there! My lifestyle diary (self-monitoring)	0
2	30	Goals sheet (goal setting) My lifestyle diary (self-monitoring)	2-3
3	30	Goals sheet (goal setting) My lifestyle diary (self-monitoring)	4-5
4 Parent(s) only	30	Exploring parents' concerns Discussing parenting skills	7-8
5 Home visit	60 Plus travel time	Goals sheet (goal setting) My lifestyle diary (self-monitoring)	11-12
6	30	Importance (assessing readiness) Coping with tricky situations (relapse prevention) Goals sheet (goal setting) Frequency recording sheets (self-monitoring)	15-16
7	30	Goals sheet (goal setting) Frequency recording sheets (self-monitoring)	20-22
8	30	Long-term goals sheet (goal setting) Frequency recording sheets (self-monitoring)	24-26

change techniques (see Figure 2) designed to enhance the child's motivation are employed: goal setting, self-monitoring, use of contracts and rewards. These techniques originate from behavioral change programs in other settings, notably in smoking cessation and alcohol reduction (16).

There is a reasonably good evidence base for more behavioral approaches to management of other chronic childhood diseases that require nutritional therapy, such as cystic fibrosis (9,17). There are a number of important differences between traditional and more behavioral approaches; however, describing these would be beyond the scope of this report and they are described in detail elsewhere (7,9).

Exploring and Reinforcing Readiness to Make Lifestyle Changes

The first appointment in our program is the longest and the most important

for setting the style and approach of the intervention as well as starting to develop a shared agenda of lifestyle changes between the child, parent, and dietetics professional. Education on energy balance and why the three aspects of lifestyle (diet, physical activity, and sedentary behavior) are targeted are explained using a simple pictorial Energy Balance sheet.

Motivation and readiness to make changes are explored in depth in this initial appointment. The child and parent are asked separately to score their perceived importance that the child make the lifestyle changes necessary to "slim down" using an Importance tool. The score ranges from 0 to 10, with 0 indicating no importance. The child is then asked to complete a decisional balance chart (pros and cons of change) in which he or she is asked to consider aspects that are "good" about

making the changes that will lead to him or her being slimmer, as well as aspects that are "not so good" about making these changes. During this part of the consultation it is essential for the dietetics professional to use open questions and to allow the child time and space to consider his or her answers. In our program, children as young as 5 years old have been able to complete this chart. Typical answers for both sides of the decisional balance are given in Figure 3.

Goal Setting and Behavioral Contracting

One of the fundamental differences between the client-centered approach in novel treatment and typical pediatric weight management in the United Kingdom is that it is the child and not the dietetics professional who sets the lifestyle change goals. The program is intended to empower the

Qualities of interviewer (dietitian) <ul style="list-style-type: none"> • Acceptance • Genuineness • Empathy 	Principles of approach <ul style="list-style-type: none"> • Client responsibility • Social influence • Collaboration • Expressing empathy • Rolling with resistance • Supporting self-efficacy • Deploying discrepancy
Skills required by interviewer <ul style="list-style-type: none"> • Appropriate use of questions (open questions) • Active listening (mirroring, paraphrasing, reflecting back) • Affirmation • Summarizing 	Strategies employed <ul style="list-style-type: none"> • Exploring readiness to change • Importance of change • Exploring ambivalence to change • Understanding current behaviours • Exchanging information • Exploring options • Problem solving • Goal setting • Self-monitoring • Preventing relapse • Use of contracts • Receiving of rewards

Figure 2. Summary of the client-centered approach.

Pros of lifestyle change <ul style="list-style-type: none"> • Will not be bullied • Will not be called names • Will be able to run faster • Will be happy • Will be able to fit into nice/fashionable clothes 	Cons of lifestyle change <ul style="list-style-type: none"> • Will miss sweets • Will miss potato chips • Will miss watching TV • Will miss playing computer games
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Figure 3. Typical patient (child) answers to decisional charts: Pros and cons of change as typically reported by the patient.

child to identify the lifestyle changes he or she can make and to consider how to make them. For example, a child who eats five packets of potato chips and two chocolate bars per day and does almost no physical activity each day may wish to decrease chocolate consumption to one bar per day, increase physical activity modestly, and continue eating five packets of chips. It is essential to the principles of a client-centered approach that the dietetics professional accepts the child's choice of goals, as ownership of his or her own goals is believed to be important for the child's adherence to the program. However, the dietetics professional in our program ensures that the goals are "SMART" (ie, small, measurable, achievable, recorded, timed). There needs to be acceptance by the dietitian of some resistance and ambivalence to change from the child. When necessary throughout

the program, the dietetics professional deals with this resistance and ambivalence by using reflective listening skills and by referring back to the decisional balance chart and reviewing the importance of change score.

In our program, the child first sets goals during the second appointment, when he or she is asked to consider two to four possible lifestyle-change goals to be kept until the next appointment. Once the goals are set, the child and parent agree on a reward for the child achieving 100% of the goals for the next appointment. These rewards should be small, relatively inexpensive, and nonfood, such as music CDs, books, or an outing. Both goals and rewards are recorded on a "My Goal" sheet, which is signed as a form of contract by the child, parent, and dietetics professional.

Parents are also encouraged to give

the child positive reinforcement for all lifestyle changes that are made. New goals and rewards are set at each appointment. However, if a child has failed to meet his or her goals, the barriers to change are explored and new or modified goals that are more achievable are set and a new reward agreed upon.

Self-Monitoring

Self-monitoring of lifestyle is a key element of behavioral change, as it enhances motivation by increasing self-awareness (18). At the start of our program, self-monitoring is used to identify lifestyle changes that could possibly be made by the child. Then, throughout the program, it is used to monitor progress as changes are made (ie, whether goals have been achieved) (16). For the first 4 months of the intervention, the child and parents are asked to keep a lifestyle diary in which diet, physical activity, and sedentary behaviors are recorded on a single sheet each day. The dietetics professional reviews the lifestyle diary at the beginning of each interview, which helps to reinforce the importance of keeping the diary and informs discussions about goal setting. At 4 months, a simpler tick sheet with 1 week to each page is introduced and families are encouraged to continue with self-monitoring using this simple tick sheet after the 6-month treatment program has finished.

Preventing Relapse

In an attempt to avoid a lapse becoming a relapse, planning for situations where it may be difficult to meet goals is an important aspect of the behavioral change approach. A worksheet entitled "Dealing with Tricky Situations" is used to help the child to consider and plan for potential difficult situations, such as birthdays, Christmas, or rainy days, when it may be difficult to achieve his or her lifestyle goals.

EVALUATION OF NOVEL TREATMENT PROGRAM

Practical Utility

Our novel treatment program was developed to be delivered by a single experienced pediatric dietetics profes-

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Parents' journey through treatment for their child's obesity: a qualitative study

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ABSTRACT

Background: Treatment for childhood obesity is characterised by patient non-attendance and drop-out, and widespread failure to achieve weight maintenance. Qualitative methods may improve our understanding of patient perceptions and so improve treatment for childhood obesity.

Aim: To provide insight into the perceptions of parents of obese children as they "journey" from pre-treatment to end of treatment.

Methods: We used purposive sampling and studied 17 parents of children (mean (SD) age 8.4 (2.1) years) attending 6-month outpatient treatments for obesity (BMI > 98th percentile). Parent's perceptions were explored by in-depth interviews, analysed using Framework methods.

Results: Parents were characterised as being unaware of their child's weight, in denial or actively seeking treatment. Parents were consistently motivated to enter treatment due to perceived benefits to their child's self-esteem or quality of life, and weight outcomes appeared typically less important. During treatment parents felt there was a lack of support for lifestyle changes outside the clinic, and noted that members of the extended family often undermined or failed to support lifestyle changes. Parents generally felt that treatment should have continued beyond 6 months and that it had provided benefits to their child's well-being, self-esteem and quality of life, and this is what motivated many to remain engaged with treatment.

Discussion: This study may help inform future treatments for childhood obesity by providing insights into the aspects of treatment of greatest importance to parents. Future treatments may need to consider providing greater support for lifestyle changes within the extended family, and may need to focus more on psycho-social outcomes.

There is a paucity of high quality evidence on how best to treat childhood obesity, and "office-based" therapy usually has modest success.^{1,2} Guidelines suggest treatments should be family based with the participation of at least one parent fundamental to the outcome.^{3,4} Yet there is little understanding of the motivation of parents to enter treatment and their continuing role in implementing and supporting recommended lifestyle changes. Qualitative methods can provide valuable information on patient's perceptions of chronic disease management,⁵ but few qualitative studies have explored the parent's feelings concerning their child's obesity management. The aim of this study was to use qualitative methods to gain insight into the journey of parents of obese children to and through treatment. These findings will assist in the development of theories on

parental influences on treatment outcomes and help health care professionals in their approaches to family based treatments.

METHODS

We undertook in-depth interviews with the principal carers of primary school age children who had taken part in 6-month dietetic interventions for childhood obesity (BMI > 98th percentile, UK 1990 charts) previously described in detail.⁶

We used a purposive sampling strategy⁷ with the following criteria:

- ▶ successful outcome/unsuccessful outcome of treatment,
- ▶ age of child (5–8 years and 9–11 years),
- ▶ location (Edinburgh/Glasgow),
- ▶ gender of child,
- ▶ family situation, eg, two/one parent family, main carer not a parent.

Interviews took place 12 months after the start of treatment. Of the 79 families available, 17 parents (one from each family) consented to participate. The study received ethical approval from the multi-centre research ethics committee for Scotland.

Taped interviews followed a topic guide with no set questions. Interviews were conducted by two of the authors (LS and JC), who were unknown to the parents, and lasted for 50–80 min. Recordings were fully transcribed and the Framework method of content matrix data analysis was used.¹⁰ Both interviewers and VP developed the themes independently and then agreed principal themes and sub-themes. The themes were coded using Nvivo software (QSR International, Melbourne, Australia).

Peer consultation took place with all authors on coding of transcripts, charting and mapping data, and final interpretations. This was important to help counter any bias that may have emerged during data interpretation. To ensure a transparent audit trail, all the audiotapes, paperwork, Nvivo coding, charts and mappings are available for review.

RESULTS

Characteristics of participants

Seventeen principal carers (14 mothers, two fathers and one grandmother) from varied backgrounds and with diverse family circumstances were interviewed. The characteristics of participating families in the present study are noted in table 1 and were similar to those referred for obesity management to the two major paediatric centres in Scotland.¹¹

Original article

Table 1 Characteristics of participating parents

Characteristics	
Treatment goal met*	7
Treatment goal unmet*	10
Male (child)	8
Female (child)	9
5–8 years old	8
9–11 years old	9
Parent(s) obese†	10
Mid-high socio-economic status	9
Low socio-economic status	8

*Goal met signifies BMI maintenance/loss; goal unmet signifies BMI gain; †parental weight was self-reported.

Socio-economic status is derived from place of residence using the Carstairs score where 1–4 is defined as middle-high and 5–7 as low.

Throughout this paper anonymised verbatim quotes from the parents are used where (1) indicates child's BMI decreased and (2) indicates child's BMI increased.

Beginning the journey: why enter treatment?

One parent in each family appeared to have the "lead" parenting role in the child's weight management; this was generally, although not exclusively, the mother. Prior to seeking help for their child's weight, there were varying degrees of awareness among parents regarding their child's weight, ranging from being highly aware and actively seeking help to being oblivious to any problem. We distinguished between those parents who appeared to be aware of their child's weight problem and those unaware of their child's weight.

Among parents who talked of being aware of their child's weight problem, there were two groups. The first group sought help after realising the problem and we called these "seekers":

...because of the amount of food he was eating constantly and I thought I need to do something before it spirals out of control. Then going out and getting clothes, nothing would fit him and I thought, you know, I need to do something. (2)

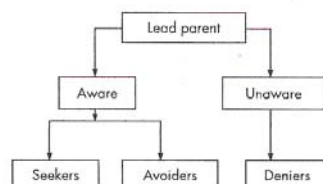


Figure 1 Diagram representing parents' typologies at the beginning of the journey. Lead parent: parent who takes most responsibility for the child's weight. Aware: parents who have recognised their child has a weight problem. Unaware: parents who have not recognised that their child has a weight problem. Seekers: parents who actively seek help for their child's weight. Avoiders: parents who avoid discussing their child's weight. Deniers: parents who are unaware of their child's weight.

There was a second group of aware parents who felt unable or unwilling to discuss their concerns with the child and/or raise the issue with health professionals and we called this group "avoiders":

Not as sitting down and saying you're over (weight), because at the age she was at you're frightened you're going to push them the other way. (1)

Parents who appeared to be unaware that their child was obese generally described their child as a normal weight for their age:

I didn't realise he was so overweight, I didn't realise he was that, because he doesn't actually look it because he's broad, so he carried it well, but I was quite shocked to find out his actual weight. (1)

Since all these children had BMIs above the 2 SD score, we called these parents "deniers". These typologies are illustrated in fig 1.

Overwhelmingly, general practitioners (GPs) were the main gatekeepers to dietetic referrals for weight management. Seekers approached their GP asking for help, while avoiders and deniers were typically attending for another reason and the GP raised the child's weight. A number of avoiders and deniers became seekers once the weight concerns had been pointed out to them. When discussed, there was a feeling that the health professional who had raised the issue had been insensitive to the feelings of the child and/or the parent.

This pre-treatment phase highlighted the parents' intense and often conflicting feeling and anxieties:

...all my childhood bad feelings that I had were coming back. It is cruel to let a child overeat, I know that, but some times, and I'm not a stupid person – I'm quite a bright person, but some times commonsense doesn't come into it, when you love someone you want to make them feel happy. (1)

During treatment: the need for support

Parents strongly and persistently voiced their need for support. Repeatedly the parents talked of looking for "someone" outside of the family who could motivate the child and in particular give the child "a wake-up call". Support and help was sought for the child's self-esteem, focus on necessary changes and to reinforce changes already implemented. Less persistently but intensely voiced was the need for support in justifying to other family members (including the other parent) the necessity for an intervention and lifestyle changes:

I just knew I wanted help 'cause I felt that my husband wasn't listening to me, my friends, my mum was very similar. I need someone then to say so – also I could say to my husband, I have been to the doctor and there is a problem. (2)

All parents described to varying degrees the support that they needed from significant others, summarised as

- ▶ not offering/giving/tempting the child with foods they should be avoiding/cutting down (commonly mentioned were sweets, chocolate biscuits, cakes),
- ▶ not undermining the actions and lifestyle changes agreed with/being imposed by the lead parent,
- ▶ reinforcing to the child, both by action and verbally, the agreed lifestyle changes,
- ▶ supporting the initial decision to seek and enter treatment.

Table 2 Quotes from parents on lack of support from the nucleus and extended family

Q1	"We knew it would be difficult when her cousins came over, but because they are boys they were running about all the time, they would have a bag of crisps or something"	1
Q2	"He sees his brother, 'he's gonna eat pizza why can't I eat pizza', and that's part of our problem"	1
Q3	"At times I think I was struggling as well because his older brother keeps calling him fatty and things like that"	2
Q4	"It's sort of friends and visits to friends, classmates and sleepovers and things like that then, if he spends company with other children then he will get into a habit of eating sweets that he wouldn't eat at home"	2
Q5	"I think he cheated when he was with his mum, if mum wasn't watching he took the opportunity because I just changed what was in the house which is different from the way he was with mum"	2
Q6	"With granny and granddad, if they are hungry they will let them eat anything. Because they couldn't give us these things, they see these foods as a celebration. I don't think they really understand that it can be cruel to just give in all the time"	1
Q7	"His granddad has never changed – 'she wean wants it the wean will get it' – I try not to take him anymore"	2
Q8	"Granny just likes to buy them sweets to spoil them"	1

1, child's BMI decreased; 2, child's BMI increased.

Parents often conveyed a distinction in the level of support given by the nucleus family (those in the same house) and the extended family (eg, grandparents, separated parents, aunts, cousins and significant family friends). The nucleus family was generally discussed as being supportive. However, it was less typical for the extended family and friends to be seen as supportive (Q1, Q2, Q3, Q4 and Q5 in table 2). The group most persistently mentioned by most parents as being unsupportive were grandparents (Q6, Q7 and Q8 in table 2). Most parents consistently reported that grandparents were not understanding, gave foods the parents had repeatedly asked them not to and sneaked little treats to the child. However, in the minority of cases where the extended family including grandparents was supportive this was appreciated:

...no, even his gran was helping and his aunty was helping, was saying to him try this and you're not having this. Try and maybe give him a bit of fruit and he was quite happy with that, because if it was going to help him no one was too bothered. (2)

In one family where the grandparents were the child's main guardians with the grandmother in the lead parent role, the child's natural parents took over the typical unsupportive grandparent role:

They (mum and dad) want to treat them, but you know that is what I was saying to my husband – I often end up as the baddie. (1)

Post treatment: was it all worth it?

Parents commonly felt that the outside support ceased when the treatment finished. They noted that continuing treatment and support "such as that given by Weight Watchers" would have benefited the child and that continuous support was needed for treatment to be successful. There was a widespread view that parents and children had not adhered to all of the changes implemented during treatment but had continued with relevant positive lifestyle changes. Parents talked of having made lots of changes and a complete change in what was eaten and of trying to maintain changes.

The persistent feeling of most parents was that their and their child's overall experience of obesity treatment had been positive and successful. Parents repeatedly talked of the interventions being worthwhile, educational, the best thing they had done and being treated with respect by the dietician. An exceptional but strongly voiced view was that the experience had been negative, the treatment not as successful as hoped and there was a poor relationship with the dietician:

I didn't think it would make a difference where it was, I just think he felt that the whole experience was a bit negative for him. I don't think he enjoyed any of it. That's why I left and never came back. (1)

Parents expressed these positive and negative views regardless of the child's weight outcome.

Table 3 Quotes from parents on treatment outcomes

Weight		
Q1	"I mean, it was, the big huge jump in weight had sort of stopped, which is what we wanted and as she will grow into it, and that is about as much as we could have hoped for"	2
Q2	"Because she is still gaining weight, I don't know why. She's had tests again for thyroid and diabetes, but they've come back negative and she's still gaining weight"	2
Q3	"Well, she kept that weight that she originally had, but when she stretched up she slimmed down rather than losing it all at the same time, she kept it the same"	1
Q4	"Overall I think he has just put on slightly compared to what he started at. Which again wouldn't be too bad over the year, what I mean, because if he hadnae been doing it, he'd have probably put on a lot more I would say"	2
Self-esteem		
Q5	"He used to wear jogging bottoms for comfort, but we managed to get him to dress [in] trousers for school. He was saying its really good isn't it, it has been really good for him."	2
Q6	"I think it was good for her self-esteem, she was really starting to feel good about herself. Which is more important, she has really taken it on"	1
Q7	"She used to be embarrassed at school 'cause there were things she couldn't do in PE that she can now do"	1
Q8	"To actually put the thought in her head of what she wanted to do and achieve, and set her own goals. It has been much better than what I expected"	1

1, child's BMI decreased; 2, child's BMI increased.

Original article

Table 4 Summary of main features of the parents' journey

Journey phase	Feature	Sub-feature
Pre-treatment	Aware of weight	Seekers
		Avoiders
	Unaware of weight	Deniers
	Emotional	Fear Anger Guilt Confusion
During treatment	Needing support	From nucleus family From extended family From health professionals
	Unsupportive	Mainly extended family Particularly grandparents
	Weight outcome	Ambivalence Best it could be Would have been worse
After treatment	Self-esteem	Important to parents Child more confident Child happier

When discussing their child's weight, all parents' comments had varying degrees of ambivalence and ambiguity. The most frequent comment was that even though weight had increased, it probably would have been worse if they had not taken part (Q1, Q2, Q3 and Q4 in table 3). Importantly, what most parents did note as a positive and concrete outcome were improvements in the child's self-esteem and confidence. This was generally discussed in terms of style of clothes they could now wear, increased enjoyment in participating in PE and improved peer relationships (Q5, Q6, Q7 and Q8 in table 3). Indeed by this stage of the journey, most parents overwhelmingly saw these positive changes in self-esteem as the key outcome, more important than weight change, and for them an affirmation of successful treatment.

DISCUSSION

In this study we set out to identify and understand – from the parents' perspective – factors that may have influenced the decision to seek treatment, barriers to engaging during treatment and the parents' perceived key outcomes of treatment (summarised in table 4). Resource limitations did not allow us to interview more parents or to further explore our findings with other groups. However, this study contributes by adding to a very limited evidence base on the feelings and influences of the parents of obese children in treatment programmes. For the parents there appeared to be several distinct phases characterised by us as a "journey". Parents interviewed cited the child's low self-esteem, poor quality of life, awareness of the child being called names and worries about the child's future self-esteem as reasons for seeking treatment; health was not commonly mentioned as a motivation for seeking treatment.

We identified parents whom we called deniers and others as avoiders. A number of studies have reported that parents often do not appear to recognise their children as being obese or overweight or the health implications of their child's weight.^{12–16} However, none have investigated parents who are aware of their child's weight but feel unable or unwillingly to discuss these concerns. The qualitative study of Murtagh *et al*¹⁷ supports some of these observations, but from the child's point of view.

Being a parent who actively sought treatment was not an obvious indicator of family motivation during treatment or of a

successful clinical outcome. Avoiders and deniers often converted to seekers after the issue of weight had been raised. The discussing of weight by GPs was acceptable to these parents. This is an important message for GPs not to avoid the issue of excess weight but to raise it in a sensitive manner and offer parents help.

The present study suggests that support mechanisms within the family may be of great importance in achieving and maintaining lifestyle changes. The lead parent may often need help and full cooperation from the nucleus and extended family to make and sustain such changes. We have identified the type of support the parents need from significant others. The strength of feelings voiced by the parents regarding the role of the unsupportive extended family (in undermining lifestyle changes) raises issues for those working with obese children and their parents. Similar problems, particularly with grandparents, have also been raised by Dixey *et al*.¹⁸ Those developing treatment programmes and clinicians delivering treatment should consider engaging the whole nucleus family and possibly the extended family in treatment to improve success, although this would require a form of care quite different to current office-based and low intensity treatments usually directed at the mother and child.¹ The level of support provided by highly intensive treatments may be an important contributor to their success.⁹

An overwhelming theme that emerged from the parents we interviewed was a perceived positive outcome of treatment regarding their child's self-esteem and quality of life. Indeed, this appeared to be more important to parents than a successful weight outcome. The parents interviewed by Dixey *et al*¹⁸ reported comparable views concerning self-esteem as a positive outcome. Murtagh *et al*¹⁷ illustrated the importance of self-esteem for clinical samples of obese children, and we have previously shown in this sample that quality of life was significantly impaired.¹⁹ For the children in the study by Murtagh *et al*, it was the desire to be "socially acceptable" in the school playground and not long-term health which motivated them to seek treatment for obesity. Health professionals may need to be aware of the importance of this issue for the parents and the child and have more understanding of the need to support self-confidence and self-esteem in obese children. For clinicians, outcomes such as weight and BMI SD scores are of fundamental importance in the treatment of childhood obesity. However for the parents interviewed, weight and BMI were not a priority at the end of treatment. There is perhaps a need for health care professionals to reconsider their outcome measures and perhaps seek greater concordance between the priorities of the family and those of the health system.

CONCLUSIONS

Qualitative research is a powerful tool for illuminating peoples' feelings and capturing participants' stories of experiences and how programmes felt from the inside.²⁰ The present study may aid in the development of theories and practices on how to empower and support parents through treatment for their child's obesity. In particular, our study highlights potential opportunities for future treatment such as providing more support for families than can be achieved by short office-based consultations, describing to families the types of feelings which other families undergoing treatment have experienced, helping parents make lifestyle changes by addressing the wider family environment, and giving outcomes of treatment which are important to parents (psycho-social outcomes) higher priority in management.

Original article

What is already known on this topic

- Treatment of childhood obesity is often unsuccessful, but the precise reasons for this are poorly understood at present.
- The parent perspective on treatment of childhood obesity has not been studied systematically.

What this study adds

- Parents often feel that other members of the close and extended family, particularly grandparents, undermine efforts to change lifestyle.
- Psychosocial difficulties often bring parents to treatment, and improvements in this area may be what motivates them to remain in treatment.

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Randomized, Controlled Trial of a Best-Practice Individualized Behavioral Program for Treatment of Childhood Overweight: Scottish Childhood Overweight Treatment Trial (SCOTT)

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ABSTRACT

OBJECTIVE. The objective of this study was to determine whether a generalizable best-practice individualized behavioral intervention reduced BMI *z* score relative to standard dietetic care among overweight children.

METHODS. The design consisted of an assessor-blinded, randomized, controlled trial involving 134 overweight children (59 boys, 75 girls; BMI \geq 98th centile relative to United Kingdom 1990 reference data for children aged 5–11 years) who were randomly assigned to a best-practice behavioral program (intervention) or standard care (control). The intervention used family-centered counseling and behavioral strategies to modify diet, physical activity, and sedentary behavior. BMI *z* score, weight, objectively measured physical activity and sedentary behavior, fat distribution, quality of life, and height *z* score were recorded at baseline and at 6 and 12 months.

RESULTS. The intervention had no significant effect relative to standard care on BMI *z* score from baseline to 6 months and 12 months. BMI *z* score decreased significantly in both groups from baseline to 6 and 12 months. For those who complied with treatment, there was a significantly smaller weight increase in those in the intervention group compared with control subjects from baseline to 6 months. There were significant between-group differences in favor of the intervention for changes in total physical activity, percentage of time spent in sedentary behavior, and light-intensity physical activity.

CONCLUSIONS. A generalizable, best-practice individualized behavioral intervention had modest benefits on objectively measured physical activity and sedentary behavior but no significant effect on BMI *z* score compared with standard care among overweight children. The modest magnitude of the benefits observed perhaps argues for a longer-term and more intense intervention, although such treatments may not be realistic for many health care systems.

THERE HAS BEEN a rapid rise in the prevalence of childhood overweight in recent years. Overweight is now 1 of the most common pediatric health problems,¹ and it has significant adverse effects on physical and psychosocial health in childhood and adulthood.²

Systematic reviews^{3–5} reported that previous randomized, controlled trials (RCTs) of childhood overweight treatment had methodologic flaws, such as small sample sizes, high dropout rates, short-term follow-up, lack of details about the randomiza-

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Dr Reilly is guarantor; Drs Reilly and Hughes had full access to data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis; all authors were involved in obtaining funding, conception, and design of the study, interpretation of the data, critical revision of the manuscript, and final approval of the submitted manuscript; Dr Reilly was involved in developing the intervention, study supervision, and drafting the manuscript; Dr Hughes was involved in developing the intervention, drafting the manuscript, collecting all outcome measures, and analyzing the data; Ms Stewart and Ms Chapple developed and delivered the intervention and drafted the manuscript; and Mr McColl was the trial statistician and participated in randomization procedures and supervising data analysis. This trial has been registered at the Current Controlled Trial Ltd (www.controlled-trials.com; identifier ISRCTN41383109).

Key Words

obesity, overweight, children, treatment, BMI, physical activity, sedentary behavior, randomized, controlled trial

Abbreviations

RCT—randomized, controlled trial
QoL—quality of life
IQR—interquartile range
df—degrees of freedom
CI—confidence interval

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tion process, lack of blinding, and failure to use intention-to-treat analysis. Intensive, behavioral treatment programs for overweight children have proved successful in clinical studies from 1 center in the United States^{3,4}; however, because these interventions were intense and required a number of health professionals, they may not be readily generalizable to all health care systems. Systematic reviews have therefore concluded that high-quality studies that test more generalizable interventions to treat childhood overweight are needed urgently.³⁻⁵

These systematic reviews identified a number of promising treatment strategies that can now be regarded as evidence based: use a theoretical basis for treatment, direct treatment at motivated families, involve the entire family in treatment, aim for weight maintenance rather than weight loss, be more intensive in treatment (more frequent and longer appointments), and combine dietary modification with changes in physical activity and/or sedentary behavior (eg, television viewing).³⁻⁵ We developed a behavioral intervention, based on recommendations from systematic reviews³⁻⁵ and expert committee guidance,⁶ that was intended to treat overweight children within a health care setting with limited resources. Our intervention used a family-centered approach^{7,8} and behavior change techniques⁹⁻¹⁰ to manage childhood overweight and can be regarded as a best-practice approach on the basis of current evidence. To our knowledge, this is the first RCT to implement best-practice recommendations in a relatively low-intensity, office-based setting using a single health professional, thus making the intervention practical and generally applicable to a range of health care settings.

The primary aim of this assessor-blinded RCT was to test the efficacy of our generalizable, best-practice individualized behavioral intervention relative to standard dietetic care (control condition) to reduce BMI z score among overweight children (BMI \geq 98th centile relative to United Kingdom 1990 reference data) aged between 5 and 11 years. We also determined the impact of the intervention relative to the control condition on weight, objectively measured physical activity and sedentary behavior, fat distribution, growth, and quality of life (QoL). Design, conduct, and reporting of the trial followed Consolidated Standards of Reporting Trials (CONSORT) guidelines.¹¹

METHODS

Participants

This study was conducted at the Royal Hospitals for Sick Children in Glasgow and Edinburgh, Scotland. Eligibility criteria were overweight children (BMI \geq 98th centile relative to United Kingdom 1990 reference data, usually referred to as obesity in the United Kingdom)^{3,4} who were aged 5 to 11 years and attending a standard elementary school and had at least 1 parent who perceived the child's weight as a problem and was willing to make lifestyle changes. We excluded children who had an underlying medical cause for their overweight or serious comorbidity that required urgent treatment or who had

received treatment for overweight in the past year. Overweight children were recruited from dietetic waiting lists and were referred from hospital doctors, family physicians, school nurses, community dietitians, and community pediatricians in Glasgow and Edinburgh. Ethical approval was obtained from the research ethics committee at each participating site. Written informed consent was obtained from all children and their parents/guardians.

Randomization and Concealment

Children attended a baseline assessment, where the researcher obtained consent, recorded baseline measurements, and assigned a study code. For ensuring concealment, the study code was sent to a statistician, who produced a computer-generated randomization list and allocated participants to the intervention or control group. Randomization was in blocks of 10 (ratio 1:1) and was stratified by gender and study center (Edinburgh or Glasgow). The statistician informed the research dietitians, who were delivering the intervention of the group allocation and who then informed participants of their groups. Participants commenced intervention or control treatments within 3 weeks of the baseline measurements.

Intervention

The intervention has been published elsewhere.⁷ Briefly, this is a practical, best-practice behavioral program delivered by experienced pediatric dietitians who are trained in behavior change counseling^{8,12} on a 1-to-1 basis (ie, 1 dietitian saw 1 family). The program consisted of 8 appointments (7 outpatient visits and 1 home visit) during 26 weeks with a total patient contact time of ~5 hours. The program used a family-centered approach whereby the child (and family) took control of his or her own lifestyle changes.^{8,13} We used various behavioral change techniques, guided by models of behavior change, to enhance the child's motivation for making lifestyle changes: exploring motivation to make changes, exploring pros and cons of change, identifying barriers to change, problem-solving barriers, goal-setting, rewards, self-monitoring, social support, and preventing relapse.^{8-10,12,14} Although these behavioral techniques were developed for adults, they are increasingly being used to elicit lifestyle changes in children¹⁵; however, the dietitians had to modify their explanation of these strategies to the children, particularly with younger children. The strategies were directed at the children, although parents and the dietitian helped the child (especially younger children) understand and engage with the behavioral techniques. An article describing our intervention in more detail has been published.⁷

Children were encouraged to alter their diet by using a modified traffic-light approach [reduce intake of foods high in fat and sugar (red), increase intake of fruit and vegetables (green)]^{3,16} increase their physical activity,¹⁷ and restrict their sedentary behavior (television viewing and playing computer/video games) to no more than 2 hours per day or the equivalent of 14 hours per week as is widely recommended.^{4,6} Because the intervention fo-

TABLE 1 Comparison of the Best-Practice Individualized Behavioral Intervention With Standard Dietetic Care

Parameter	Standard Care	Intervention
No. of appointments	3–4	8
Appointment style	Dietitian centered	Family centered
Duration of treatment	1.5 h over 6–10 mo	5 h over 6 mo
Diet	General healthy eating advice	Modified traffic light diet approach
Physical activity	General advice given	Aim to increase to 1 h/d
Sedentary behavior	Not targeted	Aim to reduce to <2 h/d
Motivation explored	Not explored	Importance score and decisional balance chart
Goals	Set by dietitian	Set by child
Lifestyle self-monitoring	Not used	Used throughout program

cused on behavior change rather than weight change, children were weighed only 3 times during the 6-month program.

All written materials were reviewed by several pediatric dietitians throughout Scotland. The dietitians received 18 hours of training on behavioral change counseling, conducted selected reading,⁸ and practiced the behavior change techniques and written materials with a small number of obese children before delivering the intervention in the main trial. For ensuring that the core skills and behavioral techniques involved in the intervention were being correctly implemented by the dietitians, 6 patient consultations from the main trial were assessed by 2 independent experts on behavior change counseling (not involved in the training). Assessments were scored 1 (minimum) to 7 (maximum); scores were 5 to 6 for global rating (patient-centeredness), 6 to 7 for core conditions (empathy, genuineness, and acceptance), 5 to 6 for guiding principles (client responsibility, social influence, and collaboration), 5 to 7 for affirmation, and 4 to 7 for pace of interviews. The assessment concluded that both dietitians were highly skilled in these techniques.

Control Group

Children who were randomly assigned to the control group received typical dietetic care currently are offered for overweight individuals by hospital and community dietetic services in Scotland. This involved 3 to 4 outpatient appointments delivered by pediatric dietitians during 6 to 10 months with a total patient contact time of ~1.5 hours. Standard care did not reflect best practice, because it was very low intensity, concentrated on dietary change with minimal focus on physical activity or sedentary behavior, and involved a didactic “medical model” rather than a behavioral, client-centered approach. In addition, advice on weight management was mainly directed toward the parents rather than the child, as described elsewhere.⁷ A process evaluation of the dietitians who conducted standard care confirmed this description of typical dietetic treatment. Table 1 describes the differences between standard care and our best practice, behavioral intervention. Weight maintenance was the aim of both treatment conditions.^{3,4,6}

Outcomes and Blinding

Outcome measures were recorded at baseline and then at 6 months and 12 months after the start of treatment by the same trained researcher, who was blinded to group allocation throughout the trial. Measures were put in place to ensure blinding, and the researcher had to report incidents of possible unblinding, which occurred in <5% of participants.

Our primary outcome was BMI *z* score. BMI was calculated by measurement of height to 0.1 cm and weight to 0.1 kg in duplicate using a portable stadiometer (Leicester Height Measure; Child Growth Foundation, London, England) and portable scales (TANITA 300GS; Cranlea & Co, Birmingham, England) with children in light indoor clothing and no socks and shoes. BMI and height were expressed relative to United Kingdom 1990 population reference data as *z* scores.¹⁸ Waist circumference was expressed relative to United Kingdom reference data¹⁹ as a *z* score to provide an index of fat distribution.

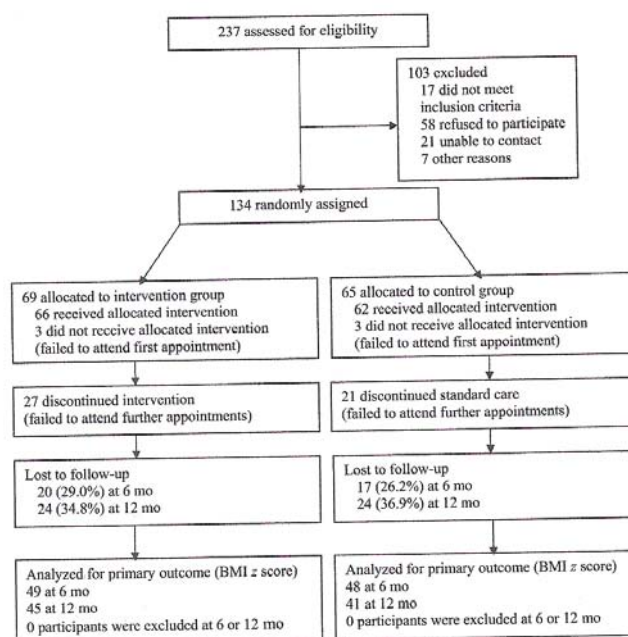
We measured habitual physical activity and sedentary behavior objectively for 7 days during all waking hours using the CSA/MTI WAM-7164 accelerometer (Manufacturing Technology Inc, Fort Walton Beach, FL), as previously described.^{20,21} Activity data were summarized as total physical activity (accelerometer count per minute) and percentage of waking hours in sedentary behavior, light-intensity physical activity, and moderate to vigorous physical activity using cut points validated against direct observation and energy expended during free-living activities for children.^{22,23}

We assessed QoL of participating children by using the Pediatric Quality of Life Inventory 4.0, which provides valid and reliable assessments^{24,25} and includes parallel parent proxy reports and child self-report versions for those aged 5 to 7 and 8 to 12 years. We categorized socioeconomic status using a standard area-based measure, the deprivation category based on Carstairs scores from the 2001 Scottish census.²⁶ The amount of time spent by the intervention and control dietitians interviewing children, administration after the interviews, and traveling for home visits (intervention only) and training costs (intervention only) were recorded to estimate economic costs of novel treatment and standard care.

Sample Size and Power

We used a between-group difference of -0.25 in the change in BMI *z* score over 6 months. Before the study, we assumed an SD of change in BMI *z* score of 0.4, but observed SD for change in BMI *z* score was 0.21, giving a *z* of 1.15 ($0.25/0.21$). Thus, with power 0.90, 0.05 significance level, and a 2-sided test, the required sample size was 34 per group. For allowing for dropout, 134 participants were entered at baseline; dropout at 6 months was 27.6%, thus 97 participants were included in the analysis of the primary outcome (BMI *z* score) at 6 months. Our achieved power was 0.9999 for detection of a difference in BMI *z* score between groups of -0.25 over 6 months.

FIGURE 1
Flow of participants through the trial and analyzed for the primary outcome (BMI z score).



Statistical Methods

Not all outcome measures were normally distributed. Differences between groups for the median change in outcomes from baseline to 6 and 12 months were analyzed using Mann-Whitney tests. Categorical data were analyzed by using χ^2 tests. The primary analysis was performed on an intention-to-treat basis for each outcome measure and involved all participants who attended for follow-up measures, regardless of whether they completed the treatment. We also performed a planned per-protocol analysis for BMI z score and weight (kilograms) using only intervention and control participants who complied well with the assigned treatment, defined as those who attended $\geq 75\%$ of scheduled appointments.

RESULTS

Flow of Participants Through the Trial

Figure 1 describes the flow of participants through the trial. Participants were recruited from June 2003 to June 2004, and outcome measures were recorded at baseline and then at 6 months (median: 27 weeks; interquartile range [IQR]: 26–28) after the start of treatment and 12 months after the start (median: 54 weeks; IQR: 52–55). Of the 237 children assessed for eligibility, 134 (56.5%) consented and were randomly assigned to the intervention ($n = 69$) or control group ($n = 65$). Of the 134 children who were randomly assigned, 97 (72.4%) at-

tended the 6-month follow-up and 86 (64.2%) attended at 12 months (Fig 1); the primary outcome (BMI z score) and weight and height z score were available for all of these participants. Follow-up in each group was similar at 6 months ($\chi^2 = 0.1$, degrees of freedom [df] = 1, $P = .7$) and 12 months ($\chi^2 = 0.07$, $df = 1$, $P = .8$). Baseline characteristics of study participants are shown in Table 2; there were no significant differences between groups at baseline. The median BMI z score at baseline was >3 in both groups.

Physical activity and sedentary behavior measurements were obtained in 117 participants at baseline and 67 at 6 months; however, compliance with wearing the accelerometer was very poor at 12 months; therefore, we did not have sufficient data to perform an analysis at 12 months. QoL scores from baseline to 6 months were analyzed for 94 parent proxy reports and 92 child self-reports.

Of the 69 participants assigned to the intervention, 44 (63.8%) complied well with treatment, defined as attendance at $\geq 75\%$ of scheduled appointments. Of the 65 participants assigned to the control condition, 46 (70.8%) attended $\geq 75\%$ of scheduled appointments ($\chi^2 = 0.75$, $df = 1$, $P = .39$).

Primary Outcome: BMI z Score

There were no significant differences between the intervention and control groups for changes in BMI z score

TABLE 2 Baseline Characteristics of Study Participants According to Group

Variable	Control Group (n = 65)	Intervention Group (n = 69)
Age, mean (SD), y	8.5 (1.9)	9.1 (1.7)
Male/female	29/36	30/39
Maternal BMI, median (IQR), kg/m ^{2a}	30.0 (25.2 to 35.8)	28.0 (24.2 to 32.8)
Paternal BMI, median (IQR), kg/m ^{2a}	27.1 (24.7 to 31.7)	26.1 (23.7 to 31.5)
Socioeconomic status		
Nondeprived (1–4), n (%)	30 (46.2)	28 (40.6)
Deprived (5–7), n (%)	35 (53.8)	41 (59.4)
BMI z score, median (IQR)	3.3 (2.8 to 3.6)	3.2 (2.7 to 3.6)
Weight, median (IQR), kg	49.0 (41.2 to 61.7)	52.6 (43.8 to 61.2)
Waist circumference z score, median (IQR)	3.3 (2.9 to 3.7)	3.3 (2.9 to 3.6)
Height z score, median (IQR)	1.07 (–0.90 to 3.54)	0.74 (–2.04 to 4.13)
Total activity, median (IQR), cpm	646 (526 to 821)	649 (508 to 749)
Monitored time, median (IQR), %		
Sedentary behavior	80.7 (75.4 to 84.9)	81.2 (76.5 to 86.4)
Light-intensity activity	16.5 (13.3 to 20.3)	15.8 (11.4 to 19.4)
Moderate to vigorous activity	2.6 (1.8 to 4.5)	2.3 (1.8 to 4.1)
QoL summary scales, median (IQR)		
Child self-report		
Physical health	71.9 (56.2 to 81.2)	75.0 (64.1 to 87.5)
Psychosocial health	75.0 (59.2 to 83.3)	73.3 (62.5 to 84.2)
Parent proxy report		
Physical health	71.9 (55.5 to 87.5)	68.8 (59.4 to 78.1)
Psychosocial health	66.4 (53.1 to 75.0)	63.3 (55.0 to 76.7)

There were no significant differences between groups at baseline.

^aParental weight and height were self-reported.

and weight (kg) from baseline to 6 and 12 months (Table 3). BMI z score significantly decreased in both groups from baseline to 6 months (intervention: 95% confidence interval [CI]: –0.18 to –0.07; control: 95% CI: –0.16 to –0.03) and baseline to 12 months (intervention: 95% CI: –0.22 to –0.04; control: 95% CI: –0.26 to –0.08). Weight (kg) significantly increased in both groups from baseline to 6 months (intervention: 95% CI: 2.2–3.6; control: 95% CI: 2.8–4.4) and 12 months (intervention: 95% CI: 5.4–7.8; control: 95% CI: 5.5–7.7). Table 4 presents actual median values for BMI z score and weight at baseline and at 6 and 12 months.

Fat Distribution

There were no significant between-group differences for changes in waist circumference z score from baseline to 6 and 12 months (Table 5).

Objectively Measured Physical Activity and Sedentary Behavior

At baseline, the proportion of monitored time spent in sedentary behavior was high and participation in moderate to vigorous physical activity was low in both groups (Table 2). The median duration of activity monitoring over 7 days was 11.3 hours/day (IQR: 10.4–12.2) in the intervention group and 11.5 hours/day (IQR: 10.6–12.7) in the control group. There were significant between-group differences for the change in total activity (mean counts per minute) and percentage of time spent in sedentary behavior and light-intensity activity from baseline to 6 months in favor of the intervention group (Table 5).

Other Secondary Outcomes

There were no significant between-group differences for the change in height z score from baseline to 6 and 12

TABLE 3 Change in BMI z Score (Primary Outcome) and Weight From Baseline to 6 and 12 Months in the Control and Intervention Groups

Parameter	Control, Median Change (IQR)	Intervention, Median Change (IQR)	Between-Group Difference in Change From Baseline	
			Median Difference (95% CI)	P
BMI z score				
0–6 mo	–0.06 (–0.22 to 0.05) ^a	–0.10 (–0.24 to –0.02) ^a	0.03 (–0.05 to 0.11)	.4
0–12 mo	–0.19 (–0.31 to 0.02) ^a	–0.07 (–0.32 to 0.04) ^a	–0.04 (–0.17 to 0.07)	.5
Weight (kg)				
0–6 mo	4.0 (2.6 to 5.5) ^a	3.2 (1.3 to 4.2) ^a	0.8 (–0.2 to 1.8)	.1
0–12 mo	7.2 (4.5 to 8.5) ^a	7.0 (3.9 to 9.0) ^a	–0.1 (–1.5 to 1.5)	.9

^aP < .01 for change from baseline.

^bP < .001 for change from baseline.

TABLE 4 Median (IQR) for BMI z Score and Weight at Baseline and 6 and 12 Months in the Control and Intervention Groups

Parameter	Baseline	6 mo	12 mo
BMI z score			
Control	3.3 (2.8–3.6)	3.2 (2.7–3.5)	3.1 (2.7–3.5)
Intervention	3.2 (2.7–3.6)	3.0 (2.5–3.4)	2.8 (2.4–3.4)
Weight (kg)			
Control	49.0 (41.2–61.7)	53.0 (43.2–66.4)	53.9 (46.8–66.0)
Intervention	52.6 (43.8–61.2)	54.8 (46.8–62.3)	58.1 (52.1–64.5)

months (Table 5). Similarly, no significant between-group differences were found for changes in QoL scores for the child self-report or parent proxy report from baseline to 6 months (Table 5). Parent-reported QoL scores significantly improved from baseline to 6 months in both groups (Table 5). The cost (for 1 patient) of delivering the novel intervention was £108 (\$192 US) and £29 (\$52 US) for the standard treatment.

Per-Protocol Analysis

We also performed a planned per-protocol analysis for BMI z score and weight using only intervention and control participants who complied with the assigned treatment, defined as those who attended $\geq 75\%$ of scheduled appointments; 84 participants were included in analysis at 6 months, and 77 were analyzed at 12 months. The intervention had no significant effect on BMI z score relative to control subjects from baseline to 6 months (Mann-Whitney test, 95% CI: -0.02 to 0.14 ; $P = .2$) and 12 months (Mann-Whitney test, 95% CI: -0.14 to 0.11 ; $P = .8$). There was a

significantly smaller increase in weight in the intervention group compared with the control subjects from baseline to 6 months (Mann-Whitney test, 95% CI: 0.05 – 2.25 ; $P = .04$) for participants who complied with treatment, but this effect was not evident at 12 months (Mann-Whitney test, 95% CI: -1.5 to 1.9 ; $P = .8$). Median weight increase was 2.9 kg (IQR: 1.1 – 4.1) in the intervention group and 4.0 kg (IQR: 2.4 – 5.6) in the control group.

DISCUSSION

The generalizable best-practice individualized behavioral program that was tested in this study had modest benefits for BMI z score, for objectively measured physical activity and sedentary behavior, and for QoL. Furthermore, for participants who complied well with treatment, weight gain was significantly lower in the intervention group compared with the control subjects from baseline to 6 months. However, we observed no significant differences between the best-practice approach and standard care for BMI z score, weight, and fat distribution over 12 months among overweight children of elementary school age. The significant benefits in physical activity and sedentary behavior in favor of the best-practice intervention group may reflect differences in treatment targets: our intervention focused on diet, physical activity, and sedentary behavior, whereas standard care had minimal emphasis on physical activity and did not target sedentary behavior. This study therefore provides some evidence that inclusion of these behavioral targets as part of treatment is worthwhile, although the changes in activity and sedentary behavior actually

TABLE 5 Change in Secondary Outcomes From Baseline to 6 and 12 Months in the Control and Intervention Groups

Parameter	Control, Median Change (IQR)	Intervention, Median Change (IQR)	Between-Group Difference in Change From Baseline	
			Median Difference (95% CI)	P
Waist z score				
0–6 mo	-0.10 (-0.30 to -0.01) ^a	-0.20 (-0.30 to -0.04) ^a	0.05 (-0.05 to 0.14)	.400
0–12 mo	-0.20 (-0.40 to 0.05) ^a	-0.20 (-0.50 to -0.03) ^b	0.04 (-0.10 to 0.20)	.500
Height z score				
0–6 mo	0.03 (-0.07 to 0.10)	-0.02 (-0.12 to 0.11)	0.04 (-0.03 to 0.09)	.200
0–12 mo	0.05 (-0.07 to 0.16)	0.01 (-0.11 to 0.14)	0.04 (-0.04 to 0.13)	.300
Total activity (accelerometry cpm)	-115 (-194 to 2) ^a	21 (-129 to 157)	-112 (-199 to -31)	.009
Monitored time, %				
Sedentary behavior	4.50 (0.02 to 6.20) ^a	0.05 (-4.80 to 3.80)	3.60 (0.80 to 6.30)	.009
Light activity	-3.8 (-5.2 to -0.6) ^b	-0.5 (-3.5 to 2.6)	-2.5 (-4.8 to -0.5)	.020
MVPA ^c	-0.7 (-1.8 to 1.0)	0.2 (-0.8 to 1.4)	-0.8 (-1.7 to 0.1)	.100
QoL summary scales				
Child self-report				
Physical health	8.0 (3.1 to 18.8) ^b	3.1 (-6.2 to 15.6)	6.2 (0.0 to 12.5)	.050
Psychosocial health	5.0 (0.0 to 10.0) ^a	3.3 (-5.8 to 10.8)	1.7 (-3.3 to 6.7)	.400
Parent proxy report				
Physical health	6.2 (-6.2 to 14.1) ^c	3.1 (-4.7 to 15.0) ^c	0.0 (-6.2 to 6.2)	.800
Psychosocial health	3.3 (-3.3 to 11.0) ^c	5.0 (-1.7 to 9.2) ^c	0.0 (-3.3 to 4.6)	.800

MVPA indicates moderate-to-vigorous physical activity.

^a $P < .01$ for change from baseline.

^b $P < .001$ for change from baseline.

^c $P < .05$ for change from baseline.

observed were modest. Information on dietary intake was not collected in this study but may have added to our understanding of the lifestyle changes observed.

There is widespread concern, particularly from parents, that treating overweight children may increase the risk for adverse effects; however, research in this area is limited.^{4,27} We found that our best-practice program, which was family-centered and intensive, did not adversely affect the child's growth or QoL. There were significant improvements in health-related QoL over time in both groups in this study. We previously showed that QoL is impaired in our clinical sample of overweight children compared with lean control subjects matched for age, gender, and socioeconomic status.²⁸ Improvements in QoL in this study moved overweight children's QoL scores into the range for healthy lean children.²⁸

It is possible that both treatments may have been successful relative to a no-treatment control group and that our decision to use a standard care control group attenuated differences between groups. Previous studies in the United Kingdom showed that BMI z scores continued to increase in overweight children who did not receive treatment.^{29,30} In contrast, in this study, we found small but significant decreases in BMI z scores over 12 months in both groups; however, the clinical significance of these changes is unclear because evidence suggests that a decrease in BMI z score of 0.5 over 1 year may be needed to improve cardiovascular and metabolic risk factors in overweight children.³¹ It should also be noted that other studies that used a waiting list control group found significant improvements in anthropometric outcomes in the control condition.³² It is possible that the detection of obesity through recruitment and baseline assessment may make families aware of the issue and motivate them to change behavior. The mean BMI z score of our sample was >3, indicating the degree of overweight was extreme and, therefore, families in this study may have been more resistant to treatment.

Systematic reviews have recommended that future treatment programs be both generalizable and evidence-based, using the elements of treatment likely to be most effective from previous studies.^{3-5,33} In addition, treatment programs that use a more behavioral approach to changing lifestyle in children are more likely to be successful in the treatment of overweight and other chronic childhood diseases than more traditional, didactic approaches to treatment^{6,9,10}; therefore, we used these recommendations to develop a generalizable, best-practice behavioral intervention delivered by a single pediatric dietitian in an office-based setting, thereby making the manpower burden and treatment costs generalizable (less than \$200 per patient). We also ensured that the behavioral approach used in the intervention was of a very high quality. The intervention group dietitians were highly trained in behavior change counseling, and several consultations were assessed by 2 independent experts in health behavior change counseling.

We rigorously tested the efficacy of this intervention in a high-quality RCT that followed Consolidated Standards of Reporting Trials guidelines. In contrast to many previous studies included in systematic reviews of child-

hood obesity treatment,^{3-5,33} this study was adequately powered, follow-up was longer than most previous trials, compliance to both intervention and standard care treatments was good and retention rates at follow-up assessments were high, outcomes were recorded by a blinded researcher, habitual physical activity and sedentary behavior were measured objectively, and we used intention-to-treat analysis and properly conducted randomization procedures. We maximized generalizability by recruiting obese children from a number of health professionals in the 2 major cities in Scotland. In addition, the intervention tested was generalizable (as previously discussed), and the control condition accurately reflected current treatment of overweight children in Scotland.

It is possible that a more intense and/or longer duration intervention than that used in this study may have been more successful, but our aim was to test an intervention that was practical and so likely to be generally applicable. Alternatively, the family-centered approach used in the intervention may have allowed families to set lifestyle goals that were not substantial enough to have a marked effect on BMI z score.

CONCLUSIONS

The generalizable, best-practice individualized behavioral intervention that was tested in this study had modest benefits on objectively measured physical activity and sedentary behavior. Furthermore, the intervention had a positive effect on weight for those who complied with the program. Both treatments had a small but significant effect on BMI z score over the 12 months. The modest magnitude of the benefits observed perhaps argues for a longer term and even more intense approach to treatment of pediatric overweight, although such treatments may not be realistic for many health care systems. These findings may be useful in the development of future treatment programs.

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