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Treatment of severe obesity in adolescents; a mixed method approach

REECE, Lindsey <<http://orcid.org/0000-0003-2883-3963>>

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**TREATMENT OF SEVERE OBESITY IN ADOLESCENTS;
A MIXED METHOD APPROACH**

Lindsey Jane Reece

**A thesis submitted in partial fulfilment of the requirements of
Sheffield Hallam University
for the degree of Doctor of Philosophy**

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ABSTRACT

Adolescent obesity is a public health problem associated with significant immediate and long-term health complications (Kelly et al. 2013). Amongst obese adolescents, a third are severely obese (BMI >99.6th centile UK90 reference charts) (Ogden et al. 2012) with severe obesity the fastest growing classification in this age group (Wang et al. 2011). The evidence for managing and treating child and adolescent obesity generally is poor, with multidisciplinary lifestyle programmes failing to derive significant and sustained weight loss and often reporting high attrition (Luttikhuis et al. 2009). Furthermore, this evidence has predominantly focused on young people as a whole with little differentiation of treatment and outcomes by age and severity of obesity. As a result, successful treatments for severely obese adolescents are lacking with permanent bariatric surgery increasingly considered. This thesis aimed to enhance the understanding of the needs of obese adolescents, contribute to what is known about current treatment options for severely obese adolescents specifically and pilot a novel treatment approach within this population.

A qualitative enquiry (Study 1) of the lived experiences of obese adolescents (n = 12) reinforced the complexity of the impact of obesity on the lives of obese adolescents across social, emotional, behavioural and cultural contexts. All participants experienced low self-esteem and feelings of shame and there were frequent accounts of debilitating bullying. Adolescents required intensive support to develop skills for coping and managing emotional choices, and the importance of family-support within treatment was highlighted. Data confirmed weight loss programmes need to consider the complex experience of obese adolescents in their design, focusing on how to implement long-term lifestyle changes into their 'real' lives.

Informed by the findings from Study 1 and a comprehensive review of existing treatment options for severely obese adolescents, the use of an intra-gastric balloon alongside a lifestyle support programme (BOB; Study 2) to promote weight loss was piloted in 12 severely obese adolescents (5 males, 7 females; mean age 15 yrs; BMI >3.5 SD; puberty stage 4 or above). Mean weight loss at 12 months (n=9) was 3.05 kg \pm 14.69; $d=0.002$ with improvements in psychosocial health, physical activity and cardiorespiratory fitness also maintained at 12 months. Although, the use of an intra-gastric balloon as an adjunct to a lifestyle programme was well tolerated by participants, large variations in outcome data suggest alternative treatment solutions in this population are warranted. That said, the comprehensive reporting of the intervention and the focus on validated behaviour change techniques to support change is a strength of this study.

The qualitative experiences of treatment for participants and their family members were captured throughout treatment (Study 3). All participants acknowledged the experience was harder than anticipated, but recognised the importance of creating shared ownership over making lifestyle changes. Single case data pointed to successful and sustained weight loss where the whole family were actively engaged in treatment, modelling positive lifestyle changes alongside the adolescent. Future studies are encouraged to explore the most effective methods for engaging family members in treatment.

CANDIDATE'S STATEMENT

I declare that the work in this thesis was carried out in accordance with the regulations of the Sheffield Hallam University and is original except where indicated by specific reference in the text. No part of the thesis has been submitted as part of any other academic award. The thesis has not been presented to any other education institution in the United Kingdom or overseas. Any views expressed in the thesis are those of the author and in no way represent those of the University.

Lindsey Jane Reece

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Publications

Reece, L.J., Wright, N.P., Sachdev, P., Thomson, M., Wales, J.K., Copeland, R.J. (2016) Intra-gastric balloon as an adjunct to lifestyle support in severely obese adolescents. *International Journal of Obesity (Under Review)*

Reece, L. J., Bissell, P. and Copeland, R. J. (2015), 'I just don't want to get bullied anymore, then I can lead a normal life'; Insights into life as an obese adolescent and their views on obesity treatment. *Health Expectations*. doi: 10.1111/hex.12385

Reece, L., Copeland, R.J., Sachdev, P., Thomson M., Wales, J.K and Wright, N. (2014). Protocol for: The use of intra-gastric balloons as an adjunct to a lifestyle support programme to promote weight loss in severely obese adolescents. *Journal of Child and Adolescent Behaviour*. 2:5.

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Sachdev P, **Reece L.J.**, Copeland R, Wales, J, Wright N.A feasibility study of intra-gastric balloons (supported by a lifestyle programme) for the treatment of severe adolescent obesity-the Balloons in Obesity(BOB) study. *Endocrine Abstracts* (2013) vol 33.DOI: 10.1530/endoabs.33.OC3.6

Conference and Research Presentations

Reece, L.J., Copeland, R.J., Sachdev, P., Thomson, M., Wales, J., and Wright, N.P. (2014) Promoting weight loss in severely obese adolescents: a novel approach [Oral presentation] 24th European childhood obesity group, Salzburg, 2014

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Reece, L.J., Sachdev, P., Copeland, R.J., Thomson, M., Wales, J., and Wright, N.P. (2014). Pilot study: Use of intra-Gastric balloons and a lifestyle support programme to promote weight loss in severely obese adolescents: The BOB study. [poster presentation] 12th International congress on obesity, Kuala Lumpur, Malaysia.

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Reece, L.J., Copeland, R.J., Wright, N.P., Wales, J. (2011) Protocol for: An efficacy trial of intra-gastric balloons for the treatment of severe obesity in adolescents. [Poster presentation]Faculty of Health and Wellbeing research day, Sheffield Hallam University

Thomson, M, Sachdev, P., **Reece, L.J.**, Copeland, R.J., Natarajan, A., Wales, J., Wright, N.P. (2014) Endoscopic placement of Intra-Gastric bariatric balloons is safe and effective for short term weight reduction in obese adolescents. [Oral/poster presentation]47th Annual meeting of the European society for Paediatric gastroenterology, Hepatology and Nutrition, Jerusalem, Israel

ABBREVIATIONS

BMI	Body mass index
BMI SDS	Body mass index standard deviation score
BMI Z SCORE	Body mass index standard deviation score
BOB	Balloon in obesity study participant
CI	Confidence interval
CY-SPP	Child and youth self-perception profile
DXA	Dual X-ray absorptromy
EBWL	Excess body weight lost
GLP-1	Glucagon-like peptide-1
HDL	High density lipoprotein cholesterol
HOMA	Homeostasis model assessment
HRpQCT	High-resolution peripheral quantitative computed tomography
HRQOL	Health related quality of life
IGB	Intra-gastric balloon
IMD	Indices of multiple deprivation
LDL	Low density lipoprotein cholesterol
MI	Motivational interviewing
Mother or Father BOB	Parent of a BOB participant
MVPA	Moderate to vigorous physical activity
NCMP	National child measurement programme
NICE	National institute for health and care excellence
PAQ-A	Physical activity questionnaire for adolescents
PCERT	Pictorial children's exercise rating table
PedsQL	Paediatric quality of life
RPE	Rating of perceived exertion
SD	Standard deviation
TPB	Theory of planned behaviour
UK90	1990 growth reference charts (Cole, 1997)

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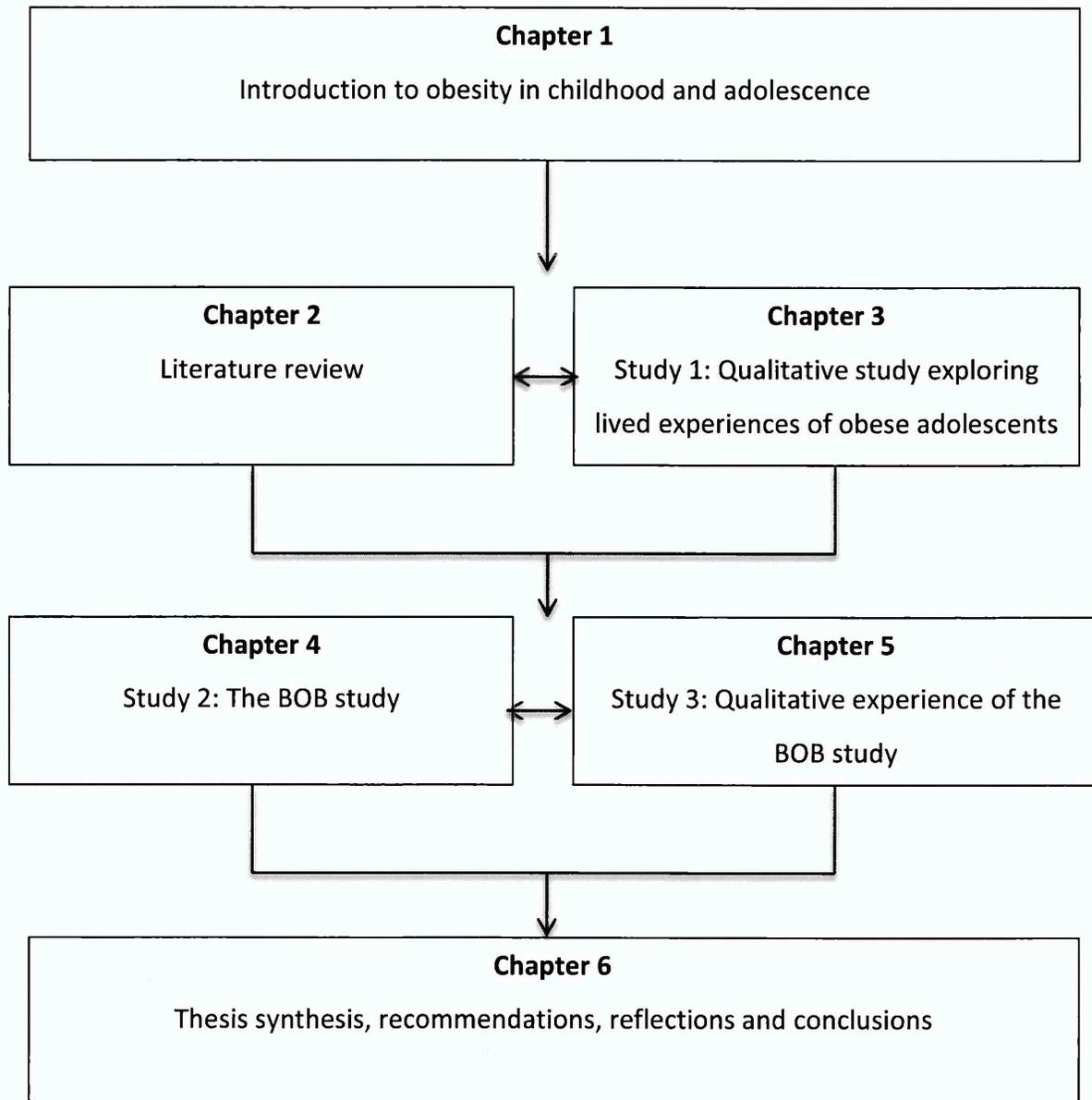
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STRUCTURAL DIAGRAM OF THESIS



The studies presented in this thesis are not linear in nature nor are they to be interpreted as discrete phases. The process was dynamic, with some studies conducted in parallel. The synthesis in Chapter 6 is therefore a product of the learning gained throughout the thesis.

Chapter One

The introductory Chapter presents the prevalence of obesity in children and adolescents, highlighting severe obesity within the adolescent age group as an important and discrete category. The short and long-term impact of the disease on health and psychosocial outcomes are considered along with an overview of the current treatment options available. Collectively, this provides rationale for the identification of adolescents as a distinct population group and the need to focus on tailoring treatment options for severely obese adolescents.

Chapter Two

This Chapter presents a thorough review of the current qualitative and quantitative evidence and critically appraises current treatment approaches for severely obese adolescents and their families via a scoping review method.

Chapter Three

The Chapter details a qualitative study (Study 1) exploring the lived experience from the obese adolescents perspective and their engagement with obesity treatments.

Chapter Four

This Chapter details the rationale, design, implementation, and outcomes of a pilot treatment programme that uses an intra-gastric balloon as an adjunct to a multidisciplinary lifestyle support programme (BOB) tailored for severely obese adolescents and their families (Study 2). Particular attention is given to the theoretical underpinning and the use of behavioural change techniques in the design and delivery of the multidisciplinary lifestyle programme within BOB.

Chapter Five

Chapter five presents the findings from a qualitative study that explored participant experiences and acceptability of the BOB programme (Study 3). Interviews and in-depth case studies are used in an attempt to understand the variability in programme outcomes across participants.

Chapter Six

The final Chapter of this thesis collectively assesses findings from all studies herein and presents the key points of learning. Recommendations to inform future research and practice in the treatment of severely obese adolescents and their families are presented.

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CHAPTER 1: OBESITY IN CHILDHOOD AND ADOLESCENCE

1.0 Introduction

The following Chapter presents data on the prevalence of obesity in childhood and adolescence and highlights severe obesity as an important and distinct category. The impact on health and wellbeing of severe obesity is considered along with potential causes. The Chapter then makes the important case to consider adolescents as a discrete population in terms of treatment and in doing so briefly outlines current treatment options for this group. Finally, the Chapter sets out the aims and objectives of the thesis.

1.1 Prevalence of obesity

Over the past three decades overweight and obesity prevalence in children and adolescents has risen substantially (Lobstein et al., 2015). In developed countries prevalence is estimated at 23.8% for boys and 22.6% for girls, with developing countries estimated at 12.9% for boys and 13.4% girls (Ells, 2015). In the United Kingdom (UK) the prevalence of obesity in children has increased since 1995, when 11% of boys and 12% of girls aged 2-15 were obese (Health Survey for England, 2015), with rates now at 18% and 19% for boys and girls respectively (Health Survey for England, 2015). Some countries have reported a plateau within their obesity rates (Wang et al. 2011), for example prevalence of child and adolescent obesity was reported at 16.9% in the United States in 2007/2008 which remained unchanged in 2009/2010 (Ogden et al., 2012). In the UK, data collected from the National Child Measurement Programme (NCMP) infers a broad stabilisation of obesity at reception age (Public Health England, 2015) but perhaps most worrying is the international data that reports severe obesity¹ as the fastest growing sub category of obesity in childhood and adolescence worldwide (Ogden et al., 2010).

¹ In this thesis categorised as obesity > 99.6th centile

1.2 Prevalence of severe obesity

The United States (US) National Health and Nutrition Examination Survey 1999– 2012 identified an upward trend in the rates of severe obesity (equivalent to a BMI > 99th centile) with the latest data (2011–2012) showing a prevalence of 5.9% in children aged 2–19 years (Flegal et al., 2012). This study also demonstrated that severe obesity prevalence was highest among adolescents, and those from Hispanic and non-Hispanic black populations. In England, 1.9% of girls and 2.3% of boys aged 4 –5 yrs and 2.9% of girls and 3.9% of boy's aged 10–11 yrs are classified as severely obese (falling on or above the 99.6th centile of the UK90 growth charts) in 2012/2013 (Ells, 2015). This equates to a total of 12,316 of 4 yrs to 5 yrs and 16, 775 of 10 yrs to 11 yrs children with severe obesity (Ells, 2015). Black ethnic groups had a higher prevalence than white, mixed, Asian, Chinese and other groups, with Black Caribbean children aged 10-11 yrs showing some of the highest rates of obesity (Ells, 2015). Prevalence of severe obesity also varies significantly geographically across the UK with severe obesity highest in children living in the most deprived areas (Ells, 2015). This study by Ells (2015) is the first detailed analysis of severe obesity prevalence amongst children in UK schools and raises awareness of not just the increasing prevalence of severe obesity amongst adolescents, but of the need to intervene with effective treatments.

A point of clarification here is that there is currently no universal definition of severe obesity, rather several across the international research community. All available definitions for severe obesity are presented in table 1.0. In the UK, the British 1990 (UK 90) growth charts are frequently used with the highest category being > 99.6th centile (Cole, 1997). With this in mind, obesity > 99.6th centile will be categorised as severe obesity throughout this thesis.

Table 1.0 – Severe obesity classifications for children and adolescents

Source	Severe obesity classification
British 1990 (UK90) (Cole 1997; NICE 2013)	Weight status defined according to age and sex, severe obesity >99.6 th centile or 3.5 SDS
International Obesity Taskforce (IOTF) (Cole and Lobstein., 2012)	Morbid Obesity in children corresponds to an adult BMI value of 35 kg/m ²
USA Centre for Disease control and Prevention expert committee (Barlow et al., 2007)	Severe obesity equivalent to a BMI >99 th centile
USA Centre for Disease control and Prevention expert committee (Flegal et al., 2009)	Severe obesity equivalent to a BMI >120% of the 95% centile.

1.3 Impact of severe obesity on health and wellbeing of children and adolescents

The consequences of overweight and obesity on the health and wellbeing of children and adolescents has been well documented (Reilly et al., 2003). Specifically here, severe obesity has been shown to have marked immediate and long-term consequences (Kelly et al., 2013). When compared with overweight and obese children and adolescents, those with severe obesity have a worse cardio-metabolic risk factor profile, have early signs of vascular dysfunction as well as a stronger tracking of obesity from childhood to adulthood (Freedman et al., 2007). Longer-term, this correlates with an increased risk of type II diabetes (Kelly et al., 2013), cardiovascular disease (Franks et al. 2010) and premature death (Parks et al., 2012). Additional problems include; hyperinsulinemia, poor glucose tolerance, sleep apnoea (Lobstein Baur and Uauy., 2004) polycystic ovarian syndrome, respiratory, orthopaedic, and hepatic abnormalities (Reilly et al., 2003). Associations in adolescence with asthma (Noal et al., 2011) have been observed with mixed outcomes reported for its relation to stroke (Park et al., 2012). Adolescence is also a transitional life stage associated, not only with a

heightened risk of obesity, but also mental health and wellbeing problems (Flegal et al. 2012; Merikangas 2010). There is mixed evidence related to the prevalence of severe obesity and psychosocial problems in young people (Kelly et al., 2013) although overall health related quality of life in severely obese adolescents has been shown to be lower than scores in healthy weight children (Schwimmer et al., 2003; Zeller et al., 2015). It is, however, unclear whether severe obesity precedes these issues or whether psychosocial issues are a direct cause of being severely obese (Kelly et al., 2013). What is known from obese children and adolescents is that they are at a greater risk of developing psychiatric conditions such as mood issues (Pesa Syre and Jones., 2000) hopelessness and suicide attempts (Falkner et al., 2001). High BMI (i.e. above the 99th centile) is associated with lower body image and self-esteem in young people (Cornette., 2008), with many exhibiting social difficulties often due to enduring episodes of being bullied and teased about their weight. Obese children are also usually socially isolated and find it difficult to form relationships (Wills et al., 2006). Differentiating the impact of obesity from severe obesity requires further research, yet what remains clear is that severe obesity is associated with a number of serious immediate and long-term health problems (Ells, 2015).

1.4 Causes of childhood and adolescent obesity

The causes of obesity are complex and multifaceted (Foresight., 2007) including social, cultural, environment, biological and psychological influences (Rutter, 2012).As the causes for obesity and severe obesity cannot be differentiated, the causes of obesity generally will be considered here. Whilst the specific factors that explain the rapid increase in the prevalence of global obesity are unknown, the genetic explanation can be largely excluded, due to the relative stability of the population gene pool (Wang et al., 2011). At the heart of the complex problem, is the simplistic balancing equation with energy consumed in relation to energy expended, thus any factor that increases energy intake or decreases energy expenditure will lead to obesity in the longer-term (Ebbeling et al., 2002). The 'whole systems' map produced for the UK government Foresight report (2007) demonstrates this complex picture in a comprehensive manner, allowing the identification of key determinants of obesity and the relationships between them. Determinants are grouped into seven sub themes

namely; 1) Physiology (biological and genetic variables); 2) Individual activity (individual or group level of recreational, occupational or transport physical activity); 3) Physical activity environment (factors that facilitate or obstruct physical activity such as cost); 4) Food consumption (characteristics of the food market such as level of food abundance and variety); 5) Food production (drivers of the food industry such as market price of food); 6) Individual psychology (a number of psychological variables such as self-esteem and stress) and 7) Social psychology (variables that influence at a societal level such as education, media availability and consumption).

Specifically looking at correlates of obesity in young people, the presence of sugar-sweetened beverages, eating away from the home, increased portion sizes and sedentary behaviour are all associated with youth obesity (Davis et al., 2007). The role of the home and family environment are influential in the adoption and maintenance of health behaviours through role-modelling, provision of healthy foods, providing support for engaging in healthy behaviours, and creating a supportive climate for health behaviour change (Benton 2004; Ward-Begnoche and Speaker, 2006). Studies have however been conducted in clinical settings (Luttikhuis et al., 2009) warranting further research on successful strategies and programmes that not only engage families within treatment, but consider the social and environmental influences to tackle adolescent obesity (Upton et al., 2014).

1.5 Adolescents as a distinct population

Adolescents, defined as young people aged 10 – 19 yrs old (World Health Organisation, 2000), make up 12% of the population in the UK and have experienced the least improvement in health status across the lifespan in the last 50 years. Adolescence is arguably the most significant period in the life course for the initiation of a wide range of health behaviours including physical activity and healthy lifestyle habits, hence being frequently described as a critical life stage (Steinbeck, 2012). Adolescence is however associated with characteristics of turbulence and stress, and can be characterised as a time of major psycho-developmental and behavioural change. In early adolescence, body image alters rapidly as a result of pubertal growth and development. During mid-adolescence there are typically powerful drives for independence and peer association (Wills et al., 2006). Whilst later in adolescence,

individuals strive for greater stability and a better ability to self-regulate their own behavioural patterns seeking autonomy (Steinbeck, 2009). That said, research in adolescents, particularly in health improvement, is limited despite the potential to positively influence short and long-term health (Steinbeck, 2009). Adolescence is a transitional life stage associated with a heightened risk of obesity and mental health and wellbeing problems (Flegal et al., 2012; Merikangas, 2010). This early onset of disease not only has an immediate impact on health but also increases the number of years spent with impaired health as adolescents develop into adults. Lifestyle habits such as diet and physical activity behaviours, if not addressed during adolescence, can become entrenched into adult behaviour patterns potentially affecting subsequent generations (Steinbeck, 2009). There is also potential for any gains to be made in chronic disease management during earlier childhood to be lost as a result of behavioural choices made during adolescence with the impact being negative long-term health and wellbeing (Kelly and Reilly., 2013). Collectively these present a challenge for researchers and practitioners yet it does signify an opportunity to appreciate adolescents as a discrete population group. Research during adolescence could enhance knowledge on adolescent health and what drives their motives to influence health status whilst also informing the design of treatment services. The opportunities to undertake quality research in adolescents are likely to be enhanced by the use of novel approaches that acknowledge the unique features of adolescents and their perspectives on the world (Steinbeck, 2009). This will be explored in further detail in Chapter 2 of this thesis.

1.6 Introduction to obesity treatment

A comprehensive review of treatment in severely obese adolescents is presented in Chapter 2, briefly here; multicomponent programmes that incorporate dietary advice and physical activity, along with behavioural change skills that support an individual to successfully implement and maintain lifestyle changes, are recommended as the most appropriate option for treatment of all categories of obesity in children and young people aged < 18 years old (Luttikhuis et al., 2009; NICE 2006; 2014; 2015). To date, very few studies of lifestyle modification have focused on severely obese adolescents (Kelly et al., 2013), with those that have, demonstrating limited effectiveness in promoting weight loss, especially in the longer-term (Baur et al., 2011). In addition, the

small number of studies in this area and the lack of consistency regarding the detail of programme design make it challenging to accurately define the implementation of behavioural change programmes as well as assess the impact of behavioural lifestyle interventions in the severe obese population.

The use of obesity medication, Orlistat is recommended only in severely obese young people aged 12 yrs or over (NICE, 2014). Its use has demonstrated modest weight loss efficacy in the short term (Chanoine et al., 2005) with many unable to maintain weight loss over a longer time period (Braet and Van Winkel, 2000). The adherence to a low fat diet and the management of distressing gastrointestinal side effects have also limited the acceptability amongst adolescents (Baur, Hazeldon and Shrewsbury, 2011), drawing into question the efficacy of its use in this population (Luttikhuis et al., 2009).

In light of the lack of effective lifestyle and pharmacological treatment strategies in severely obese adolescents, the use of bariatric surgery is frequently being considered (Black et al., 2013). Bariatric surgery has been used successfully in severely obese adults resulting in positive long-term weight outcomes and improvement in co-morbidities (Sachdev et al., 2014). There is however a marked reluctance to refer young people for surgery with concerns over safety, long-term implications and taking consent from minors (Sachdev et al., 2014). To summarise, effective treatment strategies for severely obese adolescents remain far from clear (Hearnshaw and Matya, 2010) reinforcing the need for targeted research with severely obese adolescents.

1.7 Purpose of this thesis

Despite the marked increase in prevalence and the serious immediate and long-term health complications associated with severe adolescent obesity, little is known about how best to intervene in this population. There is a limited evidence base in terms of treatment and few treatment programmes focus on adolescents as a discrete group. All of which mean drawing conclusions about the effectiveness of specific treatments is extremely challenging.

The primary aim of the thesis is therefore to enhance understanding of the needs of obese adolescents, contribute to what is known about current treatment options for

severely obese adolescents specifically, and pilot a novel treatment approach within a severely obese adolescent population.

To achieve this, there are several research objectives to be met; 1) Better understand the unique characteristics and needs of adolescents as a distinct population and explore how this knowledge can be used to inform the design of treatment programmes; 2) Determine the current effective treatments that specifically focus on severe obesity amongst adolescents and establish how current evidence can be used to inform novel and effective treatments going forwards; 3) Enhance the quality and reporting of the detail of programmes that intend to treat obesity in adolescents; 4) Pilot the use of an intra-gastric balloon alongside a multidisciplinary lifestyle support programme to promote weight loss and behaviour change in severely obese adolescents; 5) Explore the adolescent experience of engaging in treatment to inform future work.

CHAPTER 2: LITERATURE REVIEW

2.0 Introduction

This thesis aims to improve understanding of the needs of severely obese adolescents and consider the most effective treatments to support weight loss and behaviour change. The introduction (Chapter 1) identified two clear gaps in the literature that will be reviewed here. The first, the need to focus on adolescents as a distinct population and to understand the nuances of that population to inform the design of future obesity treatment. The second, to understand the effective treatment strategies, which are tailored to severely obese adolescents and critique the current evidence base for treatment in more detail.

In line with the research objectives identified for this thesis (Chapter 1), Part A of this literature review will focus on the unique characteristics and needs of the severely obese adolescent population with Part B critiquing the effectiveness of current treatment for severely obese adolescents using a scoping review method.

2.1 Part A: Need to focus on adolescents

Adolescence² has been termed a '*critical period*' for the initiation and maintenance of health behaviours, including smoking, alcohol (Steinbeck, 2005) and obesity. Despite this, adolescent medicine remains a relatively young area of research compared to paediatric and adult healthcare (Steinbeck et al. 2009). Reports including 'The Lancet' series on adolescent health (Kleinhert, 2007), United Nations children's fund (UNICEF) Progress for Children: a Report Card on Adolescents (UNICEF, 2012) and WHO Health for the World's Adolescents report (Dick and Ferguson., 2015) highlight the importance of adolescence as a critical period in development where investment and intervention are needed. Five of the top 10 risk factors including smoking and physical activity, which contribute to the total burden of disease in adults, are initiated and shaped in adolescence. In addition, the early onset of diseases like obesity at this time, reinforce the need to focus on improving lifestyle behaviours early to prevent unhealthy habits tracking into adulthood negatively influencing health (Steinbeck et al. 2009). Although adolescence is a complex period of life associated with dramatic

² Life stage between 10 – 19 years (WHO, 2000)

physical and cognitive change, it presents an opportunity to intervene as the capacity to learn increases, enabling the initiation of new habits (Steinbeck et al. 2009).

2.2 Adolescent awareness and recognition of obesity

Adolescent perceptions of obesity and fatness are complex and, at times, contradictory (Wills et al., 2006). On the one hand, adolescents appear aware of their obesity blaming factors such as genetics, culture and socioeconomic status as potential causes (Puhl et al. 2003), whilst on the other hand evidence suggests they do not consider current or future consequences of their weight status on their health (Smith et al., 2012). In contrast, adolescents have described obesity as synonymous with ill health along with high incidences of being bullied (Lachal et al., 2012). Lachal et al., (2012) considered the perspectives of young people, parents and professionals focusing on representations of obesity and personal experiences of treatment. Adolescents and parents were found to often define obesity and make judgements on the extent of the issue, based upon appearance and clothes size, in contrast to health professionals who used BMI (Lachal et al., 2013). Normalisation of obesity was reinforced in adolescents whose parents and peers were overweight themselves, with obese parents frequently underestimating their child's size (Smith et al., 2012). This resulted in the young person finding it difficult to recognise the true extent of their obesity (Lachal et al., 2013).

Psychological distress has been strongly correlated with concerns about weight, appearance and shape, irrespective of BMI (Smith et al., 2014). In contrast, other evidence suggests that even '*normal*' weight adolescents who disliked their bodies were anxious, inferring that body dissatisfaction might not be obesity specific, and could in fact be a characteristic of adolescence. Studies demonstrate that stereotyping is common (Rees et al., 2014) with obese adolescents feeling stigmatised, and associated with undesirable behaviours such as laziness, greediness and gluttony (Puhl and Heuer., 2009). Research with obese adults frequently elicits feelings of hurt and sadness, with evidence of long-term emotional consequences including mental health issues (Thomas et al., 2008). Of importance here though, is that often obesity began in childhood for these obese adults. This reinforces the need to intervene pre-adulthood

in an attempt to prevent negative consequences in later life with further research needed to explore the lived experiences of obese adolescents (Holland et al., 2012).

2.3 Social consequences of living as an obese adolescent

Peer acceptance is crucial during adolescence (Wills et al., 2006) with peer relationships valued highly (Fox and Farrow., 2009). Frequently, adolescents report feeling stressed in response to peer reactions and appearance (Fox and Farrow., 2009) with the ability to wear socially acceptable clothing a key consideration of the impact of their obesity. A high incidence of emotional eating is prevalent amongst adolescents (Holland et al., 2012), with young people predominantly using food to manage difficult emotional experiences. Food is often a source of comfort and coping strategy for living with their obesity (Holland et al., 2012). Difficult emotional experiences frequently allude to challenges with social interactions at school and problems forming peer relationships (Lachal et al., 2012). Being overweight or obese is a risk factor for experiencing bullying and peer victimization (Fox et al., 2009) with the detrimental effects of this on adolescent wellbeing well recognised (Moore et al., 2014; Thomas et al., 2014). Low self-esteem specifically related to physical appearance (Faulkener et al. 2001) and higher levels of body dissatisfaction (Wardle and Cooke., 2005) have been shown in obese adolescents. Collectively, these traits appear to reinforce a vicious cycle of health behaviours that do not support optimal health and wellbeing for the individual.

2.4 Weight loss attempts during adolescence

Frequent issues discussed by adolescents in relation to weight loss involve dealing with peer pressure and avoiding emotional eating (Wills et al., 2006). Little data is available on the role of emotional eating on weight loss although adolescents acknowledge that finding a healthier outlet for managing their negative emotions would be a beneficial strategy (Wardle and Cooke., 2005). Adolescents describe successful weight loss attempts positively with feelings of excitement and pride reported (Rees et al., 2014). Attributes, namely control willpower and self-confidence, are all associated with successful weight loss (Fox et al., 2009). The challenge to change was also recognised with feelings of frustration felt if weight loss was not achieved (Wills et al., 2006). Increased physical activity was seen as a more effective way to lose weight, with adolescent boys more likely to participate in structured physical activity than girls

(Wills et al., 2006). Gender differences have also been observed in relation to weight loss goals; with boys more focused on sporting achievements whilst girls focused mainly on physical appearance (Lachal et al., 2013). Combining this with earlier findings by Smith et al., (2012) infers that as obese adolescents are driven by short-term goals, which are predominantly weight loss orientated, it could have significant implications for the outcomes of multidisciplinary treatment that focus on longer-term behaviour change.

2.5 Parental and familial role within obesity treatment

Becoming aware of their child's obesity appears to be a complex process for parents with frequent underestimations of weight status (Smith et al., 2014). One of the strongest predictors of child's weight though is the weight status of parents (Whitaker et al., 1997; Kelly et al., 2013). Given the significant role that parents play in establishing patterns of behaviour, including eating patterns and physical activity, recent studies and professional guidelines (NICE, 2013; Janicke et al., 2014) increasingly stress the importance of parental involvement throughout the treatment process. Treatment programmes therefore encourage one or both parents to attend and are strongly urged to follow the same healthy lifestyle recommendations along with their child, irrespective of their weight status. Parents are frequently identified as the main agents of change (Spear et al., 2007), with adolescents themselves even identifying their role especially in relation to attending and accessing obesity treatment (Murtagh, 2006). Contrastingly, parents perceive their role in supporting their son or daughter to make lifestyle changes as challenging - frequently bearing the brunt of their child's resistance (Banks et al., 2014). A third of overweight and a half of obese adolescents were teased about their weight by their families (Van der berg et al., 2008). Subsequently, this increased the risk of low body satisfaction, low self-esteem, depression and suicidal thoughts (Eisenberg et al., 2003).

2.6 Barriers to attending and adhering to obesity treatment

Accessible treatments for obese adolescents and their families are lacking (Skelton and Beech, 2011). For those who do actively seek treatment, the majority do not complete (Smith et al., 2014). Attrition rates are highest amongst severely obese children and families, individuals with multiple co-morbidities and behavioural issues (Skelton and Beech., 2010). Vulnerable families, those from racial and minority backgrounds, poor

and single parent households also appear to be at risk of dropping out. Whilst there is a need for efficacious treatment for obese adolescents, the high attrition associated with treatment programmes requires consideration (Skelton and Beech., 2010). An understanding of the enablers and barriers to accessing and attending obesity treatment would help to improve the success of weight management interventions with qualitative research offering an improved understanding of the evidence base to inform practitioners and policy makers (Smith et al., 2014). A brief overview of the literature addressing these factors will now be considered.

The stigma associated with being obese is a major barrier for obese adolescents preventing their attendance at treatment programmes (Smith et al., 2014). This is in line with previous work that highlights obese adolescents are at an increased risk of social isolation and mental health issues (Strauss, 2000). The fear of humiliation or experience of being bullied has been found overwhelming for some obese adolescents influencing their ability to seek help. Adolescents were more likely to complete and adhere to a treatment programme if the location was convenient and travel was minimal (Smith et al., 2014). The relationship between the obese participants and the delivery staff of the treatment programme influenced attendance with the need for appropriately trained, passionate and enthusiastic staff recruited as programme leaders (Straker et al., 2010). A significant barrier to adhering to obesity treatment was the availability of local, accessible and affordable opportunities to be active in the community. If the environments with which the adolescent lives do not facilitate positive behaviour change, then even motivated adolescents, find it challenging lose weight (Smith et al., 2014).

Common barriers for parents associated with attendance at community weight management interventions predominantly focuses on a lack of time and attention (Brennan et al., 2012). Parents frequently report feeling concerned for the health and wellbeing of their obese child (Boutelle et al., 2012) yet often felt hopeless and useless when needing to practically work and support their child in weight management (Boutelle et al., 2012). Parents convey that they feel isolated and abnormal in society, describing their role as simply, bringing their child along to the intervention and offering emotional support (Staniford et al., 2011). Parents found it difficult to know

where to access support which, coupled with knowledge that health professionals are reluctant to raise the obesity topic (Smith et al., 2014), influences attendance and adherence at weight management programmes (Smith et al., 2014).

2.7 Stakeholder perspectives towards obesity treatment

Rarely have qualitative studies evaluated the delivery of adolescent obesity treatment strategies from a broad stakeholder perspective, namely obese individuals themselves, parents, carers and healthcare professionals (Hesketh et al., 2005). As a result the views and experiences of these individuals fail to inform the design and delivery of interventions (Staniford et al., 2011). That said, Staniford et al., (2011) considered the key stakeholder perspectives for childhood obesity interventions broadly (albeit some obese adolescents were included) and found an incongruence between treatment deliverers (health professionals) who felt treatment should create autonomous individuals, and treatment recipients (children and parents) who reported a need for further support in maintaining health promoting and weight regulating behaviours post treatment (Pryor and O'Connell., 2008; Staniford et al., 2011). All stakeholders agreed that delivery programmes should incorporate behavioural modification strategies to encourage physical activity and nutritional related behavioural change (Barlow et al., 2007). Consistent with findings observed in the qualitative adolescent obesity literature discussed above (Skelton and Beech., 2011; Banks et al., 2014), the importance of social support was highlighted as a major theme in relation to initiating and maintaining a healthy lifestyle. Health professionals suggested interventions should aim to create autonomous individuals who exit treatment and independently sustain behaviour change. Parents and children reported being positive about improvements in psychosocial functioning, whilst health professionals were committed to report significant weight loss (Staniford et al., 2011). Health professionals also emphasised the role of whole family support (Staniford et al., 2011) whilst acknowledging that parents played a primary responsibility in initiating and supporting change (Staniford et al., 2011). Crucially when relating back to obese adolescents, health professionals within Staniford et al., (2011) work highlighted the need for interventions to be tailored to the needs of the individuals considering age and classification of obesity – reiterating the need to consider adolescents as a discrete population.

Few studies have explored the perspectives of key stakeholders towards adolescent obesity and their treatment, although those that have, largely focus on the challenging decision regarding appropriateness of bariatric surgery (Woolford et al., 2010; Penna et al., 2013). Woolford's study surveyed primary care paediatricians and GP's, 46% of whom felt that the minimum age at which professionals would make a referral for bariatric surgery was 18 years old with an overwhelming sense of reluctance to refer. Healthcare professionals perceived parental involvement as key to any treatment for obese adolescents. Whilst acknowledging that bariatric surgery was an acceptable treatment modality, there was a strong consensus that it should only be seen as a last resort (Penna et al., 2013). Professionals perceived that all obese adolescents should have adhered to a lifestyle weight management intervention for at least 12 months prior to considering bariatric surgery (Woolford et al., 2010). This presents additional challenges considering there is a lack of accessible and effective obesity support for adolescents (Luttikhuis et al., 2009).

2.8 Summary

Being obese during adolescence is associated with significant health and social problems (Baur et al., 2011; Lobstein et al., 2015) yet there is limited evidence addressing the needs of obese adolescents as a discrete population group. Previous research identifies that treatment programmes for overweight and obese children are associated with high attrition and high dropout rates (Luttikhuis et al., 2009), with limited research on how to overcome barriers to engage in obesity lifestyle treatment (Smith et al., 2014). Reasons for drop out have been attributed to personal characteristics including a fear of humiliation or an experience of bullying, whilst other practical reasons such as location and timing of the programmes have been highlighted as important. The parental role in supporting children to initiate and maintain lifestyle change appears complex, with discrepancies around their role and optimal level of engagement within treatment to promote positive change (Brennan et al. 2010; Boutelle et al., 2012). Whilst acknowledging some of these studies have included adolescents within their work (Staniford et al., 2011; Lachal et al., 2013; Smith et al. 2014), further research is needed to understand the specific needs of obese adolescents and their families as a distinct population of their own. In addition, obese

adolescents experiences of engaging with obesity treatment are needed to inform the design and implementation of effective and tailored treatment programmes.

This gap in the literature provides the rationale for the first qualitative study (Study 1), which seeks to explore the lived experience of obese adolescents and their engagement with obesity treatments. This study is described in detail in Chapter 3.

Part B of this literature review will now assess the effectiveness of current obesity treatments with severely obese adolescents.

2.9 Part B: Critique of current treatment for severely obese adolescents

Evidence for the treatment of obese adolescents is more limited than for younger children and for adults (Baur et al., 2011). Published over a decade ago, Jelalian and Saelens (1999) conducted a review that concluded behavioural lifestyle interventions for adolescents were '*promising*' owing to the limited number of outcome studies at this time.

Previous evidence reviews (Summerbell et al., 2003; Luttikhuis et al., 2009; Staniford et al., 2010) offer consensus that multifaceted lifestyle interventions focusing on dietary change, physical activity, with the inclusion of a behavioural change component are the appropriate, available options for treatment of overweight and obesity in children and young people aged <18 years old. Multifaceted interventions should be delivered by a multidisciplinary team who have received expert training and who tailor the intervention to the degree of obesity and age of the child (Barlow 2007; Luttikhuis et al., 2009; Staniford et al., 2010). In the 2009 Cochrane review (Luttikhuis et al., 2009) two studies focused on dietary interventions in adolescents were included (Ebbeling 2003; Rolland-Cachera 2004) and three that focused on physical activity and lifestyle (Carrel, 2005; Daley, 2006; Gutin, 2002) - all of which concluded that lifestyle programmes can reduce the level of overweight and obesity, producing statistically significant and clinically meaningful results at 6-12 months after commencing the treatment.

To date, several reviews (Young et al., 2007; Luttikhuis et al., 2009; Whitlock et al. 2010; Janicke et al., 2014) have examined the efficacy of lifestyle interventions on achieving weight loss and behavioural change that included a family behavioural component. Young et al., (2007) identified 31 studies with children aged 5-12 yrs old and concluded behavioural lifestyle interventions that involved parents/family produced larger effects than usual care. Whilst Luttikhuis et al., (2009) selected eight behavioural family lifestyle interventions that qualified for separate analyses examining outcomes in the short and long term. The meta analysis of studies in the Cochrane review (Luttikhuis et al., 2009) in children under 12 yrs led to a significantly greater reduction in BMI Z-score at 6 months (-0.06; 95% CI -0.12 to 0.01) than

standard care albeit the effect small (Luttikhuis et al., 2009). Accounting for limitations, the authors concluded that the interventions produced significant and clinically meaningful changes in weight status for children. Neither the amount of time spent by parents engaged in an intervention nor the specific targeting of parental behaviours correlated with weight related outcomes (Janicke et al., 2014). This is in line with previous evidence that found limited support for the notion that greater parental involvement led to improved weight outcomes for the child (Faith et al., 2012). The impact on lifestyle behaviours such as dietary intake and physical activity along with detail on other moderators of treatment effects would be useful (Janicke et al., 2014). Considering the significant lack of data involving the obese adolescent population, the extent to which parents and family promote the positive achievement of behavioural change and weight loss in obese adolescents is somewhat limited (Luttikhuis et al., 2009). Many studies included in these reviews do not explicitly define the role families played within a given intervention nor do they identify the specific behavioural components included (Janicke et al., 2014), making recommendations for the delivery of obesity treatment challenging. Intervention research that extends to a broader exploration of family dynamics, the home environment along with the explicit reporting of behavioural strategies for obese adolescents and their families is warranted.

Building upon its previous review by Summerbell, (2003), this 2009 Cochrane review (Luttikhuis et al., 2009) introduced consideration of drug trials and surgical interventions for the treatment of obesity in children and adolescents. Of importance in this thesis, the majority of previous reviews focused on childhood and adolescence as a whole population despite explicit recommendations for tailored treatment according to a child's BMI and age (Spear et al., 2007; NICE 2013). Severe obesity is the fastest growing sub category of adolescents (Ogden, 2010; Wang, 2011) and just like age, previous reviews have considered all various degrees of obesity which has not helped produce an evidence base for effective treatment in severely obese adolescents. Collectively, this makes any assessment of effective treatment strategies for the adolescent age group, a challenge.

To overcome this challenge a scoping review of the current evidence base for severely obese adolescents was conducted. The scoping review would identify treatment methods, delivery and programme content, along with an exploration of treatment outcomes and treatment limitations.

2.10 Scoping review of current treatment for severely obese adolescents

A scoping review was conducted to consider the evidence for the treatment of severe obesity in the adolescent age group. A scoping review is a process of mapping existing data providing a snapshot into the current evidence base (Arksey and Malley, 2005). They are useful in identifying research gaps as well as summarising existing outcomes of research (Arksey and Malley, 2005). Scoping reviews differ from neither systematic reviews as a robust formal assessment of the quality of studies is not performed, nor an extensive data synthesis undertaken (Brien et al., 2010). That said, scoping reviews offer a structured approach to gathering background information on a broad research topic hence they are deemed an appropriate method to adopt here. To strengthen the research rigour of this method Arskey and Malley, (2005) and more recently Levac et al., (2010), established a framework with which to conduct a scoping review (table 2.0). This was adhered to within this thesis.

Table 2.0 Framework for scoping review (Arskey and Malley 2005; Levac et al.2010)

1	Identifying the research question
2	Identifying relevant studies
3	Study selection
4	Charting the data
5	Collating summarising and reporting the results
6	Optional consultation

2.10.1 Search Strategy

Articles were identified using academic electronic search databases including; SPORT discus, PsychINFO, Medline, EBSCO host, Google scholar and PubMed. The reference lists of Cochrane review for obesity treatment in children (Luttikhuis et al., 2009; Ells,

2015) were also scanned for additional appropriate papers. Key words to conduct the search included; “adolescent”, “adolescence”, “teen”, “teenager,” “young people”, “morbid” and “severe obese” and “obesity”, “weight management”, “lifestyle behavioural modification” “multicomponent” and “multidisciplinary”, “medication”, “pharmacotherapy”, “bariatric surgery”, “severe complex and morbid obesity treatment”. Hard copies of all appropriate articles were obtained in line with the identified inclusion criteria. A data management system (Refworks) was also used within the filtering process to help collate the documents.

2.10.2 Rationale for criterion for scoping review

The criterion for this scoping review was based upon the current evidence base. Adolescents were defined as individuals aged between 10 and 19 years (World Health Organisation, 2014). Obesity treatment guidelines were defined by age and in line with NICE guidance (2006; 2013) that categorises specialist treatment for young people as 12 yrs and older (Luttikhuis et al., 2009; NICE 2013). Severe adolescent obesity was defined as > 99.6th percentile (Cole et al., 1999). Table 3.0 provides additional details on all available treatments for severely obese adolescents, their associated eligibility criteria, side effects and any potential issues.

The following criteria were used to select the appropriate research papers:

- Original research
- All research designs including uncontrolled research designs
- Research conducted and published in a peer-reviewed journal between January 2000 and January 2016 ³.
- Adolescent population with a mean age between 10 – 19 yrs (World Health Organisation, 2014).
- Severe obesity defined as above or equal 99.6th percentile, >3.5 SD. (BMI >35 with co morbidities or > 40 kg/m² are included to reflect international work).
- Theoretical underpinning and use of behavioural change strategies was assessed.
- Licenced medication in the UK (Orlistat and Metformin)

³ The scoping review was updated during 2016 to include the most up to date literature.

- All forms of bariatric surgery including; Gastric Bypass, Gastric Band, Intra-Gastric Balloon and Sleeve Gastrectomy.
- Primary or secondary outcome weight status measured by at least one objective measure (including BMI, BMI-SDS, waist circumference, skinfold thickness & percentage overweight and percentage excess weight).
- Searches limited to those published in English language

The following criteria were used to directly exclude papers:

- Articles were excluded if they were not available in the English Language
- Unpublished studies and dissertations/theses.

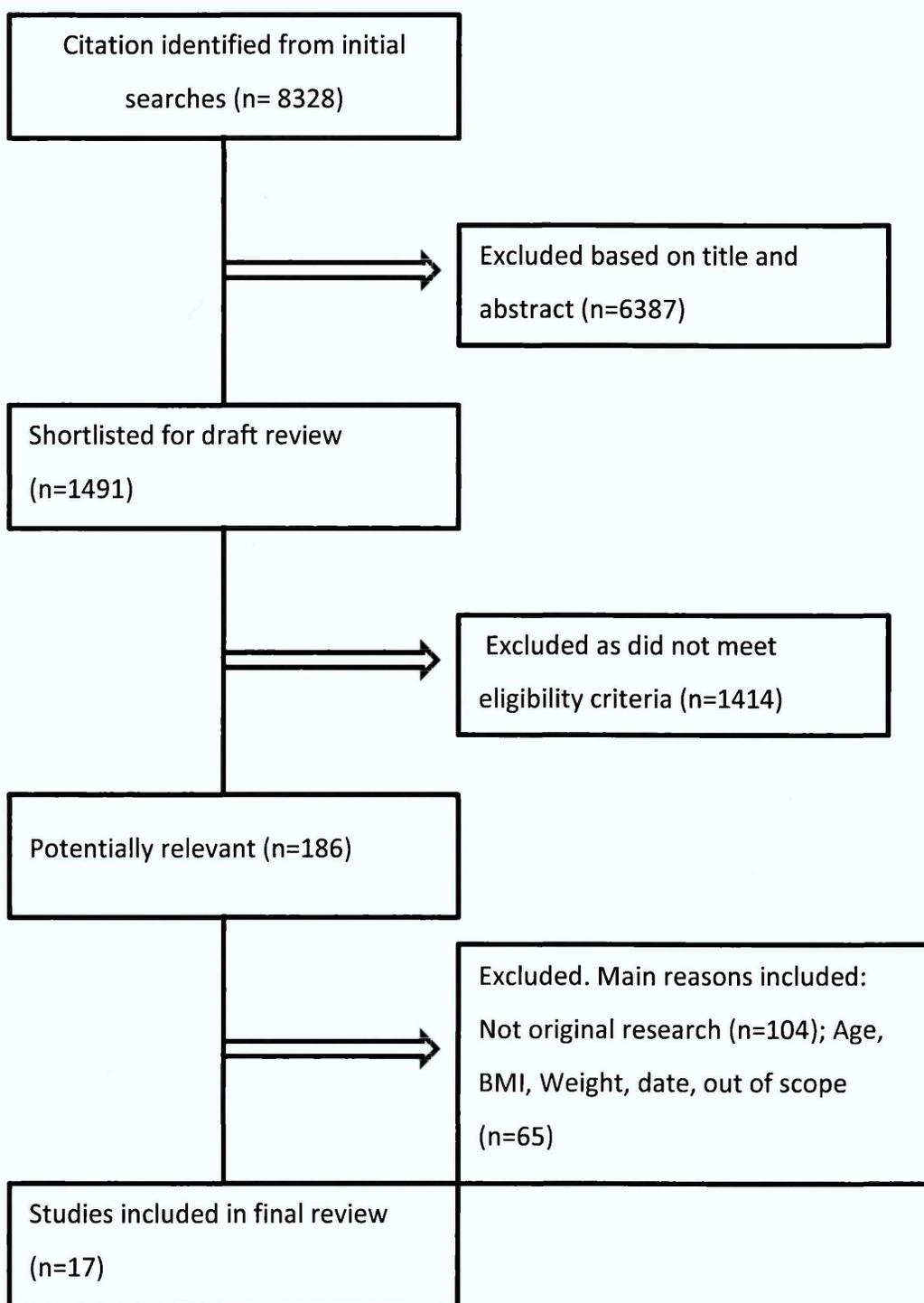


Figure 1.0- Scoping review selection and filtering process for current treatments available for severely obese adolescents (aged 10-19 yrs; BMI > 3.5 SD).

2.11 Scoping review results

The scoping review identified 17 studies, presented in table 4.0, that focused on treatment specifically for severely obese adolescents aged 10 -19 years, with a BMI > 99.6th percentile (Cole, 1997). Of the 17 studies eligible for inclusion, three clusters of treatment were identified; Four papers focused on multidisciplinary lifestyle programmes (Lazzer et al., 2004; Skelton et al., 2008; Krebs et al., 2010; Luca et al., 2014) Four papers involved the prescription of medication (Orlistat and Metformin) (Ozkan et al., 2004; McDuffie et al., 2002; Maahs et al., 2006; Burgert et al., 2008) with the remaining nine papers focusing on various techniques of bariatric surgery (Fielding et al., 2005; Nadler et al., 2009; O'Brien et al., 2010; Holterman et al., 2010; Olbers et al., 2012; Zeinoddini et al., 2014; Pedroso et al., 2015; Pourcher et al., 2015; Dubnov-raz, et al., 2015). The results of the scoping review will now be critiqued within the three clusters identified. In brief, these results highlight an apparent trend towards the use of more invasive treatments for use with severely obese adolescents.

Table 3.0 - Descriptions of all available obesity treatment options

Treatment and Eligibility	Name (s)	Description	Side effects/Issues
<p>(NICE, 2006; 2013; 2015)</p> <p>Lifestyle Intervention</p> <p>(Tier 2 services)</p> <p>Children aged 5 – 19years old</p> <p>Over 85th Percentile and on or below 95th centile.</p> <p>>95th centile</p>	<p>Commercially available or local authority led.</p>	<p>Aim is to maintain the growing child’s existing weight in the short term (promoting healthy BMI longer term).</p> <p>Programme’s should focus on:</p> <ul style="list-style-type: none"> • Diet and healthy eating habits • Physical Activity • Reduce sedentary time • Strategies for changing the behavior of the child or young person and all close family members 	<p>N/A</p> <p>Poor attendance with high dropout rates.</p>
<p>(NICE 2006; 2015)</p> <p>Pharmaceutical Intervention</p> <p>Only considered if evidence lifestyle interventions started and evaluated.</p>	<p>⁴Orlistat</p> <p>Xenical</p> <p>Alli (therapeutic)</p>	<p>Lipase inhibitor, reducing intestinal fat absorption by acting as an inhibitor of pancreatic lipase. Thus only about one-third of the dietary intake of triglycerides is not absorbed (Dolinsky et al 2013). It is administered orally three times per day (Kelly et al, 2013) at a dose of 120mg.</p>	<p>Good safety. Poor compliance and adherence due to nasty side effects including oily stools.</p>

⁴ At the time of NICE publication (November 2014), Orlistat did not have a UK marketing authorisation for use in children.

<p>Children aged 12 years and older. Recommended only if physical comorbidities (such as orthopedic problems or sleep apnea) or severe psychological comorbidities are present. Treatment should be started in a specialist pediatric setting, by multidisciplinary teams with experience of prescribing in this age group (NICE 2006)</p>			
	Sibutramine	<p>Is a serotonin and norepinephrine re-uptake inhibitor. They work by weakly inhibiting dopamine, causing satiety when taken at therapeutic doses.</p>	<p>Withdrawn from the international market in 2010 due to adverse cardiovascular health in adults (Baur et al, 2011).-</p>
	Metformin	<p>A biguanide primarily used for glycemic control in type II diabetes, has been evaluated for its effect on weight loss (Kelly et al, 2013). Metformin is administered orally with dosages varying between 1 to 2 g.</p>	<p>Not marketed as a weight loss medication, has been involved in a small number of studies with adolescents to promote weight loss (Kay et al, 2001; Freemark, 2001). Data limited as many studies involve obese patients whom are also diabetic.</p>
<p>Bariatric Surgery Presence of severe obesity for the last 5 years– no specific BMI centiles for children are detailed in NICE (2006). Surgery is generally not recommended for children. Only to be considered in</p>	BioEnterics Intra-gastric Balloon	<p>Balloons are made of silicone and sphere shaped, filled with 400-700ml of saline solution. Balloons reduce the stomach capacity and are designed to provide mechanically a sensation of satiety, resulting in decreased food ingestion and facilitating the learning of new dietary and behavioural routines.</p> <p>Balloons can remain in the stomach for up to 6 months.</p>	<p>Reduced risk as no general anaesthesia. Sickness and diarrhoea common when first inserted. Early balloon removal occurred in 2-4% of cases due to unpleasant side effects. Gastric ulcers and erosions, esophagitis,</p>

<p>exceptional circumstances and if physiological maturity has been, or is nearly achieved. Evidence of exhaustion of other treatment options e.g. evidence of engagement and attendance at tier 3 services. All young people require a comprehensive psychological, educational, family and social assessment before undergoing bariatric surgery. Final decision made by specialist hospital bariatric team.</p>		<p>Insertion and removal are performed under endoscopic conditions.</p>	<p>gastroesophageal reflux, abdominal pain, spontaneous balloon deflation, small bowel obstruction, gastric dilation and hypokalemia.</p>
<p><i>In obese adults guidelines state BMI of 40 kg/m² or more, or between 35 kg/m² and 40 kg/m² and other significant disease (for example, type 2 diabetes or</i></p>	<p>Roux-en-Y procedure (RYGB) Malabsorptive /restrictive procedure.</p> <p>Adjustable Gastric banding (AGB) Restrictive procedure.</p>	<p>Performed laproscopically under general anaesthetics. A line of staples, creating a small 'pouch' stomach, divides off the top section of the stomach. A new exit from this pouch is made into a 'Y' loop from the small intestine so that food bypasses your old stomach and part (about 100-150cm) of the small intestine. The size of stomach pouch and the length of small intestine that is bypassed are carefully calculated to ensure that patients will be able to eat enough for their body's needs at normal weight.</p> <p>Performed laproscopically under general anaesthetic. Helps reduce the amount of food eaten. It acts like a belt around the top portion of the stomach, creating a small pouch. Patients feel full after eating only a small quantity of food.</p>	<p>Failure of the staple partition, leaks at the junction of the stomach and small intestine, acute gastric dilatation, and delayed gastric emptying either spontaneously or secondary to a blockage. Permanent procedure.</p> <p>Reversible. Can be adjusted.</p> <p>Side effects associated with the surgery itself; splenic injury, oesophageal injury, wound infection, band slippage, band erosion, reservoir leak/deflation, vomiting, acid reflux.</p>

<p><i>high blood pressure). Surgery is the first option for adults with a BMI > 50 kg/m² when other interventions have not been effective.</i></p>	<p>Gastric plication</p>	<p>Performed laparoscopically and is a restrictive procedure. Dissection starts at the greater curvature of the stomach in contact to the gastric wall from prepyloric area to 2cm proximal to the his angle preserving the anatomy of the his angle.</p>	<p>Vitamin/mineral deficiency.</p>
<p>Sleeve Gastreectomy</p>	<p>Performed laporiscopically under general anaesthetic. Can be done as a two-part procedure. Divides stomach vertically to reduce stomach size by 25% from its original. The pyloric valve in the stomach is not affected meaning the function and digestions of the stomach are unaltered.</p>	<p>Risks are slightly reduced as operation is quicker and digestion unaltered. Leaking from the new stomach is possible and vomiting can be caused due to over eating. Rarely used in adolescents (Fitzgerald and Baur, 2014)</p>	

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
<i>Multidisciplinary Lifestyle Programmes</i>							
Lazzer, S., Boirie, Y., Montaurier, C., Vernet, J., Meyer, M and Vermorel, M. (2004) France	A weight reduction programme preserves fat free mass but not metabolic rate in obese adolescents	To determine effects of multidisciplinary weight reduction programme on body composition and energy expenditure in 26 severely obese adolescents (aged 12-16 yrs, mean BMI 33.9 kg/m ²). Adolescents followed a 9-month weight reduction including	10 months, 5 days per week, in a specialised institution. Participants followed a 9-month personalised weight reduction programme consisting of lifestyle education, physical activity, and dietary and psychological follow-up. Personalised diets developed on the basis of the results obtained during the initial Basal Metabolic Rate (BMR) assessment. Energy intake adjusted according to BMR. Dietetics lessons including choice and cooking of foods.	Adolescents lost 16.9 kg ± 1.3 body weight; lost 15.2 kg ± 0.9 fat mass and 1.8 kg ± 0.5 free fat mass. BMR, sedentary and daily energy expenditure were 8% to 14% lower 9 months after starting.	Weight reduction programme combining energy restriction and physical training resulted in greater body weight and fat mass losses, an improvement in energy expenditure and fitness.	Self-monitoring, Graded tasks.	None stated.

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
		<p>moderate energy restriction and progressive endurance and resistance training.</p>	<p>Adolescents followed a personalised progressive physical training programme for 9 months including two 40-minute sessions (preceded and followed by 5 to 7 minutes of stretching) per week under medical supervision. Each programme of exercises was developed according to the results of an initial maximal oxygen uptake test for aerobic exercises. Heart rate monitoring used to ensure intensity was set at 55% to 60% of heart rate maximum. In addition, the physical activity program included 2 hours of physical</p>				

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
Skelton J., DeMattia, L., Flores, G (2008) America	A Pediatric Weight management Programme for High-risk Populations: A Preliminary Analysis	A retrospective chart review was performed on children seen in the NEW Kids Program at the Children's Hospital of Wisconsin, a family-based clinic that treats pediatric obesity	Adolescents seen in individual clinic appointments where individual care plans were devised for families. All families were encouraged to adopt lifestyle change. Therapist worked to increase awareness of lifestyle habits and transform maladaptive thoughts. Advice given on	Post intervention, there was an overall increase in absolute BMI, but a small, yet significant decrease in BMI Z-score (mean – 0.03 ± 0.16; P < 0.05).	Findings suggest a multidisciplinary pediatric weight management programme could be an effective means of reaching and treating high-risk populations of obese	Cognitive Behavioural therapy (CBT)	None stated.

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
		using medical management, nutrition education, behavioural intervention, and physical activity. Total of 66 patients mean age was 11 years (\pm 3.4), 56% were racial/ethnic minorities, 38% had a BMI \geq 40 kg/m ² .	nutrition, physical education and additional support to promote behavioural change. Visits are 1-3 months, with times between session increased based upon evidence of positive change.		children.		
Krebs, N., Gao, D., Gralla, J., Collins, J. and	Efficacy and safety of a high protein, low carbohydrate	Intervention included a 12 week randomised controlled	Both groups of participants were informally prescribed an exercise programme that included at least 30	46 adolescents (24 HPLC, 22 LF diet) initiated and 33 adolescents	High protein and low carbohydrate diet could be a safe and	Self-monitoring.	None stated.

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
Johnson, S (2010) America	(HPLC) diet for weight loss in severely obese adolescents	design comparing high protein, low carbohydrate diet vs low fat (LF) diet in producing weight loss in 51 adolescents. HPLC group (mean age 14.2±0.4; weight 109.3 kg± 4.7; BMI 38 kg/m ² ± 1.2) LF group (Mean age 13.7± 0.3; Mean weight 107.1kg ±6.1; BMI 40.1 kg/m ² ± 1.8)	minutes of daily moderately vigorous physical activity. Handouts were provided with ideas to encourage physical activity and an activity log was maintained.	completed intervention. Significant reduction in BMI Z score in both groups during intervention observed, but greater for HPLC.	effective option for medically supervised weight loss in severely obese adolescents.		
Luca, P.,	Adolescents	Severely obese	STOMP is an intensive	At 6 months	STOMP	CBT,	Not stated.

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
Dettmer, E., Khoury, M., Grewal, P., Manhiot, C., McGrindle, B., Birken, C., Hamilton, J (2014) Canada	with severe obesity: outcomes of participation in an intensive obesity programme; SickKids Team Obesity Management Programme (STOMP)	adolescents (n=75) in STOMP (15.1 years \pm 1.8; BMI Z score 4.1 \pm 1.1) were compared with adolescents (n=41) not in the programme (14.9 years \pm 2.0; BMI z score 3.1 \pm 1.1)	family focused behavioural support programme. Months 1-3 offer weekly sessions for patients and parents focusing on nutrition, exercise therapy and mental health. Educational based sessions focused on incorporating healthy food, activity and behaviour changes into their lives. Months 4-24 offers appointments every 2 weeks with individual and family therapy, fun events and educational sessions.	STOMP patients BMI was unchanged with reported improvement in quality of life and depression.	participants did not experience significant reduction in BMI but demonstrated improvement in cardio metabolic, psychological and health behaviour outcomes.	motivational interviewing and family therapy.	

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
Pharmaceutical (Orlistat and Metformin) Intervention							
Ozkan, B., Bereket, A., Turan, S., Keskin, S. (2004) Turkey	Addition of Orlistat to conventional treatment in adolescents with severe obesity	Efficacy and tolerability of Orlistat in obese adolescents, a prospective, open-label, randomised, controlled pilot trial. A total of 22 adolescents; Orlistat group (mean age 12.9 years \pm 2.4; initial BMI 32.5 kg/m ²) Control group (mean age 12.5 years \pm 2.2; BMI 31.2 kg/m ²)	Orlistat and control group were given individual diet (20% reduction in daily calories) and increased physical activity by at least 30 mins of moderate exercise per day. Participants saw a dietician bi-monthly in clinic.	Compared to initial body weight, patients in the Orlistat group lost -6.27 \pm 5.4 kg, whereas those in the control group gained 4.16 \pm 6.45 kg during the study period. Body mass index decreased in the Orlistat group by -4.09 \pm 2.9 kg/m ² while it increased by +0.11 kg/m ² \pm	Orlistat could be a useful adjunct to lifestyle treatment but side effects limit its widespread use	Self-monitoring used.	None stated

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
McDuffie, J., Calis, K., Uwaifo, G., Sebring, N., Fallon, E., Hubbard, S., Yanovski, J. (2002)	Three month tolerability of Orlistat in adolescents with obesity related comorbid conditions	20 obese white and African American adolescents (mean age 14.6 years mean BMI 44.1 kg/m ²). Open label pilot trial of Orlistat as an adjunct to lifestyle programme. Subjects evaluated before and after Orlistat 120mg 3	12-week comprehensive behavioural programme taught by dieticians and exercise physiologist/psychologist. Nutrition-education review used a game format for 15 to 30 minutes during each weekly meeting and homework assignments supplied in a program manual provided to each subject. The exercise programme consisted of:30 minutes of daily	2.49 in the control group.	In adolescents, short-term treatment with orlistat, in the context of a behavioural programme, is well tolerated and has a side-effect profile similar to adults. true benefit remains to be determined in placebo-controlled trials.	Concentrated on stimulus-control and eating-management skills. Use of self-monitoring and positive reinforcement for goal achievement.	None stated.
America				Participants who completed treatment (85%) reported taking 80% of prescribed medication. Adverse effects generally mild. Weight decreased significantly - 4.4kg ± 4.6; BMI -1.9 kg/m ² ± 2.5)			

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
		X daily and 12 week lifestyle programme	aerobic exercise and inclusion of lifestyle exercise whenever possible, monitored by pedometer readings onsite physical activities and education led by a recreation therapist for 15 to 30 minutes of each weekly meeting. The compliance was gauged through self-monitoring of medication taken, food eaten, activity performed, amount of inactive time spent, and pedometer readings recorded in a progress book reviewed by the group leaders each week. Points toward winning prizes were awarded each week				

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
Maahs, D., Gonzalez, D., Kolotkin, R., Ralston, S., Sandate, J., Qualls, C., Schade, D. (2006) America	Randomised, double blind, placebo-controlled trial of Orlistat for weight loss in adolescents.	A 6 month randomised, double blind, placebo controlled, trial to compare the effects of Orlistat (120mg 3 times daily) and a placebo on reduction of body mass index. 40 adolescents (14-18 years old, mean BMI 40 kg/m ²).	contingent on a minimum 0.5-1lb weight loss and a completed progress book. Both study groups received the same dietary and exercise counselling. The goal caloric intake was calculated by using the Harris-Benedict equation with ambulating activity factor. From this expected caloric need, 500 calories were subtracted to determine the daily calorie level for weight loss for each individual. During the inpatient stay participants were instructed to consume a low-fat (30%) exchange	No statistically significant difference was noted between the two groups for decrease in BMI from baseline to 6 months. Decrease within Orlistat group (1.3 ± 1.6 kg/m ²).	Orlistat did not significantly reduce BMI in comparison with placebo at 6 months.	Counselling techniques evident but not aligned to a specific technique. Evidence of self-monitoring.	None stated.

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
			<p>diet and were given weekly log sheets to complete. Adolescents were instructed to increase activity by using a paediatric activity pyramid and encouraged to exercise at least 3 times per week for at least 30 minutes on each occasion. At each monthly follow-up visit, all participants met with a dietician to reinforce the low-fat diet and exercise plan.</p>				

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
Burgert, T., Duran, E., Goldberg- Gell, R., Dziura, J., Yeckel, C., Katz, S., Tamborlane, W., Caprio S. (2008) America	Short-term metabolic and cardiovascular effects of metformin in markedly obese adolescents with normal glucose tolerance.	28 obese adolescents (mean BMI 40.3 \pm 5.7 kg/m ² ; mean age 15 \pm 1.3 years) recruited to a 4-month double blind clinical trial randomised to metformin or a placebo.	Both groups received lifestyle counselling involving nutritional and exercise recommendations. Participants were assessed monthly, with outcomes measured at baseline and 4 months.	Metformin group lost 1.6 kg \pm 8.4 and BMI difference of -0.9 kg/m ² \pm 2.5 compared to control group; weight gain 3.0kg \pm 4.3 and BMI change of + 1.2 kg/m ² \pm 1.9. Treatment with metformin was well tolerated and associated with a decreased BMI.	Short-term use of metformin was well tolerated by obese adolescents with a normal glucose tolerance and has a beneficial effect on BMI.	Counselling stated but not aligned to specific technique.	Not stated.

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
Bariatric Surgery							
Fielding, G., Duncome, J. (2005) Australia	Laparoscopic adjustable gastric banding in severely obese adolescents	Retrospective study reviewing outcomes of 41 adolescents (aged 12-19 yrs; mean weight 125 kg ± 9; mean BMI 42.4 kg/m ² ± 8.2)	A multidisciplinary team assessed all patients, including a nurse practitioner, psychologist, nutritionist, and the surgeon.	At 3 years post surgery mean BMI decreased to 29 kg/m ² , ± 6 which, was maintained at 5 years.	Laparoscopic gastric banding is a valid treatment option for severely obese adolescents.	No specific psychotherapy coping skills training, or family focus were offered.	None stated.
Nadler, E., Reddy, S., Isenholme, A., Young, H., Peck, V., Ren, Fielding, G. (2009)	Laparoscopic adjustable gastric banding for morbidly obese adolescents affects android fat loss,	45 adolescents (Age 14-16 years; Mean BMI 48.1 kg/m ² ± 6.4.; Mean weight 299 lbs ± 57) underwent laparoscopic adjustable gastric banding	Patients returned monthly for assessments and health checks. No structured lifestyle programme was implemented.	45 patients remained at year follow-up and 41 remained for 2-year follow-up. 47 out of 85 identified co morbidities were resolved	Short-term use of metformin was well tolerated by obese adolescents with a normal glucose tolerance and had beneficial	None stated.	None stated.

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
America	resolution of comorbidities and improved metabolic status	(LAGB) – off label.		and 25 improved in comparison.	effect on BMI. Adjustable gastric band induced weight loss and resolution of comorbidities in severely obese adolescents supporting the conclusion this could be an appropriate treatment option.		
O'Brien, P., Sawyer, S., Laurie, C., Brown, W., Skinner, S., Veit, S., Paul, E.,	Laparoscopic adjustable gastric banding in severely obese adolescents; A	Randomised controlled trial of 50 adolescents (14-18 yrs, BMI > 35 kg/m ²) assigned either to a	Programme centered on reduced energy intake (individualized diet plans ranging between 800 and 2000 kcal/d, depending on age and weight status), increased activity (target	24/25 completed gastric banding and 18/25 completed lifestyle intervention.	Gastric banding in severely obese adolescents compared with lifestyle intervention	Not stated.	None stated.

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
Burton, P., McGrice, M., Anderson, M., Dixon, J. (2010) Australia	randomised controlled trial	supervised lifestyle intervention or to undergo gastric banding and followed up for 2 years.	of >10 000 steps per day on pedometer) with a structured exercise schedule of at least 30 minutes a day and behavioural modification. Consultations every 6 weeks throughout the 24-month study period by an adolescent Doctor and a dietitian or exercise consultant, the study nurses coordinator, and a sports medicine physician. Parents were invited to participate in a specific educational programme that included sports motivational talks, nutritional education, and discussions of the	Gastric band group resulted in a mean weight loss of 34.6kg. Mean weight loss in lifestyle group was 3.0kg.21 adolescents in the banding group and 3 in the lifestyle group lost more than 50% excess weight when corrected for age. 8 procedures were reversed.	resulted in a greater percentage achieving a loss of 50% excess weight corrected for age. Associated benefits to health and Quality of Life.		

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
			psychological aspects of adolescence.				
Holterman, A., Browne, A., Tussing, L., Gomez, S., Phipps, A., Browne, N., Stahl, C., Holterman, M. (2010) America	A Prospective trial for laparoscopic adjustable gastric banding (LAGB) in morbidly obese adolescents: an interim report of weight loss, metabolic and quality of life outcomes.	The outcome of 20 adolescent patients (Mean age 16 yrs \pm 1; mean weight BMI 50 kg/m ² \pm 10) undergoing LAGB after completing 12 months of follow-up in a prospective longitudinal trial were reported	Patient-tailored service provided by a multidisciplinary team with medical, psychology, and exercise providers. Patients were enrolled into the trial following 4-6 months of treatment in the programme.	Mean follow-up at 26 months % excess weight loss was 34% \pm 22. Hypertension normalised in all patients along with improvement of lipid profiles and Quality of life.	Intermediate follow-up of a LAGB based obesity treatment programme, weight loss leads to resolution or improvement of major obesity related conditions	None stated.	None stated.
Olbers, T., Gronowitz,	Two-year outcome of	81 adolescents (aged 13-18	A requisite for inclusion on the study was that	Mean BMI at 2 years post	Severely obese adolescents	Cognitive Behavioural	None stated.

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
E., Werling, M., Marlid, S., Flodmark, C., Gothberg, G., Karlsson, J., Ekbo, K., Sjostrom, L., Dahlgren, J., Lonroth, H., Friberg, P., Marcus, C. (2012) Sweden	Laparoscopic Roux-en-Y gastric bypass in adolescents with severe obesity: results from a Swedish nationwide study (AMOS).	years; mean BMI 45.5 ± 6.1 kg/m ² underwent gastric bypass between 2006 – 2009.	adolescents had to have attended Swedish weight management programme. This treatment mainly consists of individualised or family-based counseling and cognitive behaviour therapy concerning diet and physical activity. This study however only assessed bariatric procedure.	surgery was 30.2 kg/m ² corresponding to a 32% weight loss and 76% loss of excess BMI. Surgery generally well tolerated with overall quality of life improving significantly. adolescents produced similar post surgical results compared with severely obese adults. Surgical and psychological challenges	demonstrated similar results to adult following gastric bypass but presented with a higher psychopathology at baseline.	Therapy delivered more broadly and not within this study.	

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
Zeinoddini, A., Heidari, R., Talebpour, M. (2014) Iran	Laparoscopic gastric plication LGP in morbidly obese adolescents: a prospective study	A prospective study performed on 12 adolescents (mean age 13.8 yrs \pm 1; mean BMI 46.0 kg/m ² \pm 4; mean weight 112.4 kg \pm 19.7) undergoing LPG.	No structured programme was delivered beyond the routine assessments.	Mean % excess weight lost was 68.2% \pm 9.9 after 2 years. No major complications occurred.	LGP could be appropriate treatment option for severely obese adolescents as weight loss is induced and adverse psychological events were minimised.	Not stated.	None stated.
Pedroso, F., Gander, J., Oh, P., Zitsman, J. (2015)	Laparoscopic vertical sleeve gastrectomy (VSG) significantly improves	A single institution retrospective evaluation of prospectively collected	No structured lifestyle programme was delivered beyond the routine assessments.	No significant differences in weight between VSG and LAGB on day of surgery. At 24	Bariatric surgery is an effective treatment for severely obese adolescents when other	Not stated.	None stated

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
America	short term weight loss as compared to laparoscopic adjustable gastric band (LAGB) placement in morbidly obese patients	database of 174 severely obese adolescents undergoing LAGB and VSG operations. 137 patients undergoing LAGB (mean age 16.9; mean pre op weight 136.1kg; pre op BMI 48.3kg/m ²) and 37 VSG (mean age 17.3years; mean pre op weight 138.2kg; mean pre op BMI 50.1 kg/m ²)		month follow-up, patients undergoing VSG compared to LAGB displayed greater percentage excess weight loss (70.9 ±20.7 vs 35.5 ± 28.6).	medical management has failed. VSG showed greater results in the short term. Longer-term follow-up needed to assess long-term safety and efficacy.		
Pourcher, G., Filippo,	Short-term results of	All 16 adolescents	No structured lifestyle programme was delivered	One year follow-up	New procedures being tested in	Not stated.	None stated.

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
G., Ferretti, S., Piquard, C., Dagher, I., Bougneres, P. (2015) France	single port sleeve gastrectomy in adolescents with severe obesity	(mean age 17.8years; mean weight 125.5kg; mean BMI 45.3kg/m ²) underwent single port sleeve gastrectomy. All patients were insulin resistant.	beyond the routine assessments.	average weight loss was 40.3 kg resulting in decrease of excess weight loss by 70.61%. Insulin resistance decreased in all patients.	this population.		
Dubnov-Raz, G., Inge, T., Ben-Ami, M., Pienik, R., Vusiker, I., Yardeni, D. (2015) Israel	Body composition changes in adolescents after laparoscopic sleeve gastrectomy	25 severely obese adolescents (mean age 16.6yrs ± 1.5 years; mean BMI > 40kg/m ²) body weight and composition were assessed pre and 1 year	No structured lifestyle programme was delivered beyond the routine assessments.	1-year post sleeve gastrectomy weight decreased by 32% fat mass decreased by 55%, and fat free mass by 9% from baseline. Only modifiable	Acceptable procedure in adolescents. Larger studies needed to formally identify other possible predictors of body composition following sleeve	Not stated.	None stated.

Table 4.0 – Scoping review results: Summary of evidence for treatment of severely obese adolescents 2000-2016 presented in chronological order

Author (Date) Country	Title	Intervention	Lifestyle programme detail	Outcomes	Conclusion	Evidence of behaviour change strategies	Theory used
		post sleeve gastrectomy operation.		factor, which was influenced with larger decreases in body fat percentage, was physical activity.	gastrectomy.		

2.11.1 Multidisciplinary lifestyle programmes

Multidisciplinary lifestyle programmes incorporating physical activity, nutrition and behaviour change are considered the most appropriate treatment option for tackling overweight and obese broadly amongst children and adolescents (Luttikhuis et al., 2009; NICE 2014). In this scoping review, four interventions (Lazzer et al., 2004; Skelton et al., 2008; Krebs et al., 2010; Luca et al., 2015) targeted severely obese adolescents (BMI > 99th percentile; BMI Z score >3.5), adopting this approach. All studies produced weight loss in the short term amongst a total sample of 218 adolescents. Weight maintenance collected through long-term follow-up was not routinely reported - Lazzer et al., (2004) and Skelton et al., (2008) adopted pre and post intervention designs. There were no consistencies across studies in terms of protocol length, frequency, intensity of support, and follow-up period. Characteristics of each lifestyle programme were not explicitly reported with a large variation in the amount of detail described. Skelton et al., (2009) offered details on the delivery staff skills and the style of delivery aligned with CBT (Foreyt and Poston., 1998), whilst Lazzer et al. (2004) outlined a personalised weight reduction programme consisting of physical activity, dietary and psychological support was delivered. Work by Krebs et al. (2010) was the only diet only intervention, which proposed that a high protein, low carbohydrate (HPLC) diet was safe and effective in adolescents in their ability to induce weight loss in the short-term (Krebs et al., 2010). References to family involvement were made in two papers (Lazzer et al., 2004; Luca et al., 2015) but only limited information was provided on the specific role and level of engagement from families. Considering the large influence parents and families have on adolescent lifestyle behaviours (Janicke et al., 2014) further research is warranted.

Studies involving multidisciplinary lifestyle programmes highlight a distinct lack of consistency on the depth of detail reported regarding intervention design and content. None of the studies report the theoretical underpinning to their intervention. Some studies alluded to the use of behavioural change techniques (Luca et al., 2015) such as self-monitoring for the measurement of physical activity, yet rarely were these techniques aligned to a specific framework nor the detail on how these were delivered reported.

Without a universal definition for behaviour change or an explicit reporting framework for researchers to define and report the programme content being delivered, accurate assessments of the impact of multidisciplinary programmes on weight related and behaviour outcomes for obese adolescents is challenging.

2.11.2 Pharmaceutical (Orlistat and Metformin) intervention

Four studies included adopted a pharmaceutical intervention (McDuffie et al., 2002; Ozkan et al., 2004; Maahs et al., 2006; Burgert et al., 2008) involving a sample of 110 adolescents. Three out of the four studies focused on Orlistat with one looking at Metformin. Three out of the four studies (Burgert et al., 2008; Ozkan et al., 2004; McDuffie et al., 2002) included a lifestyle support programme as part of the intervention albeit variations in detail made drawing comparisons a challenge. McDuffie et al. (2002) outlined the use specific use of behavioural techniques including stimulus control, positive reinforcement of behaviours and self-monitoring of physical activity through objective measurement using a pedometer. Weight losses and BMI change observed in the three-month period with this study were the highest observed amongst the medication trials. Although, the positive outcomes cannot be directly attributed to the inclusion of behavioural change techniques, further research utilising behavioural change techniques are needed in the treatment of severely obese adolescents. The time participants took Orlistat varied, with Ozkan et al. (2004) reporting one of the longest durations, 11.7 ± 3.7 months on average. Although Orlistat appeared well tolerated in the majority of adolescents, 30% participants discontinued the medication due to adverse side effects in Ozkan et al. (2004) study whilst McDuffie et al. (2002) found 80% of the adolescents who completed the study reported not taking the sufficient dose. To comply with the dosage guidelines, adolescents are required to take three times daily with meals, which when considering this requires taking it whilst at school and college, could explain the high attrition rates. Three out of the four studies (McDuffie et al., 2002; Burgert et al., 2008; Ozkan et al., 2004;) were pilot trials in their design primarily looking to establish safety and tolerability, making assessments on effectiveness not possible. Generally, studies concluded that the use of pharmaceutical treatment, in addition to a multicomponent lifestyle programme, have the potential to significantly improve BMI in severely obese adolescents, albeit one study showed no significant difference (Maahs et al., 2006).

2.11.3 Bariatric surgery

Within the review, nine papers involved bariatric surgery; four performing gastric banding (Fielding and Duncome., 2005; Nadler et al. 2009; O'Brien et al. 2010; Holterman et al. 2010) three sleeve gastrectomy (Dubnov-raz et al., 2015; Pedroso et al., 2015; Pourcher et al. 2015; and one performing gastric bypass (Olbers et al., 2012) and Laparoscopic Gastric plication (Zeinoddini et al., 2014) giving a total sample of 391 adolescents. No studies involving temporary devices such as an intra-gastric balloon met the inclusion criteria for this scoping review. Studies performing bariatric surgery indicated higher weight loss outcomes than multidisciplinary lifestyle programmes alone and the use of medication (Dubnov-Raz et al., 2015). Evidence of a reduction in co-morbidities was also observed in patients undergoing bariatric surgery (Holterman et al., 2010).

O'Brien et al. (2010) demonstrated that in a small, predominantly female population of severely obese Australian adolescents both gastric banding and a multi component lifestyle intervention resulted in improved weight and health status. However, gastric banding resulted in a significantly greater weight loss than the lifestyle programme albeit a high rate (28%) of the banding group did have to have a revisional procedure (O'Brien et al., 2010). This is consistent with Olbers et al. (2012) who also reported the need to consider adverse events post operatively. Eating small meals slowly, was central to avoiding problems after the gastric banding procedure – something repeatedly stressed during the O'Brien et al. (2010) study. For adolescents, additional education and supervision of eating may help reduce the need for revisional surgery. This questions the active ingredients required within the content of a lifestyle support programme to effectively treat and manage this cohort of severely obese adolescents.

Generally, studies concluded that bariatric procedures were safe and well tolerated with severely obese adolescents. A high prevalence (two thirds of the patients) had a history of psychopathology in Olbers et al. (2012), reinforcing the need for psychological aspects of adolescent obesity, as well as the impact of treatment, to be carefully considered throughout the treatment pathway (Dubnov-Raz et al., 2015).

Evidence into the longer-term health and weight maintenance is however limited. Here, Olbers et al. (2012) considered outcomes at 2 years with a 100% follow-up rate.

A 32% weight loss was maintained at 2 years, albeit no significant weight changes were observed between year 1 and year 2, indicating the largest change was seen post-operatively. Adverse events were observed in 33% patients; nevertheless researchers concluded the intervention was well tolerated. Other aspects of health including quality of life and psychosocial status were rarely considered. Where quality of life was assessed there appeared positive impacts (Olbers et al., 2012) but further consideration and inclusion of this measure in bariatric studies is needed to assess the global impact on health and wellbeing especially post operatively and in the longer-term (Holterman et al., 2010).

2.12 Discussion of scoping review

2.12.1 Lack of focus on severely obese adolescents

The overwhelming finding from the scoping review was the small number of intervention studies focused on treating adolescents as a discrete population group. A lack of a universal definition for severe obesity, coupled with various definitions for the adolescent years, reinforces this challenge (Ells et al., 2015). What can however be concluded, is that there is an evidence gap for obesity treatment targeting severely obese > 99.6th percentile; BMI Z score > 3.5 (Cole, 1997) adolescents aged 10-19 years (WHO, 2000). Further research to inform age appropriate and tailored obesity treatment programmes for severely obese adolescents are needed (Steinbeck, 2013; Sousa et al., 2014).

2.12.2 Protocol content and detailed reporting

Description of lifestyle programme content was reported with a mixed level of detail making it challenging to compare and contrast effectiveness (Lazzer et al., 2005; Skelton et al., 2006). Intervention components are typically identified as '*who delivers the intervention, to whom, how often, for how long, in what format and in context with what content*' (Davidson et al. 2003). Consequently, the UK Medical Research Council guidance for developing and evaluating complex interventions calls for improved methods of specifying and reporting intervention content in order to address the problems of lack of consistency and consensus (Craig et al., 2008). The lack of reporting detail here reinforces the need for researchers to explicitly report the delivery of programmes in order to establish the active ingredients that facilitate the

mechanisms for success and weight loss (Janicke et al., 2014). Involvement of family members and carers is recognised and recommended within programmes (Janicke et al., 2013; NICE, 2015) yet no studies mentioned this within this review. Where appropriate, family members/carers should be involved in the decision-making process and future treatment participating in lifestyle management services (NICE, 2015). Studies have suggested parental weight loss is a predictor of success with increased parental weight loss in treatment associated with greater child weight loss (Goldschmidt et al., 2012). Further research is needed to understand the specific role parents and family members could play. Poor adherence and compliance, associated with the inability to promote significant and sustained weight loss long term, are crucial features influencing the effectiveness of behavioural lifestyle treatments for obese adolescents (Luttikhuis et al., 2009; Staniford et al., 2009; Sousa et al., 2014). Studies focused on the use of bariatric surgery (Holterman et al., 2010; Olbers et al., 2012) lacked consistent detail in the reporting of surgical procedures and surgical complications, patient inclusion and exclusion criteria, protocol for measurements and the schedule for follow-up appointments. This finding is reinforced in a systematic review (not included within the scoping review) of bariatric surgery amongst children and adolescents (Black et al., 2013). Despite, multidisciplinary lifestyle programmes recommended as an integral element of all obesity treatment, including invasive options such as Bariatric surgery (NICE, 2014), few studies included in the scoping review here adhered to these guidelines.

Researchers use multiple indices to measure treatment outcomes. An evident finding of this review was the inconsistent use of BMI measurement with some using BMI Z scores (Skelton et al. 2008) whilst others referred to the adult equivalent (McDuffie et al., 2002; Lazzer et al., 2004). The inconsistent use of metrics used limits comparisons between studies and could lead to a misinterpretation of the accuracy of results.

Acknowledging that bariatric surgery must be conducted within a clinical environment, all other studies included in this review were conducted within a defined treatment setting. Socio-ecological models have highlighted the role that environmental factors play in influencing health behaviours (Story et al., 2008) with the home environment representing an important influence on the development of adolescent eating behaviours (Rosenkranz and Dzewaltowski, 2008). Further research exploring the

integration of different environments within treatment programmes and consideration of broader influences, including interpersonal factors, is therefore required (Stark et al., 2011).

2.12.3 Evidence of behavioural change techniques and theoretical underpinning

It is recommended obesity treatment is evidence based, with content and delivery underpinned by a theoretical framework (NICE, 2015). Contrary to this guidance, none of the studies included in the scoping review explicitly reported their theoretical underpinning. A good theoretical understanding is needed to make an assessment of the mechanisms within the intervention that caused the change.

The scoping review also highlighted a limited attention on the use of behavioural change strategies. That said, two studies did allude to the use of behavioural change techniques (McDuffie et al., 2002; Luca et al., 2015) yet there was a distinct lack of detail on how the strategies were used, making it not only difficult to replicate, but challenging to identify the specific techniques that contributed to the effectiveness within interventions.

When utilised, behaviour change theories aim to explore when, why and how behaviour does or does not occur and identify the important sources that influence this (Michie et al. 2014). Despite there being over 82 theories of behaviour change (Davis et al. 2014), several theories have been frequently adopted as '*favourites*' within physical activity and dietary interventions, including Transtheoretical Model (TTM) (Prochaska and DiClemente 1983), Theory of Planned Behaviour (TpB) (Ajzen 1991), and Social Cognitive theory (SCT) (Bandura, 1982) (Prestwich et al., 2008). A summary of each theory is presented in Appendix 5.

A finding from the scoping review was that studies attempting to change behaviour in obese young people failed to describe their intervention components in sufficient detail for their programmes to be accurately understood as well as replicated. Looking specifically at behaviour change, Abraham and Michie, (2008) developed a taxonomy of behavioural techniques, attempting to reliably identify and categorise behaviour change techniques for consistent use in health interventions. The CALO-RE taxonomy includes 40 techniques to apply to physical activity and healthy eating behaviour

interventions (Mitchie et al., 2011) and in line with NICE (2014), recommends the use of self-monitoring, stimulus control and goal setting, all aimed to increase motivation and confidence in ability to change. In addition, positive parenting skills training, including problem-solving skills, to support changes in behaviour are recommended (NICE, 2014). Interventions that are based upon evidence-based principles of behaviour change are considered more effective than those which are not (Abraham et al. 2009; Noar and Zimmerman, 2005; NICE, 2015). Explicitly reporting the detail of obesity programme delivery against a framework like the taxonomy of behaviour change (Mitchie et al., 2011) could enhance the delivery of effective obesity treatment.

2.13 Limitations of scoping review

A scoping review is a structured method of analysing data however it was recognised at the outset that this method was not as robust as a systematic review that strictly analyses the quality of research studies (Arskey and Malley, 2005). A number of articles (n=169) were deemed ineligible for inclusion in the scoping review as a result of the eligibility criteria specified. The main reasons for ineligibility were the age and obesity classification of the study participants and the lack of original research. Throughout the literature, various definitions were used to define 'adolescent' and 'obesity' classification. Frequently studies pooled children and adolescents together in one cohort and interventions targeted obesity across multiple classifications, which in light of criterion set, were deemed ineligible for this review. This made attempts to understand the treatment effectiveness specifically for severely obese adolescents difficult.

2.14 Chapter summary

Taken collectively this Chapter sets out the evidence for the need to focus on adolescents and in addition, the need to enhance the quality and design of treatment programmes specifically targeting this severely obese adolescent group. The primary aim of this thesis is to enhance understanding of the needs of obese adolescents, contribute to what is known about current treatment options for severely obese adolescents specifically, and pilot a novel treatment approach within a severely obese adolescent population. These aims will be considered in detail in subsequent Chapters.

3.0 Study aims

To our knowledge (Chapter 2), very little is still known about the experiences of obese adolescents, combined with few studies focusing on adolescents' perceptions of treatment (Morinder et al., 2011). A detailed understanding of what life is like for overweight and obese adolescents, as a distinct population group is needed to ensure treatment programmes are tailored accordingly to ensure successful initiation and maintenance of lifestyle behaviours. Building upon findings from the literature and scoping review (Chapter 2), the purpose of this qualitative study was to explore the lived experience of obese adolescents and their engagement with obesity treatments. This study will now be considered in detail.

3.1 Theoretical considerations; Ontological and epistemological framework

Within the healthcare context in the UK, services must continually evolve to respond to patient needs. Understanding the complex needs of the health and wellbeing of patients is complex. Qualitative research is an appropriate method to explore this complexity whilst also the need for a robust methodological approach is necessary (Gale et al. 2013). Diverse qualitative methods are available that incorporate different ontological and epistemological perspectives (Page and Thomas., 2009). Careful consideration was given to the approach taken throughout this thesis and an overview of the theoretical positioning of this research will now be considered.

Conducting qualitative research is influenced by the researcher's epistemological assumptions. Such assumptions exist on a spectrum; At one end, a highly constructivist view which conforms to a meta-theoretical position that assumes that reality is local, contextually constructed and based upon an individual's own understanding and experiences (Guba and Lincoln., 1994). The opposing end of the spectrum is Positivism, which is based upon natural phenomena with information derived from sensory experience and derived through reason and logic (Page and Thomas, 2009). Critical realism reflects a post positivism movement (Guba and Lincoln., 1994) and is theoretically positioned on the spectrum between Positivism and Constructivism and adopts tenets of both models. To clarify, critical realism states that knowledge of reality is mediated by an individual's perceptions and beliefs. This recognises realism as

its ontological worldview and theorises that the social world exists independently of human understanding (Ritchie et al., 2013). In this thesis Study 1 and Study 3 required interviewing of participants to gain a descriptive account of their experience. Emerging themes from the data were then indexed and coded to interpret thesis experiences in depth, a characteristic of epistemologically realist research (Braun and Clarke., 2006). A feature of critical realism, which differs from other approaches, is the requirement of researchers to engage with prior theory during the initial stages of research (Page and Thomas, 2009). This occurred within both qualitative studies in this thesis as existing literature and researcher experiences of conducting research amongst this population informed the development of the interview scripts used to shape the qualitative interviews.

3.1.1 Overview of method choice

A growing number of methods for synthesising qualitative research have emerged within healthcare research and it is important to distinguish between these methods in order to select the most appropriate method for the research. The use of the Framework approach, developed in the 1980s by social policy researchers at the National Centre for Social Research, UK, has grown in popularity (Smith and Firth, 2011). The reason for its increased use is arguably as a result of its transparency throughout the analytical process along with its highly structured approach (Smith et al., 2011). An outline of the framework approach (Ritchie and Spencer., 1994), along with a rationale for its choice in this thesis, will now be considered.

3.1.2 Framework analysis explained

The Framework approach (Ritchie and Spencer, 1994) sits within a broad family of analytic methods frequently termed thematic or qualitative content analysis (Gale et al. 2013). Its use is appropriate when the aims and objectives of the research question are clearly identified and the researcher works with structured topic guides to elicit and manage data (Smith and Firth, 2011). These contrasts with mainly inductive approaches where the research is an iterative process developing as the research continues. A distinctive characteristic of the framework approach is the matrix output summarising data, which allows the researcher to systemically reduce the data in order to analyse by 'case' (referring to an individual participant) and 'code' (a descriptive label given to an excerpt of the raw data)(Gale et al. 2013). Comparing and

contrasting between individuals as well as within individual stories is a fundamental component of qualitative analysis and one that the Framework approach accounts for within its structure.

3.1.3 Rationale for the use of framework approach

The approach clearly details a step-by-step guide to the analyses of data making it easier when working within a multidisciplinary research team comprising several researchers. The framework approach was an appropriate choice within this thesis for several reasons; firstly, the data captured in study one and study three used semi structured interviews with participants. Secondly, both studies had clear aims and purpose from study outset. The transparent audit trail of data management and data reduction (Smith and Firth., 2011), a defining characteristic of the framework approach, ensures trustworthiness of the research undertaken. This would be further reinforced by the skills and experience of the research team overseeing the researcher as they have experience utilising this method in previous research. Finally, a crucial output of both studies is to advance knowledge, inform policy and develop practice which has been successfully observed in previous research (Staniford et al., 2011) and as a result the use of Framework approach (Ritchie and Spencer, 1994) is deemed appropriate for use in this thesis.

3.2 Study method

3.2.1 Sampling strategy

Given that the study aimed to explore adolescent experiences and their engagement with obesity treatment, a purposive sampling method was used. In light of the context, no set sample size was given at the outset but was determined by whether 'saturation' of themes was achieved (Glaser & Straus., 1967). Saturation is reached when different participants repeat the same subject matter, the same themes emerge and further interviews do not reveal further information (Glaser & Straus, 1967). Recognising this can be challenging, the team of researchers agreed when this has been fulfilled. The depth, range and the richness of data collected was considered more important than the actual number of participants in this study (Patton., 2002).

3.2.2 Procedures

National Health Service (NHS), ethics approval was granted (see Appendix 1). Twelve participants aged 11 – 16 years old (4 male 8 female) were recruited through attendance at community weight management programmes in South Yorkshire, UK. All weight management programmes involved in the recruitment for this study adhered to NICE guidance (NICE., 2006) and were delivered by multidisciplinary teams in community venues. Delivery incorporated healthy eating advice, varying degrees of behavioural change, physical activity advice and/or supervised physical activity sessions. Sessions were delivered by qualified lifestyle advisors, clinicians and physical activity specialists and can host up to 20-25 individuals in group-based sessions. Although, individual characteristics were not captured such as socio demographic information or weight status, to be eligible to attend all young people must be clinically overweight, above the 91st centile (Cole ,1999). For the purposes of anonymity all identifiable names have been removed.

Once informed consent form parents and adolescents (Appendix 2) had been obtained, the young people (n=12) took part in a semi structured, audio recorded, interview held with the lead researcher, either on their own (n=3), or in a small group with 2-3 other young people (3 groups). All adolescents were given the opportunity of having a parent present, although only one child requested this. All interviews and focus groups (n=12) were conducted at the time and venue of the weight management club with interviews lasting between 15 and 35 minutes. An interview guide was developed containing 12 open questions with prompts to support further exploration if needed (Appendix 3). This provided a deductive framework, where topics were identified from previous reviews of childhood and adolescent obesity treatment interventions along with consultations with key stakeholders involved in obesity management (Luttikhuis et al., 2009; Staniford et al., 2011). The guide included questions that focused on the exploration of the lived experiences of obesity, its physical and psychological impact and participant's experiences of engaging with community-based obesity treatments (Staniford et al, 2011). Adhering to this guide for all interviews ensured consistency, whilst remaining flexible to adapt with the emerging accounts of the young people. Recruitment was supported through strong links with community deliverers who helped promote the study.

3.2.3 Data analysis

All interviews were recorded and transcribed verbatim with all names and identifying information removed to preserve anonymity. The transcribed data were analysed using the framework method (Ritchie and Spencer, 1994) and the stages involved in this technique can be found in Table 5.0.

Table 5.0 - Stages of the framework analysis technique (Ritchie & Spencer, 1994)

Stage of analysis	Features of this phase
1. Familiarisation	Familiarisation with the data reading and re reading the transcripts.
2. Identify thematic framework	Key themes placed within a thematic framework and sorted hierarchically into main and sub themes.
3. Indexing/coding	Thematic framework is systematically applied to interview transcripts.
4. Charting	Chart displays laid out on thematic basis.
5. Mapping and Interpretation	Can now look for patterns and associations to search for explanation and meaning.

The framework analyses identifies commonalities and differences in qualitative data, before focusing on relationships between different parts of the data, thereby seeking to draw descriptive and/or explanatory conclusions clustered around themes (Gale et al. 2013). The technique was adopted for this study as it suits the data derived from semi structured interviews as well as the nature of the topic being discussed (Gale et al. 2013). To clearly present the process undertaken with the data here, a clear step-by-step guide, taken from Gale et al. (2013), was used to analyse the study findings. Tables detailing this analytical process can be found in Appendix 4.

3.3 Results *⁵

Results from the participant interviews are presented here in themes that emerged through the analysis process (Ritchie and Spencer., 1994).

3.3.1 Accounts about the determinants of obesity

Young people were asked to speak about their lives generally, and about hobbies and interests specifically to open the dialogue for the interview. Participants were asked to recall experiences of being overweight, with responses prompted, where appropriate, with questions about food, physical activity and lifestyle at home. All of the young people (n=12) volunteered reasons for being overweight, focusing on behaviours, which could be considered to be under their control, in-line with previous studies (Curtis 2008; Morinder et al., 2011). Some offered accounts that focused on the combination of physical activity and dietary components of their lifestyles, whilst others spoke of an association between their emotions and their food related practices.

“It’s not what I eat but the amount I eat. I’ll have my tea and I’ll go into the fridge and get a yogurt or something or a bag of crisps” [Boy aged 15 yrs]

Whilst young people initially referred to ‘simple’ reflections of an energy imbalance in their lifestyle, it became apparent as the conversation continued, that this often obscured a much more complex family and environmental context. In particular, many participants’ accounts were indicative of a problematic or disordered relationship with food, with many reporting that they ate as a response to upsetting events or particular social or familial cues. For example, some described eating because they felt sad, upset, anxious or bored, with a recognition that this behaviour contributed to their weight gain. Frequent allusions were made to patterns of weight cycling, weight loss and weight regain (this was also usually associated with unhappiness).

“I think one of the reasons why I probably, I comfort eat a lot and there’s like stuff going on, well used to be stuff going on at home which kind of like used to upset me a lot and I used to comfort eat” [Girl aged 15 yrs]

⁵ Findings from this study have been published - Reece, L. J., Bissell, P. and Copeland, R. J. (2015), ‘I just don’t want to get bullied anymore, then I can lead a normal life’; Insights into life as an obese adolescent and their views on obesity treatment. Health Expectations. doi: 10.1111/hex.12385

A strong finding was that young people discussed accounts of bullying and stigmatisation alongside their experiences of being obese.

"I've been bullied a lot, makes me feel sad and upset" [Girl aged 14 yrs]

The majority of young people (n=7) talked about being bullied by their peers, with many enduring name-calling and social torment.

"I used to get bullied a lot, and then when I got bullied I didn't eat, which made me put on more weight" [Boy aged 14 yrs]

There were numerous references to the negative impact of bullying on mood and emotions, with many talking openly about feeling sad, anxious and upset when bullying occurred. This reinforced feelings of low self-worth and low self-esteem.

"I used to get bullied because of my weight and I want to do something about it but I used to kind of like want because I was getting bullied, either wanting comfort food and that of like made it worse because it made me bigger, which made me get bullied"
[Girl aged 13 yrs]

None of the young people discussed seeking support for bullying, nor reported that their bullying situation had improved overtime. Most participants appeared to believe that if they lost weight and looked like their peers, they would not be bullied and would thus feel better.

"I just don't want to get bullied anymore, then I can lead a normal life" [Girl aged 16 yrs]

These accounts of being bullied appeared to act as a motivator to change and attend services, driven by the belief that the bullying would stop (n=3). This is compounded by a strong sense of wanting to 'fit in' and be 'normal', rather than health-related concerns.

"I want to play with friends, get more out of breath and be the same as everyone else"
[Girl aged 13 yrs]

"I just don't want to get bullied anymore, and then like I cannot get picked on and then I can just do a normal life without getting stared at or something" [Girl aged 13 yrs]

This drive to be socially accepted was not articulated in a desire to look a certain way but through a need to fit in, to be like their peers, to be involved with activities they were doing, and to cease the experience of being isolated and socially withdrawn. In contrast to some other studies (Lachal et al. 2011) the young people interviewed here recognised the negative impact of excess weight on their physical health (n=8), with one individual even considering the impact on her future health.

"I'm not exactly happy with my appearance, and also because of health issues. I don't want to die of something to do with my weight, and I want to live like a nice long life basically" [Girl aged 16 yrs]

"So it doesn't affect your life when you're older, like with all health problems and that" [Boy aged 14 yrs]

3.3.2 Experiences with obesity treatment

Despite the young people talking freely about wanting to change, the scale of the challenge and concerns about how to maintain change were perceived as daunting.

"You want to lose as much weight as your can but it's like an on-going process" [Girl aged 16 yrs]

Interviews highlighted uncertainty about how to change health practices, with this extending to a lack of awareness from their parents too. Given the important role parents play in supporting young people to change, this finding has implications and requires further exploration beyond the scope of this study.

"You want to change and as much as people were being horrible, it's like, I didn't really know how to deal with [it] nor did my mum either" [Girl aged 13yrs]

A strong consensus emerged that primary support for weight loss came from the facilitators and peers involved with the weight management programme, with all young people commending the support they received (n=12). All reported receiving concise messages regarding lifestyle changes during treatment.

"It were like activities and stuff, like trying to get you active, trying to change your food portions, swap like junk food for fruit and stuff"[Boy aged 15yrs]

"They [weight management programme] encouraged me to do more sports, but I liked joining [weight management programme] you get information to help you cut down what you eat and also portion sizes, and they do activities for you as well"[Boy aged 15yrs]

One of the most important findings from the study was that young people emphasised the importance of social support, embracing the opportunity to build peer relationships and valued these highly during the treatment programme (n=8).

"Everyone bonds, its like its new. It's weird but everyone becomes really close" [Girl aged 13 yrs]

Insight from the young people in this study consistently attributed successful weight loss to the professional support they had received during treatment. Some even described the experience as a significant event in their life (n=6).

"Yeah, but then because it [weight management programme] stops after a bit doesn't it, then I just like, fell back into what I was doing before, because it were only like, I can't remember how long it were but it were short and I just fell back into what I were doing before"[Boy aged 15 yrs]

"Well before I started coming to [weight management programme] and everything I weren't too happy with the way I were, but then I came here and it were alright and I got better" [Girl aged 15 yrs]

"It's all been good and it's all helped, they've taught us everything we need to know and then it's just like us going out and doing it for ourselves"[Boy aged 16 yrs]

The biggest challenge expressed by young people was the perceived and actual difficulty in maintaining lifestyle changes when they had returned into their home environments, post treatment. Continued support and follow-up were specifically recommended by participants (n=5) longer-term. This reference to the familial home-based environment is a recurrent theme throughout the adolescent accounts. This is supported by previous research with overweight and obese children and adolescents (Murtagh et al.2006; Staniford et al., 2011).

"I think if you just leave it I think that when you fall by the wayside. I think you've got to keep coming on a regular basis so that you're, you know, you're thinking about it all the time"[Boy aged 14 yrs]

"It's not short term, I mean you do your six weeks and then that's it but it takes more than six weeks, it's a lifetime thing isn't it"[Girl aged 15 yrs]

Young people also recognised the challenges with providing longer-term support from a resource perspective within healthcare settings but believed that this was needed for successful weight loss.

3.3.3 Awareness and beliefs around alterative treatment approaches

Several young people had a general awareness of alternative treatment's referring to stories shared by people they knew or from magazines and the media (n=10). Medication and bariatric surgery were mentioned briefly (n=6) yet participants displayed only limited awareness about what the treatments entailed. This perhaps reflects the widespread adoption of the notion of personal responsibility for weight-status, weight shaming and the young people felt using these methods represented a form of 'cheating' and that they would prefer to do it (weight loss) for themselves (n=3).

"I wouldn't do it. If you're going to lose weight you might as well do it to yourself not for other people. It's just cheating yourself" [Girl aged 15 yrs]

"Sometimes they [obesity medication] don't work so there's no point in taking them. I'd rather do the work for myself so be proud of myself than taking tablets" [Boy aged 15 yrs]

"I think she's [mum] had to like to get to a point where it's like you can't go back yourself and people do sometimes need surgery" [Girl aged 14 yrs]

Discussing the availability of treatment, there was strong agreement that treatments tailored to this age group were limited (n=6).

"I don't think there is anything really for them to, you know, join into and, you know, there's no support there really at all" [Girl aged 15 yrs]

"Not really. Not for like people our age, maybe older like Weight Watchers and stuff like that, but not for young people" [Girl aged 15 yrs]

Although there was an awareness of other potential treatments, young people perceived a treatment gap targeting their age group. Further exploration is needed to capture their perspectives on more invasive treatment methods.

3.4 Discussion

The aim of this study was to explore adolescent experiences of living with obesity and their engagement with obesity treatments. The discussion is structured around a number of key issues that emerged from the findings.

3.4.1 Perspectives on weight management

3.4.1.1 Individual attribution to weight gain

The young people in this study provided detailed personal accounts about being overweight and obese. Examples of disordered dietary patterns; overeating and eating as a response to emotions such as boredom and sadness, were reported as contributors to weight status. Often these were described as being the outcome of social and emotional factors, in particular - the experience of bullying. This is in agreement with previous findings (Thomas et al. 2008) where comfort and stress, along with mental health issues, were described by young people as contributing factors to their obesity. One of the major findings of the study was an overwhelming attribution of self-blame and responsibility for being overweight or obese amongst these young people to themselves, mirroring the widely held perceptions of a stigmatising social environment (Rees et al. 2014). Previous research has presented a picture of overweight and obese young people experiencing feelings of low self-esteem, low self-worth, loneliness and difficulty forming interpersonal relationships (Brighi et al. 2012) which when reinforced with feelings of blame and guilt seem only likely to exacerbate weight gain. Findings from this study also highlight the challenging nature of the lived experience of overweight and obese amongst young people and point to some of the long-term challenges associated with treatment, such as limited long-term support and failure to maintain weight loss post intervention (Whitlock et al., 2010; Smith et al., 2014). What is clear from this study is that programmes must consider the complex, lived experience of obese young people and their families (Wills

and Lawton 2014) in their design as well as considering how best to support them in long-term change. Focusing on building self-esteem, developing coping strategies for bullying and providing support to manage the broad context with which obese adolescents live within, such as the home environment (Wills and Lawton, 2014) and the broader social implications (Rees et al., 2014) appear necessary to successfully support positive healthful lifestyle change.

3.4.1.2 External attribution of successful weight loss

In the interviews, the focus of attention from young people in relation to treatment was on the professional support received from the weight management programme. Detailed accounts of knowledge gained from attending programmes were easily offered, with well-rehearsed lifestyle messages around physical activity and diet commonly heard. There was also a strong sense of awareness amongst the young people of what they *'should'* do to lose weight, and as reported earlier, attributions of self-blame. However, responsibility for successful weight loss and lifestyle change was attributed to the programme, as opposed to acknowledging their ownership and/or support offered from friends and family. This potentially diminished their engagement with the weight loss process and undermines the development of self-worth and esteem. There was also little to suggest that these young people had clear strategies on how to implement new practices into everyday life, especially when returning to their immediate family and social environments. This suggests, either, a strong emphasis of current programmes is on the *'what'* rather than the *'how'* of behaviour change, or that the internalisation of key messages had simply not occurred. The dependence on the treatment described here, supports this, potentially explaining why the maintenance of successful behaviour change is so challenging for these young people. It appears essential that treatment programmes consider the *'how'* as well as the *'what'* for obesity treatment in future.

3.4.2 Emotional and social aspects of obesity

Young people frequently described obesity in emotional terms using words such as sadness, upset and boredom. The family environment and bullying were explicitly offered as reasons contributing to overeating and food was used as a way of responding to, or managing these elements, often described as a source of comfort (Thomas et al., 2014). This reinforces the complex nature of obesity for these young

people and supports the need to integrate changes to the home environment within treatment programmes. Researchers (Watts et al., 2015) found adolescents struggled to make healthy choices at home and perceived many barriers to achieving this. The creation and maintenance of a supportive home environment requires consideration at multiple levels including parenting, relationships with siblings and modelling of appropriate practices and behaviours (Watts et al., 2015).

There is much evidence confirming that being overweight is a risk factor for bullying (Fox et al., 2006) having detrimental effects with respect to adolescents wellbeing (Griffiths et al. 2006) whilst also reinforcing a lack of social skill development, thus enhancing the probability of being bullied (Fox et al., 2006). Without doubt, the findings here highlight the significant impact of bullying on the life experiences of these young people, but also its power as a motivator for change. Although for many, this had not yet crystallised into sustained action at the level of health behaviours. Notwithstanding this, it is clear that the complex relationship between emotional upset, bullying, family dysfunction and weight gain require further longitudinal, qualitative studies to examine this relationship further (Fox et al., 2006).

3.4.3 Reasons to change

Feelings of dissatisfaction with body image and physical appearance, and negative experiences of being bullied were described as reasons for wanting to change, a finding also observed in a previous review (Lachal et al., 2013). This drive to avoid bullying and be socially accepted amongst their peers had acted as a catalyst for seeking obesity treatment among the young people interviewed here (although as we point out above, the internalisation of messages to change health behaviours were problematic). Once engaged in treatment, there was unequivocal agreement amongst the young people, that the experience of interacting with peers in a socially supportive context was enjoyable and conducive to losing weight. At one level, this reinforces looking at physical activity determinants (Thomas et al. 2008) and the importance of factors such as enjoyment and having fun as being crucial for success. It seems just as likely that this may have been one of the first times that these young people had been able to physically interact with their peers in a safe and supportive environment, and crucially one where they were not stigmatised or shamed for being overweight or obese.

3.4.4 Longer-term weight loss strategies

Engagement was often not the most difficult part of the change process. Instead, the real challenge appeared to be maintaining new behaviours, and integrating them into their broader social contexts, particularly where the family and social environment was not supportive. It was also commonly held view that the loss of professional weight management support would inhibit their ability to sustain new behaviours and also negatively shape their motivation and willingness to change. It is acknowledged that the evidence base identifying the key factors which enable adolescents to implement and maintain positive healthy behaviours is limited (Wright St Clair., 2008), and draws into question the effectiveness of strategies within existing weight management programmes. Treatment programmes may unintentionally foster dependence rather than creating autonomous individuals who have the 'life-skills' and emotional control to manage their behaviours and interact with their environment to achieve a healthy weight. Acknowledging the complex ways in which the broader family and social environment shapes adolescents health practices seems critical in maintaining long-term change, since a focus on individual characteristics and the mobilisation of personal resilience seem unlikely to be sufficient when viewed within the context of an increasingly obesogenic environment (Watts et al., 2015).

3.5 Summary of study findings

3.5.1 Key findings

In summary, adolescents provided detailed accounts of their perspectives on weight gain, alluding to disordered patterns of eating and overeating, reported as being triggered by social and emotional factors, and in particular, bullying. Avoidance of bullying and a desire to integrate socially with peers were key drivers to seek treatment. Young people reported what they '*should*' do to lose weight, yet responsibility for successful weight loss and lifestyle change was repeatedly attributed to the treatment received. The importance of the family and support networks was evident with a strong need to integrate the home based environment within the obesity treatment. Treatment programmes must consider the complex, lived experience of obese young people in their design, focusing on how to implement lifestyle changes in the long-term.

3.5.2 Implications for practice

Emerging findings from the study reinforced the complexity of living with obesity for adolescents today and the broad impact it had on their daily lifestyles, including social relationships, school life and family. It appears young people not only need to develop their own healthy patterns of behaviour but establish robust coping strategies to manage the social and cultural aspects of impact of obesity. Obese adolescents present to community weight management with complex issues including psychological distress; low self-esteem and reduced quality of life. The current delivery of programmes based upon evidence directed by NICE (2006) and broader research (Luttikhuis et al., 2009) are largely ineffective at inducing weight loss, but also are not tackling the root cause of obesity – which for many is layered within social, emotional and cultural aspects of their lives. The implications of the findings is that merely educating on energy balance could be counter-productive, and in actual fact programmes must be delivered that support young people to manage their emotions and develop strategies to interact and manage their environment effectively to lead healthy lifestyles of their choice. This infers the movement from a behavioural approach to an ‘Ecological model’ (Sallis, Own and Fisher., 2008) of delivery which would support the transfer of healthy behaviours learnt within obesity programmes back in the adolescent ‘real’ life.

The level of parental involvement within obesity interventions has received much attention (Janicke et al., 2014), with even adolescents identifying parents as key drivers for change (Lachal et al., 2013). Although the amount of parental time spent during an intervention and the targeting of adult specific behaviours has appeared unrelated to adolescent weight outcomes (Janicke et al., 2013), greater parent adherence to core behavioural strategies to address lifestyles within the home environment could be promising in terms of treatment adherence and longer-term health outcomes. Exploration into how family members are involved in the intervention in terms of setting goals for behaviour change, providing support and training in behaviour change techniques are needed (McLean et al., 2003).

As a result, community based programmes need to engage and develop adolescent specific obesity programmes, considering the family unit is at the core of its recommendations.

3.5.3 Implications for research

There remains an urgent need for research to identify active ingredients within treatment programmes and effective interventions that promote and sustain weight loss in obese adolescents and their families' longer-term. Given the limited understanding of obese adolescents as a cohort, especially in light of the findings in this study, identifying a vicious cycle of bullying and peer acceptance with negative health behaviours, requires deeper understanding. In relation to treatment, the high dropout rates within existing programmes requires further research with families and obese adolescents whom attended and later dropped out. The integration of the home environment and the roles of social networks are also of interest.

3.6 Study limitations

There are a number of limitations to this study that must be recognised. Although, the purposive sampling strategy used here was suitable, it is important to recognise it is a convenience. The sample were recruited through those actively engaged with a weight management club, and therefore does not capture the views of young people who had completed support, had dropped out or had never engaged with seeking support. The framework analysis approach (Ritchie and Spencer, 1994) adopted is popular amongst healthcare researchers, yet due to the openness within the analysis, the personal views and bias of the researchers could influence the codes that were applied, subsequently influencing the emerging themes and analysis. Control strategies were in place to promote trustworthiness of the research approach. An example of this includes a minimum of two researchers conducting the review process. If the study were to be conducted again the researcher could interview a larger sample perhaps attempting to collect data from adolescents no longer attending the weight management group. The interview guide could be piloted amongst a representative sample to ensure the measure was collecting all the appropriate information needed. The involvement of parents and guardians could have also offered further insight into the lived experience within the broader context of the adolescent lifestyle. Additional

characteristics of the young people could have also been collected such as demographic information.

**CHAPTER 4: DESIGN AND IMPLEMENTATION OF A PILOT STUDY: THE USE OF AN
INTRA-GASTRIC BALLOON AND A LIFESTYLE SUPPORT PROGRAMME TO PROMOTE
WEIGHT LOSS IN SEVERELY OBESE ADOLESCENTS (STUDY 2)**

4.0 Introduction

The literature review (Chapter 2) demonstrated that despite a plethora of research on childhood and adolescent obesity (Doyle et al., 2008) studies frequently consider children and adolescents as a collective group with little differentiation across the classifications of obesity. This makes it difficult to determine adolescent-specific outcomes and highlights a lack of appreciation of the needs of severely obese individuals (Steinbeck et al. 2009). The scoping review (Chapter 2) identified where treatment was focused on severely obese (>99.6th percentile) adolescents (aged 10-19 years) there was a shift towards the use of invasive treatment options (bariatric surgery), which had limited long term follow-up and remained a fairly new and under researched treatment option (Sachdev et al., 2014). An apparent reluctance from health care professionals to refer adolescents for bariatric surgery due to concerns about complications and a lack of belief in the appropriateness of the procedure (Woolford et al., 2010), also resulted in most healthcare professionals waiting until 18 years before making an official referral to surgical specialists (Vanguri et al., 2014). NICE (2014) guidance recommends the use of multidisciplinary lifestyle programmes across all classifications of obesity treatment, yet the scoping review identified that interventions rarely report the theoretical underpinning, nor do they offer sufficient detail on programme content or the behaviour change strategies implemented. This makes any judgement on why the intervention was effective or drawing comparisons between studies, extremely challenging.

An overview of the qualitative literature pertaining to the experiences of obese adolescents demonstrated adolescents rarely engage and sustain their engagement with, obesity services resulting in failure to lose weight and maintain weight losses longer-term. Extending this knowledge further, findings from the qualitative research study (Chapter 3; Study 1) highlighted the complex lives of obese adolescents and how the impact of obesity was evident across social, emotional, behavioural and cultural contexts. Being obese during adolescence has a strong negative impact on

psychosocial wellbeing and emotional health along with an increased likelihood of bullying (Chapter 2). Combined these factors act as significant barriers in seeking and adhering to obesity treatment (Smith et al., 2014).

Findings from Chapter 2 and Chapter 3 collectively highlight the need for an adolescent specific, theoretically underpinned, novel treatment approach to bridge the gap between ineffective multidisciplinary treatments and bariatric surgery. In response the following Chapter will detail the rationale, design, implementation and evaluation of a pilot obesity intervention specifically tailored for severely obese adolescents and their families.

4.1 Novel treatment approaches for severely obese adolescents

A finding from the scoping review (Chapter 2) was that severely obese adolescents were often being considered for pharmacotherapy or bariatric surgery (NICE, 2006) yet its use remains contentious (Woolford et al., 2002) and under researched (Sachdev et al., 2014). With treatment paradigms entrenched in facilitating lifestyle change (Chapter 1 and Chapter 2), novel treatments that combine multidisciplinary lifestyle intervention (NICE, 2014) with a less invasive treatment (compared with bariatric surgery) such as a temporary aid are warranted. One such strategy is the use of Intra-Gastric Balloons as an adjunct to a lifestyle behavioural support programme.

4.1.1 Intra-gastric balloons (IGB)

Intra-gastric balloons (IGB) were first proposed as an aid for weight loss in adults more than 20 years ago (Imaz et al., 2008). Its primary objective was for the treatment of obese patients who had exhausted all clinical treatment options, other than bariatric surgery (Fernandes et al., 2007). The 1980's generation of air balloons reported many complications and placement problems that led to a new generation of fluid filled balloons (Imaz et al., 2008) namely the BioEnterics Intra-gastric Balloon (BIB®), introduced in 1991. Since then, Bioenterics fluid-filled balloons (BIB), a spherical elastic balloon of silicone filled with between 400 and 700 ml of saline solution has been used (Imaz et al. 2008). It works to induce satiety by reducing the stomach capacity, thereby reducing food intake and encouraging weight loss amongst obese populations. Patients undergoing insertion of an IGB can consume a 'normal' diet (Fernandes et al., 2007). IGB insertion and removal are performed under conscious sedation or general

anaesthesia carrying less risk than bariatric surgery (Dumonceau 2008). Therefore, the intra - gastric balloon (IGB) offers an attractive intermediate option between pharmacotherapy and bariatric surgery for younger obese patients (Dumonceau, 2008). The Orbera balloon has become the most widely used and studied IGB (Chuttani et al., 2015).

Adverse side effects can be associated with the procedure with patients needing clinical supervision throughout. Oesophageal injury and vomiting are possible due to balloon slippage. Absolute contraindications for the procedure involve a hiatus hernia and abnormalities of the pharynx or oesophagus (Fernandes et al., 2007). Significant nausea, vomiting and discomfort were typically experienced in the early insertion period (Brooks et al. 2007).

4.1.2 Effectiveness of an intra-gastric balloon to promote weight loss in adults

Previous reviews of surgical treatment options for obese adults (Colquitt et al. 2003) did not include the use of an intra-gastric balloon due to study quality and criterion set, resulting in a separate review of its use by Fernandes et al. (2007). The review highlighted that due to heterogeneous and partially incomplete data, no conclusion could be made in relation to effectiveness of an IGB compared with conventional treatment. A systematic review in obese adults by Dumonceau (2008), (4877 patients, 30 studies, 18 prospective) found the mean weight loss was 17.8 kg, ranging from 4.9 kg to 28.5 kg, in specific studies with change in BMI of 4.0 - 9.0 kg/m². A separate meta-analysis by Imaz et al. (2008) (pooled data - 15 studies, 3600 patients) suggested that at 6 months average weight loss was 14.7 kg, representing a loss of 32.1% of excess weight and a change in BMI of 5.7. Consistently, high incidences of nausea and vomiting were experienced in early days of balloon placement (Sallet et al. 2004) yet severe complications were minimal (Dumonceau 2008). Looking at weight loss maintenance, Chuttani et al. (2015) found an average weight loss at 6 and 12 months after Orbera balloon removal was 113.1 kg (average loss of 15.9 kg) and 96.8 kg (average loss of 8.7 kg), respectively. This data indicates that, on average, 52% of the weight lost during Orbera balloon therapy was sustained 12 months after Orbera balloon removal. Generally the balloon was safe, albeit management of initial side effects, with the IGB effective in promoting short term weight loss (Dumonceau 2008).

Also, strong evidence suggests weight loss improves co-morbidities in obese adults (Dumonceau 2008). Such weight loss data, presents a strong rationale for its use in light of its highly clinically significance and its ability to substantially reduce health related complications (Imax et al. 2000).

4.1.3 Rationale for use of intra-gastric balloon treatment in severely obese adolescents

Adolescents have been included in some studies assessing the use of an IGB (Vandenplas et al., 1999; Sallet et al., 2004), yet their outcomes are rarely separated from other patients (Dumoncea 2008). It is because of this lack of focus on adolescents and the dates with which the interventions occurred, that these studies were not included in the scoping review in Chapter 2. A study by Vandenplas et al., (1999) demonstrated a transient beneficial effect with a positive reduction in BMI at 3 month yet this was only identified in five adolescents and was not maintained. In Sallet et al. (2004) study 483 adolescents received an intra-gastric balloon, with 250 patients at 6 month follow-up showing a global weight reduction from baseline BMI of $38.2 \text{ kg/m}^2 \pm 9.4$ to 6-month BMI of $32.9 \text{ kg/m}^2 \pm 8.3$, with a significant reductions in weight status, $15.2 \pm 10.5 \text{ kg}$ (Sallet et al., 2004). Sallet et al. (2004) concluded, in contrast to Vandenplas et al. (1999), that obese adolescents who had failed clinical treatment could be a promising target group for the intra-gastric balloon, because the shorter duration of obesity allowing them the greater possibility for change (Sallet et al., 2004). Neither study reported the inclusion of a multidisciplinary lifestyle programme.

4.1.4 Current UK management of severely obese adolescents

Bariatric surgery for severe obesity in adolescents is undoubtedly efficacious but its use remains controversial (Wright and Wales, 2016). NICE makes provision within its guidance for consideration of obesity surgery in adolescents in exceptional circumstances. NHS England is currently examining the commissioning of tier 4 bariatric services for adolescents (Wright and Wales, 2016) but while there are no formally commissioned services, several UK centres offer surgery in exceptional circumstances. Intra-gastric balloons are not routinely used due to a lack of evidence in the severely obese adolescent population.

4.2 Summary

The use of an intra-gastric balloon is tested and safe in obese adults, offering a minimally invasive, temporary option for severely obese adolescents whom have exhausted all clinical treatment options. The inclusion of a multidisciplinary lifestyle programme, alongside a temporary aid like an IGB, that focuses on behavioural change (drawing from the learning in Chapter 2) is needed as current studies looking at the use of IGB in adolescents and adults has not consistently reported this (Dumonceau et al., 2008). In light of the scarcity of data in severely obese adolescents, pilot studies that explore the feasibility and safety of using an IGB alongside a multidisciplinary lifestyle programme with severely obese adolescents are warranted.

4.3 Study 2 aims

This pilot study aims to explore the use of an intra-gastric balloon alongside a multidisciplinary lifestyle programme to promote weight loss and behaviour change in severely obese adolescents. In light of the findings from the scoping review (Chapter 2), the multidisciplinary programme will explicitly detail the delivery protocol against the theoretical underpinning. The outcomes of the pilot study will include weight loss and BMI Z score change whilst also assessing Quality of Life, Self-esteem and the perceived competence to maintain lifestyle behaviours longer-term (Diet, Physical Activity, Cardio-respiratory Fitness). The study will be family focused to explore the role the home-based environment and families play within the treatment programme (Chapter 2).

4.4 Method

4.4.1 Study design

Severely obese adolescents attending the paediatric weight management clinic at Sheffield Children's Hospital were invited to attend focus groups during the design phase of the study. Two patients (aged 13 & 17 and 3 parents - who between them had experience of IGB & bariatric surgery) collaborated on study design. Randomisation or the use of a control group was not acceptable due to the participant group clearly stating '*there was nothing in a control study for them*'. A lack of a control group does make assessments of effectiveness against usual treatment care a

challenge. A sham procedure control group was discussed but was not ethically acceptable to patients and clinicians and was therefore dismissed. The benefit of conducting a pilot study allows researchers to assess whether the intervention can be successful and if the intervention protocol designed is realistic. It also helps establish if the appropriate recruitment strategies are in place, the intervention content is appropriate and the duration of the programme is optimal & setting feasible. Ultimately it allows the researcher to identify whether it would be feasible to conduct the intervention on a larger scale (Thabane et al., 2010).

With all this in mind, a pilot study was the most appropriate approach to explore the use of the intra-gastric balloon and multidisciplinary lifestyle support programme with severely obese adolescents and their families. The study was entitled Balloons in Obesity – BOB. BOB was conducted as an open non-randomised pilot study.

4.4.2 Sample size

The sample size (n=12) was selected as the optimal size for a pilot study (Julious, 2005), balancing the requirements of obtaining data on potential outcomes, and recruitment, with the number of individuals receiving an unproven treatment modality (Julious, 2005).

4.4.3 Ethical approval

Significant public and patient involvement was sought during the project development. Full ethical approval for this study was obtained from the NHS Sheffield research ethics committee (Appendix 6). Written informed consent was required from all participants and their parents prior to commencing the study (appendix 7).

4.4.3.1 Ethical considerations; Risks and potential burdens

Possible risks associated with the intra-gastric balloon include:

1) Intestinal obstruction (seen in about 1 of 1000 patients) by the intra-gastric balloon which could need removal surgically or endoscopically. This has only been noted in patients with previous bowel surgery and as a result was a specific exclusion criterion in the study. The key risk resulting from this is a serious adverse event such as gastric perforation, which could conceivably result in death. The mortality rate for intra-gastric balloons is 0.07%, which is much lower than the 0.5-1% for bariatric surgery.

2) Injury to the digestive tract during placement of the intra-gastric balloon. To minimise the risks associated with balloon placement and removal, experienced paediatric gastroenterologists and anaesthetists carried out the procedure.

3) Gastric discomfort, feelings of nausea and vomiting and heaviness in the abdomen (which are quite common after balloon placement as the digestive system adjusts to the presence of the balloon) were described in the information leaflets and symptoms given to participants with appropriate medications.

4) Gastroesophageal reflux disease was treated with oral medication. The participants were prescribed a proton pump inhibitor during the 6 months the balloon is in situ as per advice from the gastroenterologists.

6) Intra-gastric balloon deflation - Sometimes the balloon can deflate early (hunger, weight gain and loss of satiety will be some of the signs) and usually would pass right through and come out in stool. Very occasionally, early removal could be needed with replacement of the balloon is possible.

7) Other problems; ulcers (1 in 1000) and inflammation of the lining of the oesophagus (oesophagitis, 2 in 1000) were treated with oral medicines. The contraindications and cautions related to balloon use were adhered to diligently and a 24-hour contact from the research team will be provided to the participant in case of any concerns/queries while the balloon is in situ. Signs and symptoms of complications will be made clear verbally as well as in the participant information leaflets.

4.4.4 Participant eligibility

Participants were recruited according to the following inclusion criteria: (1) Clinically severely obese (BMI > 99.6th percentile; BMI Z score > 3.5); 2) Adolescent aged 13 – 16 years old (3) had attained or nearly attained adult stature and stage 4 pubertal development; (4) Have previously attempted weight loss through a structured management programme (5) Able to attend weekly sessions with researchers in Sheffield and capable of adhering to the lifestyle changes advised, assessed by the multidisciplinary research team.

Exclusion criteria were as follows: (1) previous oesophageal or gastric surgery or history of intestinal obstruction; (2) history of inflammatory disease of the gastrointestinal tract such as oesophagitis, gastric or duodenal ulcers or congenital anomalies such as atresia's or stenosis; (3) Hiatus hernia >5 cm (assessed at balloon insertion); (4) History of, or current significant psychological disorder (permission sought from lead care giver).

4.4.5 Participant recruitment

Severely obese adolescents and their families were recruited from the existing clinical population at Sheffield Children's Hospital (SCH) South Yorkshire, and other adjacent district general hospitals, in Nottingham, Manchester, Leeds, Liverpool and Hull. Additional recruitment was supported from local weight management programmes such as SHINE (Self Help Independence, Nutrition and Exercise), WATCH-IT with advertisements in the local press.

For patients recruited from the clinics at SCH, their health care team initially approached patients at the time of the study. For patients, who self-referred or responded to the adverts placed around the hospital, a doctor at SCH contacted them by phone call or email and arranged a meeting.

4.4.6 Study interventions

4.4.6.1 Research team

The BOB programme was delivered, by a multi-disciplinary team with the medical component of the study overseen by Consultant Paediatrician, delivered by research paediatrician, and the behavioural programme overseen by Chartered Psychologist and delivered by a Research Fellow. Details of the medical components of the programmes and biomedical outcomes are beyond the scope of this thesis.

4.4.6.2 Intra – gastric Balloon (IGB)

An intra-gastric balloon (ORBERA TM– inflated to 500-700ml) was placed in-situ endoscopically under general anaesthesia. The intra-gastric balloon remained in place for 6 months (in line with the intra-gastric balloon manufacturer's guidance) with monthly assessments by the research paediatrician and gastroenterologist to ensure correct balloon placement and provide routine medical check.

4.4.6.3 Lifestyle behavioural support intervention

4.4.6.3.1 Background to the BOB intervention design

The lifestyle programme was underpinned by recognised models of health-related behaviour change including the Transtheoretical model and Theory of Planned Behaviour (Prochaska and DiClemente., 1983; Ajzen 1991).An overview of the commonly used behaviour change theories can be found in Appendix 5. Previously efficacious behavioural change approaches with overweight and obese young people were also adhered to (Daley et al., 2006; Rudolf et al; Luttikhuis et al., 2009; NICE, 2014).

To achieve a person-centred approach, sessions were delivered in accordance within the spirit of Motivational Interviewing (MI) (Miller and Rollnick., 1991) a technique expressing empathy and adopting the key communication skills of OARS (open questions, affirmations, reflective listening and summaries). The research fellow delivering the intervention was trained to an advanced level in motivational interviewing. To promote self-efficacy and enhance the capacity of the adolescents to draw on their strengths, skills and capacities (NICE, 2007), the philosophy of solution-focused therapy was also adopted (DeShazer, 1985). This was alongside the processes of change described within the Transtheoretical Model (TTM) for behaviour change, providing a solid theoretical foundation (Prochaska & DiClemente, 1983; Prochaska, DiClemente, & Norcross, 1992). Furthermore, the lifestyle programme utilised a variety of commonly applied behaviour change techniques (Abraham and Michie, 2008; Michie et al., 2011) to enhance physical activity and diet-related behaviour.

A unique feature of the BOB intervention design was the explicit mapping of all the behaviour change techniques involved within the protocol. This was in response to the overwhelming call within the literature for the improvement of the specification of obesity treatment programmes (Michie et al., 2011). Techniques adopted the consistent terminology observed within the taxonomy of behaviour change for physical activity and healthy eating behaviours (Michie et al., 2011) and were built upon the existing evidence (Chapter 2) of obesity related programmes. In addition, examples highlighting when, where and how the specific techniques would be delivered throughout BOB programme are detailed in table 6.0.

4.4.6.3.2 Linking behavioural change techniques with theoretical mechanisms of change

Behaviour change techniques are observable and replicable components of an intervention aimed at influencing change. The explicit mapping of behaviour change techniques delivered within an intervention to a consistent framework enables the possibility of identifying the active ingredients within interventions (Mitchie et al, 2011). With that in mind, Dombrowski et al (2012) found the number of behaviour change techniques did not necessarily predict efficacy, but that having a theoretical basis did. Theories identify key constructs, relationships and underlying scientific explanations for how, when and why a change might occur. The importance of utilising theories for intervention design is clear (Craig et al., 2008), hence the strong theoretical underpinning within this study (Study 2). That said, whilst behaviour change techniques can provide consistencies for intervention delivery, the techniques themselves are not theory-driven. Mapping behaviour change techniques to the theoretical concepts however, could provide a more detailed understanding of the role behaviour change techniques play in initiating behaviour change within interventions (Mitchie et al, 2011). With this in mind, (although not a main aim of Study 2), Figure 2.0 attempts to map the behaviour change techniques delivered throughout BOB, to the theory of planned behaviour (Ajzen, 1991), which was used to underpin the intervention. In addition, the elements of programme design, such as the inclusion of the pre-intervention phase, which related to the processes of change inherent within the Transtheoretical model of change (Prochaska and DiClemente, 1983), are also explored in the narrative of the next section.

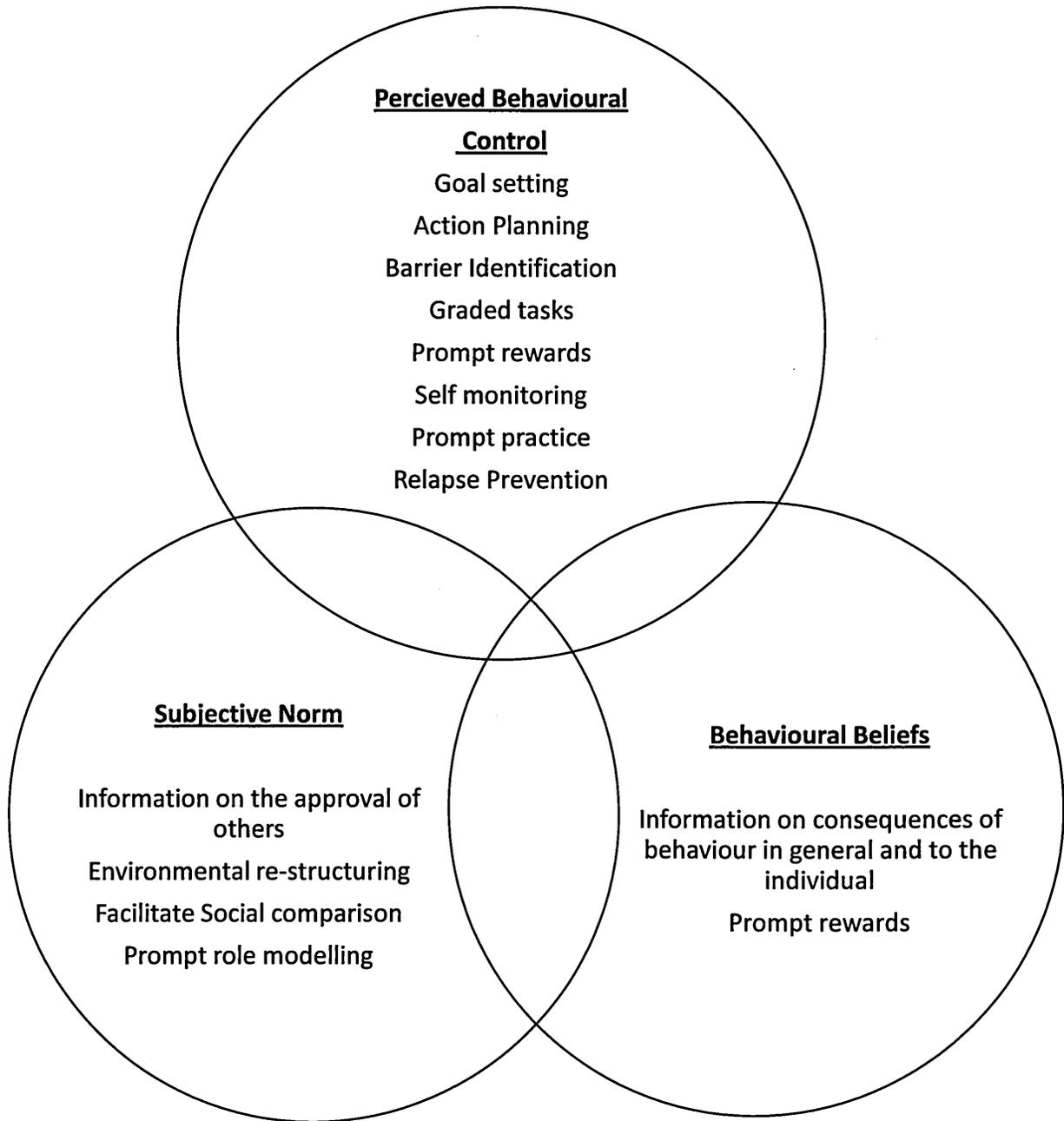


Figure 2.0 – Mapping of Behaviour change techniques to the Theory of Planned Behaviour

4.4.6.4 Overview of intervention

The primary aim of the lifestyle programme was to reduce weight and promote positive behaviour change. It also aimed to maintain these positive outcomes in the longer-term through encouraging young people and their families, to focus on achieving a healthy, active lifestyle as well as addressing emotional wellbeing. Integration of the home environment and family members were crucial in helping to identify and support progress. Therefore there was the option of 6 sessions that could be delivered in the families' home and local community (upon family request). The degree to which the family were engaged within the programme was decided upon a family-by-family basis. In line with clinical guidelines and current evidence (NICE, 2007; 2014; Luttikhuis et al. 2009) the multi component intervention included behaviour change strategies to increase families' physical activity, improve eating behaviour, and provides social support as well as supervised exercise sessions. Activities made links between thoughts and emotional responses that could affect an adolescent or family member's behaviour, all focused on enhancing the families' ability to cope and respond to everyday tasks in a healthy way, e.g. overcoming emotional eating (a behaviour observed in study 1).

Once recruited, families began a four-week preparatory phase prior to the intra-gastric balloon insertion, and then underwent six month weekly, lifestyle support, and an eight-week relapse prevention phase post-balloon removal. Follow-ups with both the paediatrician and research fellow took place at 6 and 12 months post-balloon removal (Figure 3.0).

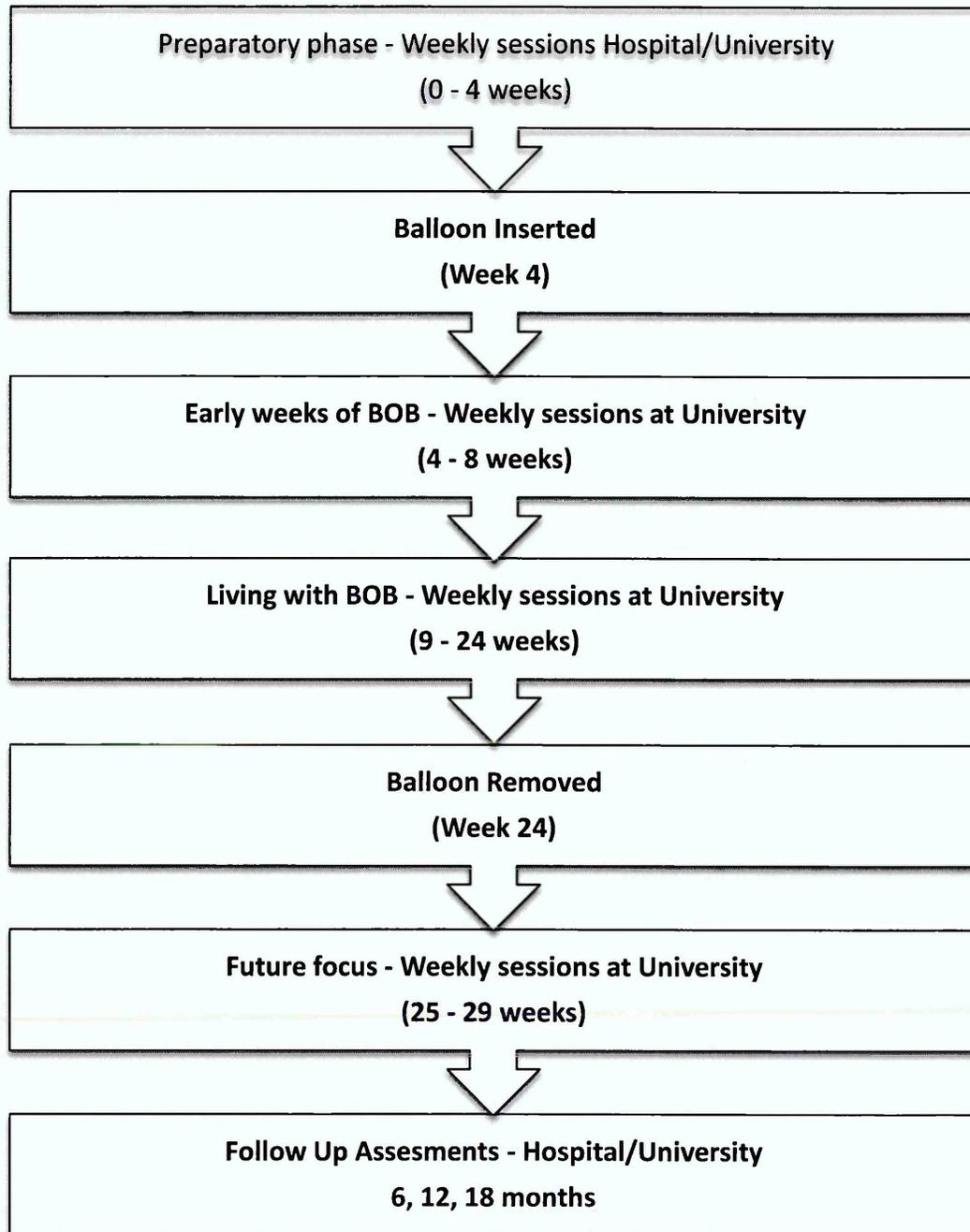


Figure 3.0 – Overview of lifestyle structure led by Research Fellow

4.4.6.4.1 Overview of session structure

Treatment sessions commenced with a review of the previous session from the previous week, *e.g. tell me three things that have gone well this week*, with a discussion of goal achievement and monitoring. The session material was then explored with the opportunity for discussion, questions and practice of the strategies learnt. Adolescents were encouraged to complete exercises (*e.g.*, identifying opportunities for physical activity, reading nutritional labels, problem solving) within the session and were then assisted to set their own goals (*e.g.*, walk part of the way to school, sit down as a family and plan the food shopping) utilising the strategies prior to the next session. Each treatment session ended with a summary of the session material and if agreed, an overview of the home tasks, *e.g.* keeping a food diary. Details of each stage are explained now.

4.4.6.4.2 'Pre-intervention' preparatory phase (0-4 weeks)

Once recruited and informed consent given, all families commenced the study by undergoing weekly sessions for four weeks. Familiarisation sessions involved a tour of the university and hospital facilities and sessions were allocated for the measurement of baseline assessments (further details given later in this section). The primary goal of this phase was to prepare the adolescent and their families for the intervention ahead, build rapport between the participants and research teams (Miller and Rollnick., 1993) and familiarise the participants with the intervention detail. This also ensured families were certain of their decision to participate, were fully aware of the implications of their decision and were happy to commit and sign the consent forms. Utilising the TTM, researchers could also establish the level of readiness of the family to change (Barlow et al. 2007), thereby assessing suitability for the intervention and could tailor session content accordingly.

The rationale for including a pre-intervention preparatory phase was that its inclusion has been shown as an effective way to increase social and cognitive constructs (Staniford et al., 2011), identified through the TTM processes of change, which have

potential to yield a greater effect in eliciting behavioural change through the subsequent intervention (Collins et al. 2004). In line with the process of change from the TTM (Prochaska and DiClemente., 1983) initial stages of the lifestyle programme focused initially on the cognitive elements of change focusing on the severely obese adolescent primarily, however familial engagement was also encouraged. This involved consciousness raising (increasing knowledge and awareness of current situation), an understanding of the impact of adolescents weight on daily life, thoughts and feelings, (environmental regulation and self-evaluation) and exploration of the negative consequences associated with continuing with current behaviours (Dramatic relief). Individuals can increasingly employ the processes of change in helping them progress through the stages of change; thus, cognitions change helping to successfully implement the chosen behaviours more frequently for example, those in the pre-contemplation stage are assumed to use fewer processes of change than those in any other stage.

Participant goals and expectations were also explored; *What would you like to achieve from the intervention; Tell me your main reasons for participating?* This information was collated to ensure the programme delivery was tailored for each adolescent and their family. This informed the nature of tailored support, logistical issues such as ideal days and times to hold the sessions and general '*ground rules*' for behaviour throughout the programme. For example giving prior warning should sessions need to be re-scheduled, being honest and the importance of listening to each other.

4.4.6.4.3 Balloon insertion (Week 4)

The medical team at Sheffield Children's Hospital predominantly led this stage of the intervention. Prior to the procedure, families were given the chance to ask questions and talk through the procedure as well as receiving a healthy eating booklet and information guides, developed by the research team in partnership with the research dietician. Families were offered information around potential side effects, adverse effects to look out for, emergency procedures should anything arise requiring medical attention and what to eat the few days' prior and post procedure. Physical activity was advised but only at a level – deemed 'low- normal' for each individual.

The intra-gastric balloon was inserted on week 4 of the BOB protocol by a gastroenterologist at Sheffield Children's Hospital. The procedure involved general anaesthetic and resulted in a one-night stay in hospital with close supervision by the medical staff. From a medical perspective, the focus for the following four weeks was optimising participant safety ensuring balloon placement was correct and offering weekly medical check-ups with associated appropriate tests.

4.4.6.4.4 Healthy eating advice (pre and post Intra-gastric balloon)

All participants and families received two, one-hour sessions with a specialist dietician. One session before the balloon was inserted to support participants from a full fluid diet through to the re-introduction of solid foods, and one session after the intra-gastric balloon was removed to reinforce the maintenance of reduced calories, portion size and encourage commitment to a healthy balanced diet. Under specialist circumstances participants could access dietetic support throughout the programme; however key healthy eating messages would underpin the weekly delivery of the lifestyle support programme content.

4.4.6.4.5 Early weeks of BOB (4-8 weeks)

The behavioural programme moved onto the *living with the balloon* phase, which provided further opportunities for rapport building between the research team and families, and progressed further with the cognitive elements of change (Prochaska and DiClemente., 1983). Insight into the adolescent's thoughts and feelings, as well as views towards their obesity and lifestyle, were re-visited from the pre-intervention preparatory phase in further detail. This conversation, or several conversations over several sessions depending on the individual and their families, was facilitated using a 'formulation sheet'. This tool helps to understand the way individuals views the world and therefore when embedded within a treatment programme results in a better engagement with therapy (Roth and Pilling., 2007).The focus here was on completion of the first element of the exercise which captures historical information and lists identified thoughts, emotions, physical sensations and behaviours. The predisposing factors, *why me*, focused on the adolescents perspective of factors which contributed to their obesity from a personal and contextual perspective. Precipitating factors, *why now*, helped give insight why the problem is occurring now with prompts about seeking treatment now, giving information about motivations, attitudes towards

treatment and even barriers for change. Protective factors, *what helps*, is positive in comparison with adolescents thinking through what attributes they have, support networks around them, as well factors for previous successes if applicable. Triggers relating to their unhealthy patterns, (as seen from Study 1) were also explored which offered invaluable insight into how the adolescents currently coped with negative situations, helping to inform treatment strategies within the maintenance phase later in the programme.

The longer-term programme aspirations and expectations were also re-visited from the preparatory phase in through detail. Once agreed, the steps needed to achieve this longer-term goal were discussed and subsequently informed the content of the weekly sessions. The rationale behind conducting this exercise was to understand the adolescent and families goals, to understand where they want to go and ensure the treatment supports them to get there. Goals are a fundamental principle of behaviour change (NICE, 2007) and cognitive behavioural therapy (Roth and Pilling., 2007). The young people were asked to identify a specific behaviour they wanted to change first, then applying the SMART (Specific, measurable, achievable, realistic and time limited) principle (Locke, 2000) produced a goal for the following week. Goals were owned by the individual and reviewed weekly with a discussion on their achievement and associated reasons for achieving or not achieving.

4.4.6.4.6 Living with BOB (9–20 weeks)

The remaining 5 months with the balloon inserted saw the continuation of the behavioural support programme but additionally, involved individuals and their families/friends doing structured physical activity within the university research facility. The rationale for undertaking supervised activity here was to build confidence and competency, within a safe environment for these severely obese adolescents in their ability to move. Many severely obese adolescents associate being active with a negative experience thus frequently avoid doing it. Therefore the rationale here was for the young people and their families to learn about their bodies, the way they move and feel when being active, gradually increasing intensity and duration over the weekly sessions. The researcher continually offered positive reinforcement, with praise given for achievement of tasks.

Participants, their families and friends (attendance was participant choice) were offered a range of aerobic exercise modalities including gym-based equipment (e.g. treadmills and bikes), outdoor activities such as walking, as well as the use of exercise DVD's. The exercise sessions were tailored to the individual, delivered in small bouts of no more than 10-minutes and were of moderate intensity, in line with Public Health England recommendations (Department of Health., 2011). During the sessions the rating of perceived exertion was measured using the pictorial children's effort rating table (PCERT) (Yelling et al., 2002). Participants were asked to point to how they feel the exertion compares against a 10-point scale; the higher the number the higher they perceive their effort. Sessions included family mini-games and self-referenced competitions to help motivate and build self-worth. These approaches have been shown to help build global self-worth and promote adherence to the intervention (Daley et al. 2006). Music was played throughout the sessions as every effort was made to make the sessions fun and enjoyable for all.

At a pace led by the individual, the behavioural support progressed from cognitive phases of change to combine behavioural focused techniques (Prochaska and DiClemente., 1983) aiming to facilitate the maintenance of change post intervention and in the longer-term. Goal setting was a core component each week and as the young people became more skilled in their use, ways they could optimise the achievement of such goals were explored. Ways to do this included; stimulus control (cues for action) tasks that prompt healthy behaviours, e.g. storing trainers by the backdoor in preparation for going for a walk; detailed action planning of what the person will do including, when, in which situation and/or where to act. 'When' may describe frequency (such as how many times a day/week or duration (e.g. for how long) and continual prompting of reflection and environmental re-evaluation, to ensure strategies are directive, moving towards the achievement of the long term goal – whatever that is for the individual.

A person's behaviour is not solely determined by the motivational variables of feasibility and desirability (Oettingen, Honig and Gollwitzer., 2000). The way people frame goals and how their goal pursuits are self-regulated are said to make an additional contribution (Gollwitzer, 2000). The formulation of implementation

intentions or 'what if' plans which make a link between an anticipated situations with a goal-directed behaviours, rather than the mere thinking about good opportunities to act, makes implementation intentions facilitate action (Oettingen, Honig and Gollwitzer., 2000). For example, *going for a walk after school is a good time to be active but if it is raining I won't want to go out so I will hula-hoop on the Wii fit for 20 minutes instead*. These skills were then practised, developed and enhanced over the weekly sessions with the aim of enhancing the resources available for the young people to promote and maintain positive behavioural change (NICE, 2007).

4.4.6.4.7 Intra-gastric balloon removal (Week 21)

Medical staff at Sheffield Children's hospital led this component of the programme, with the removal procedure conducted by the gastroenterologist. There were less risks associated with this, and no side effects so all patients went home the same day in all cases.

4.4.6.4.8 Post BOB (20-28 weeks)

To promote the maintenance of behaviours successfully implemented throughout the time the balloon was inserted; all participants were encouraged to continue to attend the weekly sessions at the university for a two-month maintenance phase. Home sessions were also available at this point upon request from families. Goal setting continued with the prompt review of progress. Reflection of progress over the course of the programme was also considered to help boost self-esteem and confidence in progress. Future action plans were re-visited to consider life back home without research support.

Table 6.0 – Mapping of behaviour change definitions and techniques to the BOB protocol (Michie et al. 2011)

Label	Definition	Sessions	Example from BOB
Provide information on consequences of behaviour in general	Information about the relationship between the behaviour and its possible or likely consequences <i>in the general case</i> , usually based on epidemiological data, and not personalised for the individual	Familiarisation, Weeks 1-4	The researcher will initiate discussions regarding the impact of obesity on general health and wellbeing.
Provide information on consequences of behaviour to the individual	Information about the <i>benefits and costs</i> of action or inaction to the individual or tailored to a relevant group-based on that individual's characteristics (i.e. demographics, clinical, behavioural or psychological information).	Familiarisation, Weeks 1-4	The researcher will initiate discussions regarding the impact of obesity on the young peoples and their families' personal context. This will include the benefits of losing weight to them personally, E.g. - more able to attend college and participate in activities like other students.
Provide information about others' approval	Involves information about what other people think about the target person's behaviour. It clarifies whether others will like, approving or disapproving of what the person is doing or will do.	Familiarisation, Weeks 1-4	Discuss with the participant how the opinions of family and friends might or might not change, as a result of making changes to their lifestyle as part of the BOB research study.
Provide normative information about others' behaviour	Involves providing information about what other people are <i>doing</i> i.e. indicates that a particular behaviour or sequence of behaviours is common or uncommon amongst the population or amongst a	Familiarisation, Weeks 1-2	Researcher will explain that other young people and families are experiencing similar consequences as a result of their weight, and making lifestyle changes is also something others find difficult.

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Label	Definition	Sessions	Example from BOB
Goal setting (behaviour)	<p>specified group</p> <p>The person is encouraged to make a behavioural resolution (e.g. take more exercise next week). This is directed towards encouraging people to decide to change or maintain change.</p>	Weeks 6 - 24	<p>Researchers ask the young people to identify a specific behaviour that they plan to make changes to. E.g. walking home from school on 2 days a week. The SMART principle to goal setting will be applied here (Locke, 2000).</p>
Goal setting (outcome)	<p>The person is encouraged to set a general goal that can be achieved by behavioural means but is not defined in terms of behaviour (e.g. to reduce blood pressure or lose/maintain weight), as opposed to a goal based on changing behaviour as such.</p>	Weeks 5, 6	<p>The researcher will explore with the young people general outcomes that they would like to achieve at the end of the project. Thought will be given to what they want to look like, how they feel about this and if they consider it realistic. i.e. - weight losses, fit in specific dress size, and wear a certain outfit.</p>
Action planning	<p>Involves detailed planning of what the person will do including, as a minimum, when, in which situation and/or where to act. 'When' may describe frequency (such as how many times a day/week or duration (e.g. for how long).</p>	Weeks 4-24	<p>The researcher will develop with the young person action plans to implement new behaviours. This will follow the 'if then' principle (Gollwitzer, 1999) and SMART goal setting. i.e. - if I am having a sad day - will telephone a friend.</p>
Barrier identification/problem solving	<p>This presumes having formed an initial plan to change behaviour. The person is prompted to think about potential barriers</p>	Weeks 12 - 24, follow-ups 6mth, 12mths, 18mths	<p>Young people will be supported to consider how life events, daily activities, emotions, might affect their ability to</p>

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Label	Definition	Sessions	Example from BOB
Set graded tasks	<p>Breaking down the target behaviour into smaller easier to achieve tasks and enabling the person to build on small successes to achieve target behaviour. This may include incremental increases from baseline behaviour.</p>	<p>post balloon. On-going from weeks 9-24</p>	<p>perform their chosen goal. The researcher will elicit a list of potential barriers from the young person whilst exploring potential strategies to overcome these. The researcher will explore with the young people their expectations from engaging in the BOB study. From this, the researcher can work with the families to break down into small achievable goals, applying the SMART principle (Locke, 2000) that will build over time to achieve their desired outcome.</p>
Prompt review of behavioural goals	<p>Involves a review or analysis of the extent to which previously set <i>behavioural</i> goals (e.g. take more exercise next week) were achieved.</p>	<p>On-going weeks 9 - 24</p>	<p>The researcher will spend the start of each weekly session with the young person, discussing the progress made in relation to the young person's chosen behaviours. Achievement or failure of the goal will be explored with the participant adapting the goal in preparation for the following week.</p>
Prompt review of outcome goals	<p>Involves a review or analysis of the extent to which previously set <i>outcome</i> goals (e.g.</p>	<p>Weeks 1, 4, 4-8, 12, 16, 20, 24. 6mths,</p>	<p>Participant weight will be measured and recorded regularly along with waist and</p>

Table 6.0 – Mapping of behaviour change definitions and techniques to the BOB protocol (Michie et al. 2011)

Label	Definition	Sessions	Example from BOB
Prompt rewards contingent on effort or progress towards behaviour	to reduce blood pressure or lose/maintain weight) were achieved.	12mths and 18mths post	hip measurements. This result will then be discussed with the participant to gauge an understanding of satisfaction with progress and to support the participant with future goal setting.
Prompt rewards contingent on effort or progress towards behaviour	Involves the person using praise or rewards for attempts at achieving a behavioural goal.	On-going weeks 9 - 24	The researcher will continuously provide praise and positive affirmations when participants successfully attempt and achieve behavioural goals they have set. The family are also encouraged to provide praise throughout to support the young person's progress. Self-reward is encouraged during the weekly sessions.
Provide rewards contingent on successful behaviour	Reinforcing successful performance of the specific target behaviour. This can include praise and encouragement as well as material rewards but the reward/incentive must be explicitly linked to the achievement of the specific target behaviour i.e. the person receives the reward if they perform the specified behaviour but not if they do not perform the behaviour.	Week 25	The researcher will praise and offer positive affirmations for lifestyle changes the young person and their families achieve. A free pass to a local gym will be offered as a reward for completing the physical activity sessions during BOB, acting as an incentive to maintain the physical activity.
Shaping	Contingent rewards are first provided for	Weeks 9 -24	Any attempts made by the young people

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Label	Definition	Sessions	Example from BOB
	<p>any approximation to the target behaviour e.g. for any increase in physical activity. Then, later, only a more demanding performance, e.g. brisk walking for 10 min on 3 days a week would be rewarded. Thus, this is graded use of contingent rewards over time.</p>		<p>and their families' to be more physically active will be reinforced positively by the researcher. Throughout the programme praise will be given when this intensity of behaviour is increased. For example, during early gym session's families will be praised when completing 2 minutes on the treadmill at 1% incline at a steady pace. Towards the latter stages, this praise would be given when completing 20 minutes a 2% at gradient at a brisk pace. A free pass to a local gym will also be offered at the end of the project for successful completion.</p>
<p>Prompting generalisation of a target behaviour</p>	<p>Once behaviour is performed in a particular situation, the person is encouraged or helped to try the behaviour in another situation. The idea is to ensure that the behaviour is not tied to one situation but becomes a more integrated part of the person's life that can be performed at a variety of different times and in a variety of contexts.</p>	<p>Weeks 9-16</p>	<p>The researcher will elicit from the young person situations where they are finding it difficult to adopt their desired behaviour yet have been successful at other times, e.g. eating lunch at school. Potential strategies to overcome this will then be explored.</p>
<p>Prompt self-monitoring</p>	<p>The person is asked to keep a record of</p>	<p>Weeks 9 -24</p>	<p>The researcher will share self-monitoring</p>

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Label	Definition	Sessions	Example from BOB
of behaviour	specified behaviour(s) as a method for changing behaviour. This should be an explicitly stated intervention component, as opposed to occurring as part of completing measures for research purposes. This could e.g. take the form of a diary or completing a questionnaire about their behaviour, in terms of type, frequency, duration and/or intensity.		techniques, such as a food diary or exercise diary, with the young person/families. The researcher will then ask the young person to explore the drawbacks and benefits of their use to support them in achieving their desired outcomes.
Prompt self-monitoring of behavioural outcome	The person is asked to keep a record of specified measures expected to be influenced by the behaviour change, e.g. blood pressure, blood glucose, weight loss, physical fitness.	Week 4 – 8, 9 – 12, 16 – 20, 20-24,	The researcher will encourage the young people to monitor their desired outcomes, e.g. weight loss, through the use of pre and post photographs and clothes size.
Prompting focus on past success	Involves instructing the person to think about or list previous successes in performing the behaviour (or parts of it).	Weeks 1-4, 4-8	Young people are asked to consider what has helped them achieve their desired outcomes in the past, and how this could inform helpful strategies within BOB.
Provide feedback on performance	This involves providing the participant with data about their own recorded behaviour	Weeks 4 - 8, 12, 16, 20, 24. 6mths, 12mths and 18mths post	The researcher will give the results of tests to the young person/family and elicit feedback on results from the participant.
Provide information on	Involves telling the person about when and	Week 20 - 24	Families are given information about local

Table 6.0 – Mapping of behaviour change definitions and techniques to the BOB protocol (Michie et al. 2011)

Label	Definition	Sessions	Example from BOB
where and when to perform the behaviour	where they might be able to perform the behaviour		facilities to be active, encouraging them to move more outside of their BOB sessions.
Provide instruction on how to perform the behaviour	Involves <i>telling</i> the person <i>how</i> to perform behaviour or preparatory behaviours, either verbally or in written form.	Weeks 9 -20	The researcher will offer advice on suitable clothes to wear for the supervised physical activity sessions and essentials to bring. The researcher instructs how to use the gym equipment safely as well as how to perform body weight exercises safely.
Model/Demonstrate the behaviour	Involves <i>showing</i> the person how to perform a behaviour	Weeks 9 - 20	The researcher will provide demonstrations on how to use the gym equipment and perform certain physical movements effectively allowing the participant to observe and ask questions if needed, before attempting to perform the movement themselves.
Teach to use prompts/cues	The person is taught to identify environmental prompts, which can be used to <i>remind</i> them to perform the behaviour (or to perform an alternative, incompatible behaviour in the case of behaviours to be reduced).	Weeks 16-24	The researchers will facilitate a discussion asking the young person /family to consider their environment and identify strategies to help remind them to perform their desired behaviour. E.g. set an alert on their mobile phone to ensure the young person eats regularly

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Label	Definition	Sessions	Example from BOB
Environmental restructuring	<i>The person is prompted to alter the environment in ways so that it is more supportive of the target behaviour e.g. altering cues or reinforcers.</i>	Weeks 16 - 24	throughout the day. Families are encouraged to consider their home environment and identify ways this could be altered to support them to achieve a healthier lifestyle. E.g. Consideration given to availability of a table for the families to dine together.
Agree behavioural contract	Must involve written agreement on the performance of an explicitly specified behaviour so that there is a written record of the person's resolution witnessed by another.	Weeks 4,5	A psychological contract is drawn up between the researcher and the young person, witnessed by the family, outlining key principles all will commit to throughout the study.
Prompt practice	Prompt the person to rehearse and repeat the behaviour or preparatory behaviours numerous times. Note this will also include parts of the behaviour e.g. refusal skills in relation to unhealthy snacks.	Weeks 9-24	Young people will be asked to consider situations that they experience temptation to deviate from their desired behaviour or a situation where they find persisting with a given outcome difficult. The young person will elicit strategies to overcome this, which the researcher encourages them to practice regularly. E.g. distraction strategies such as phoning a friend, if they feel bored and are tempted to eat when they do not need to.

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Label	Definition	Sessions	Example from BOB
Use of follow-up prompts	Intervention components are gradually reduced in intensity, duration and frequency over time, e.g. letters or telephone calls instead of face to face and/or provided at longer time intervals.	Week 24, 6mths, 12mths, 18mths post balloon removal.	Weekly face to face sessions with the researcher will be reduced, with contact via telephone one month post-balloon removal. Face to face sessions will then only occur at follow-up appointments.
Facilitate social comparison	Involves explicitly drawing attention to others' performance to elicit comparisons.	On-going weeks 9 - 24 weeks	Researchers will draw on examples from other BOB families to encourage the individual to consider their progress not just individually, but also in comparison to other young people undergoing the same project.
Plan social support/social change	Involves prompting the person to plan how to elicit social support from other people to help him/her achieve their target behaviour/outcome. This will include support during interventions e.g. setting up a 'buddy' system or other forms of support and following the intervention including support provided by the individuals delivering the intervention, partner, friends and family.	Weeks 4 - 8	The researcher will encourage the young person to consider the support network around them, including family, friends, BOB research team, and what role they might play in supporting them in achieving their desired outcomes.
Prompt identification as role model/position advocate	Involves focusing on how the person may be an example to others and affect their behaviour, E.g. being a good example to	Weeks 9- 24	The young people/ families will be encouraged to talk about their experience of undergoing lifestyle changes to other

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Label	Definition	Sessions	Example from BOB
Prompt anticipated regret	<p>children. Also includes providing opportunities for participants to persuade others of the importance of adopting/changing the behaviour, for example, giving a talk or running a peer-led session.</p> <p>Involves inducing expectations of future regret about the performance or non-performance of behaviour. This includes focusing on how the person will <i>feel</i> in the future and specifically whether they will feel regret or feel sorry that they did or did not take a different course of action.</p>	Weeks 1-4, week	<p>BOB families. The young people will also be supported to offer peer support to their siblings/friends who could also require support in leading a healthier lifestyle.</p> <p>The short time frame of the BOB project (6months) will be outlined explicitly to all the young people/families. As a result, they will be encouraged to consider how they can optimise this time to support them in the short term as well as the longer-term. Throughout the project, the researcher will continuously encourage the individuals/families to consider how lifestyle changes made whilst on the project will be sustained over the longer-term after BOB.</p>
Fear arousal	Involves presentation of risk and/or mortality information relevant to the behaviour as emotive images designed to evoke a fearful response	Weeks 1-4	The risk associated with the insertion and removal procedure of the intra-Gastric balloon will be discussed, along with anaesthetic and mortality risk.

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Label	Definition	Sessions	Example from BOB
Prompt self-talk	Encourage the person to use talk to themselves (aloud or silently) before and during planned behaviours to encourage, support and maintain action.		The young people will be asked to think about challenging situations they could face day to day, and then they will be asked to develop motivational phrases which they can say to themselves to support them with carrying out their desired behaviour.
Prompt use of imagery	Teach the person to imagine successfully performing the behaviour or to imagine finding it easy to perform the behaviour, including component or easy versions of the behaviour.	Weeks 4-8	When discussing expectations of the BOB project, young people will be asked to visualise how they would like to look, clothes they would like to wear, and how they would like to feel at the end of the project.
Relapse prevention/coping planning	This relates to planning how to maintain behaviour that has been changed. The person is prompted to identify in advance, situations in which the changed behaviour may not be maintained and develop strategies to avoid or manage those situations.	Weeks 20-24, 6mths, 12mths, 18mths	Young people will be asked to consider which changes they have made during this study that they think they will struggle to continue with. Strategies will be then be developed to support these behaviours.
Stress management/emotional control training	This is a set of specific techniques (e.g. progressive relaxation) which do not target the behaviour directly but seek to reduce anxiety and stress to facilitate the	Weeks 9-24	The researcher will ask the young person to reflect on an experience where they have felt emotional and behaved in a way they did not want to. E.g. getting angry at

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Label	Definition	Sessions	Example from BOB
	<p>performance of the behaviour. It might also include techniques designed to reduce negative emotions or control mood or feelings that may interfere with performance of the behaviour, and/or to increase positive emotions that might help with the performance of the behaviour.</p>		<p>mealtimes with the family. The researcher will then teach the individual to take deep breaths to calm themselves down, allowing them time to think before they respond.</p>
Motivational interviewing	<p>This is a clinical method including a specific set of techniques involving prompting the person to engage in change talk in order to minimise resistance and resolve ambivalence to change (includes motivational counselling).</p>	<p>On-going throughout</p>	<p>The researcher draws on principles of Motivational Interviewing to deliver the intervention such as expressing empathy and being directive in conversations with the young people.</p>
Time management	<p>This includes any technique designed to teach a person how to manage their time in order to make time for the behaviour. These techniques are not directed towards performance of target behaviour but rather seek to facilitate it by freeing up times when it could be performed.</p>	<p>Week 9 - 12</p>	<p>Young people will be asked to outline their typical week detailing firm commitments, social commitments and anything else. This will facilitate a discussion that explores opportunities in the week to be physically active.</p>
General communication skills training	<p>This includes any technique directed at general communication skills but not directed towards a particular behaviour change.</p>	<p>Week 12-16</p>	<p>The researcher will discuss with the young person ways to express themselves better through communication. E.g. - educating young people on being assertive and able</p>

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Label	Definition	Sessions	Example from BOB
Stimulate anticipation of future rewards	Create anticipation of future rewards without necessarily reinforcing behaviour throughout the active period of the intervention. Code this technique when participants are told at the onset that they will be rewarded based on behavioural achievement.		to say 'No' when they don't want a big portion of food at mealtimes.
			The researcher will continually use praise and positive affirmation as a reward for achievement of a desired goal by the BOB individual/family. Free gym passes will be available for those families who successfully engage and complete the project.

4.4.7 Outcome measures

The primary outcome measure was change in body weight and BMI Z score at 12 months following adherence to the lifestyle programme for 9 months, and intra-gastric balloon insertion for 6 months. Change in body weight and BMI Z score at 6 months, intra-gastric balloon removal, were also assessed. Secondary outcomes assessed Paediatric health related quality of life, HRQoL (Varni et al. 2006), Theory of planned behaviour (Ajzen, 1991), Affect (Ebbeck and Weiss., 1998; Hagger, and Chatzisarantis, 2009), Children's physical and self-perceptions (Harter et al.1988; Raustrop et al., 2005), Self-reported physical activity (Kowalski et al.2007), Cardio-respiratory fitness (Kowalski et al., 2007) and adherence with the lifestyle programme. Further details are given in the next section.

4.4.8 Assessments

All assessments were conducted at baseline, four weeks prior to balloon insertion, balloon removal after 6 months, and 12-months, (6-months post balloon removal). A window of 2 weeks was given for the completion of all tests.

4.4.8.1 Anthropometrics

Weight was measured to the nearest 0.1kg using a balance scale. Height was measured using a wall-mounted stadiometer to the nearest 0.1cm. BMI was converted to z-scores based on the 1990 UK Growth Reference curves (Cole 1990), see Appendix 8, with a standard deviation >3.5 classified as severely obese. All participants were classified severely obese. A BMI SDS (also referred to as BMI z-score) represents how many units of the standard deviation a child's BMI is from the mean for their age and sex, and thus accounts for changes in age from baseline.

4.4.8.2 Psychosocial Measures

4.4.8.2.1 Health Related Quality of Life (HRQoL) (Varni, 2006)

Adolescent self-reported HRQoL using the Pediatric quality of life inventory, PedsQL, 4.0 generic modules (Varni, 2006) for 13-18 year olds was used. The inventory has been widely used with its feasibility, reliability, and validity strongly tested in this population (Varni, Seid, Kurtin, 2001). A global score consisting of all 23 items was reported as a total score, with a psychosocial summary score combining all 15 items

assessing emotional (“*I feel sad*”), social (“*I have trouble getting along with other teenagers*”) and school functioning (“*I find it hard to pay attention in class*”) and a physical score including 8 items (“*I find it difficult to bathe myself*”; “*I find it difficult to run*”). The parental proxy measures for the same components were also captured. Following reverse scoring, scores ranged from 0 -100 with higher scores indicating a higher health related quality of life. Individual scale scores were given and interpreted against the minimal clinically important difference specified, for example; a 4.4 change in the total scale score for child self-report is a minimal clinically meaningful difference. Likewise, a 4.5 change in the Total Scale Score for parent proxy-report is a minimal clinically meaningful difference (Varni et al., 2003).

4.4.8.2.2 Physical self-perceptions (Fox and Corbin, 1989) and self-perceptions (Harter, 1988)

Self-perception was measured on the subscale from the Children and Youth Physical Self-perception Profile (CY-PSPP) developed in 1989 (Fox and Corbin, 1989) and adapted for use in children in 1995 (Raustrop et al., 2005). The CY-PSPP contains 6 subscales; Sport/Athletic, Attractive Body Adequacy, Condition, and Strength competence as well as Physical and Global Self-Worth. The Children and Youth Physical Self-Perception Profile (CY-PSPP) assessed the degree to which young people view themselves as competent in a variety of physical domains (Raustrop et al., 2005). Each question contains two statements relating to either a positive perception of competence or a negative perception of competence. The respondent is required to choose which statement best describes the way they view themselves and answer either 'sort of true for me' or 'really true for me' for each statement. Questions are structured in an alternative format on a scale between 1 (low score) and 4 (high score). Items measuring social acceptance, scholastic competence and global self-worth were taken from Harter’s Self-Perception Profile for Adolescent (Harter 1988).The social acceptance subscale assessed the degree to which the adolescent feels accepted by their peers, feels popular, has lots of friends, and feels that he/she is easy to like. The scholastic competence items assessed participants’ perception of their competence or ability within the school context. The global self-worth subscale assesses the extent to which participants like themselves as a person and the way they are living their lives. Score responses range from 1 (very slightly) – 5 (extremely).

4.4.8.2.3 Affect (Ebbeck and Weiss, 1998)

Understanding the factors known to influence a young person's self-esteem can not only play a significant role in the design of interventions, but also on enhancing overall wellbeing (Ebbeck and Weiss., 1998). One factor known to influence self-esteem amongst young people is affect, although specific measures for adolescents are lacking and therefore elements from Ebbeck and Weiss (1998) are included in this study. *Positive affect* was defined as the extent to which individuals had experienced positive emotions (e.g., pride, enthusiasm), and *negative affect* represented the extent to which individuals had experienced negative emotions (e.g., fear, hostility) during the last week (Ebbeck and Weiss., 1998). Participants are asked to describe, using a scale of 1 (very slightly) to 5 (extremely), how they have felt the previous week. Positive items include proud, satisfied, happy, excited and relaxed and the negative effect includes unhappy, nervous, guilty and angry.

4.4.8.2.4 Theory of planned behaviour (Ajzen, 1991)

The theory of planned behaviour (TPB) was developed to predict behaviours in which individuals have incomplete volitional control (Ajzen, 1991; Daley et al., 2006). The lifestyle intervention focused on improving physical self-competence and self-efficacy towards adopting healthy lifestyles. Given that the perception of behavioural control can reflect past experiences, anticipation of upcoming circumstances, and the attitudes of the influential norm surrounding the individual, components from the TPB were assessed (Rowland 1993). Questionnaires (Courneya and Bobick., 2000) assessing subjective norm, perceived behavioural control, attitude and intention of exercise behaviour were administered at all assessment points. Participants will be asked to indicate by circling a number between one (strongly agree) and 7 (strongly disagree) to what extent they agree with statements such as; "*I would like to participate in physical activity at least three times per week*", "*If I wanted to, I could easily take part in regular physical exercise*" or "*Most people who are important to me, think I should take part in regular physical exercise*".

4.4.8.3 Physical movement

4.4.8.3.1 Rationale for measurement of physical activity and cardio-respiratory fitness

Physical activity is defined as any body movement produced by muscle action that increases energy expenditure (Ortega et al., 2008). Different levels of physical activity participation are associated with different health benefits; therefore it is important to capture physical activity data (NICE, 2014). Physical activity is the capacity to perform movement and makes reference to a full range of physiological and psychological qualities (Ortega et al. 2008) whilst cardiorespiratory fitness, also called cardiovascular fitness or maximal aerobic power, is the overall capacity of the cardiovascular and respiratory systems and the ability to carry out prolonged strenuous exercise (Ortega et al. 2008). Higher physical activity levels have been associated with a reduced obesity risk in adulthood. Although cardio-respiratory fitness is well established as a means of reducing fat mass and increasing functional capacity, the effect of aerobic exercise on other markers of morbidity in obese adolescents are less well established (Alberga et al., 2013). The WHO guidelines (2010) and Public Health England (2014) recommend for optimal health, children and youth (aged 5 to 17 years) should engage in at least 60 min of moderate- to vigorous-intensity physical activity daily. However, adolescence is associated with a decline in physical activity especially in teenage girls (Street, Wells and Hills, 2015), with only 21% of boys and 16% of girls aged 5-15 in England (Health Survey for England, 2015) taking the recommended amount of physical activity they need for good development. Collectively, the established health benefits of regular moderate intensity physical activity and the reported suboptimal activity levels of adolescents indicate a need for increased participation in PA among this population (McGoey et al., 2015).

4.4.8.3.2 Physical activity

Self-report physical activity questionnaires are an important tool gathering information on daily physical activity patterns, in an easy, flexible and low cost way (Crocker et al., 1997). The Physical Activity Questionnaire for Adolescents was developed for use in young people aged 14 – 18 years old (Janz et al., 2008). The questionnaire has demonstrated its validity and reliability as a measure of physical activity during adolescence, with its psychometric properties tested. The test-retest reliability, internal consistency, sensitivity to age and gender differences, and its convergent and

construct validity have been all reported as good (Crocker et al., 1997; 2003). When the questionnaire was correlated with a caltrac physical activity monitor, it again measured well ($r=0.33$) (Crocker et al., 1997; 2003). The questionnaire was, however, developed to assess general levels of physical activity. Therefore, does not provide an estimate of caloric expenditure or specific frequency, time, and intensity information. The questionnaire does not discriminate between specific activity intensities, such as moderate and vigorous activities; and therefore simply provides a summary activity score. Other limitations associated with this method include the difficulty adolescents can have interpreting the questions and accurately recalling their physical activity (Janz et al., 2008).

Based upon evidence (Crocker and Kowalski, 1997) the physical activity questionnaire for Adolescents, PAQ-A, (Crocker and Kowalski., 1997) was deemed the most appropriate tool to use to capture self-reported data of the adolescents participation in physical activity 7 days prior to study completion. Questions focus on 1) spare time physical activity 2) physical education 3) lunchtime physical activity 4) extracurricular activities 5) evening activity and 6) weekend activity. Scores are on a scale of 1 (not active) - 5 (very active), which were then totaled to provide an average PAQ-A, score.

4.4.8.3.3. Cardio-respiratory fitness

Treadmill exercise testing currently is the most commonly used clinical method of evaluating a patient's functional capacity (Froelicher et al., 1974). The modified Balke treadmill protocol was used to assess aerobic fitness based upon its reliability and validation in obese pediatric populations (Rowland 1993; Marinov, 2000). Participants walk consistently at a speed of 3.0 miles per hour commencing at 6% gradient, which increases incrementally by 2% every 2 minutes (Marinov, 2000). Heart rate and Rating of perceived exertion (RPE) - an individual's perception of exertion during physical effort (Yelling, Lamb and Swaine, 2002) were recorded each minute. Participants were asked to estimate two readings of RPE; 1) aerobic and 2) lower-limb, in the final ten seconds of each two-minute stage using the Pictorial Children's Exercise Rating Table (Yelling, Lamb & Swaine., 2003). The PCERT scale (Figure 4.0) uses pictures as well as descriptive language to assess ratings of perceived exertion (RPE). The test ended when the adolescent felt they could no longer continue and time terminated was recorded. The researcher provided encouragement and support.

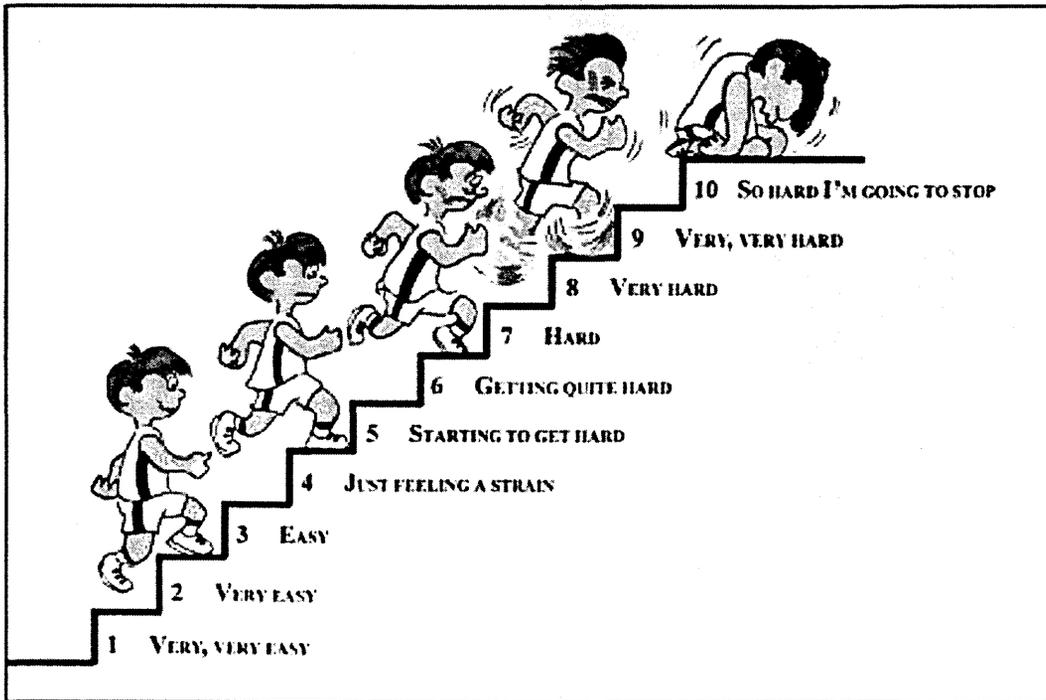


Figure 4.0 PCERT Scale to assess RPE (Yelling, Lamb and Swaine, 2000)

4.4.8.4 Control measures during the modified Balke treadmill test

To prevent injury to the participants, an assessment of risk was undertaken (appendix 9). The researcher was fully trained in first aid and was aware of university emergency procedures should an adverse event occur. All assessments of cardio-respiratory fitness were undertaken using the same treadmill, in the same laboratory. Participants were encouraged by the researcher to continue for as long as possible during the test.

4.4.8.4.1 Assessment familiarisation; Treadmill familiarisation

Part of the risk assessment undertaken to protect the safety of the researcher and participants included a treadmill familiarisation session. The researcher gave verbal instructions to detail what would happen as well as demonstrating the procedure. Key safety points were discussed including standing up tall, looking straight ahead and the emergency stop button should they need to immediately stop the test. A hoist was available if the participant felt this was needed. Participants were invited to try walking on the treadmill. The researcher controlled the treadmill at all times with speed and gradient increased and decreased only when the participants consented. The maximum speed of the treadmill during assessments was 1.34 m s^{-1} . The researcher observed the participants at all times and should any concerns regarding their health such as shortness of breath occur, the researcher stopped the test immediately. The researcher was highly skilled in fitness testing and all adequate qualifications including first aid.

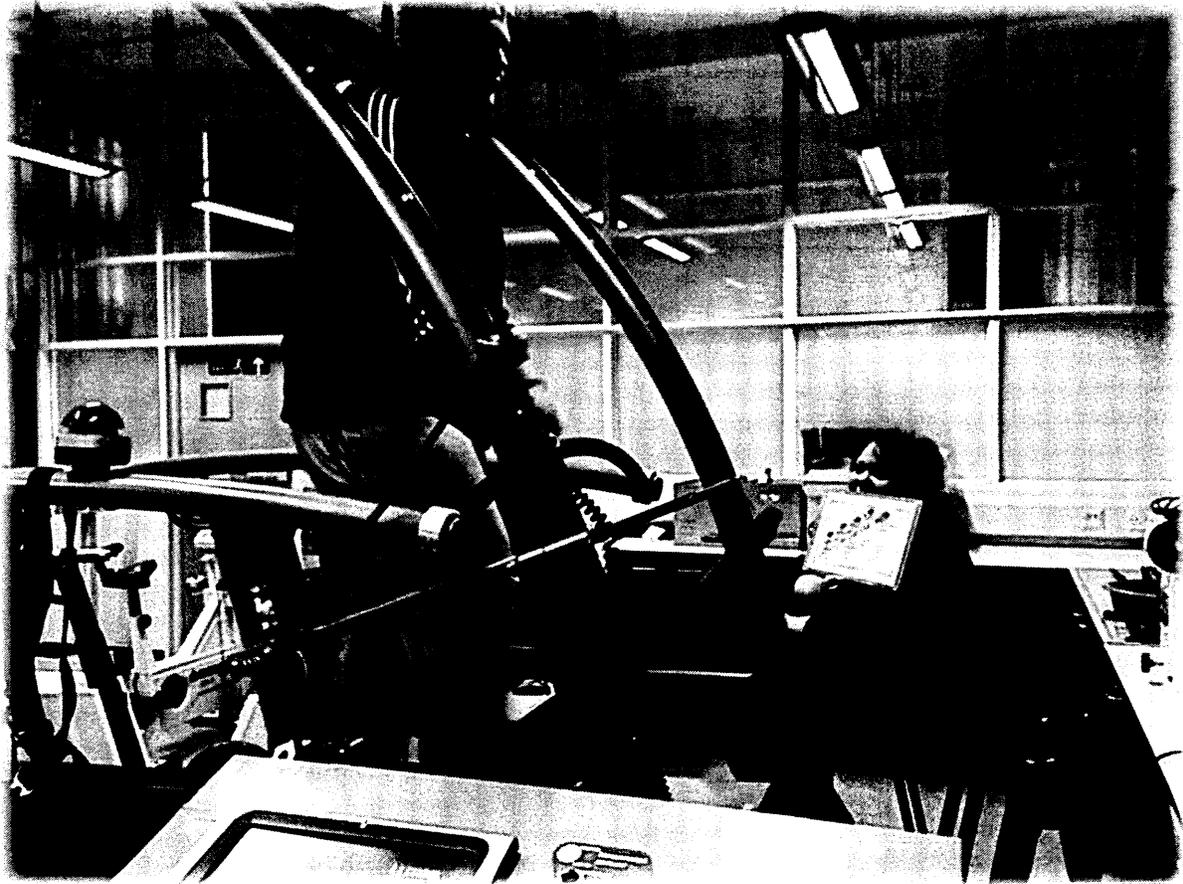


Figure 5.0– Treadmill familiarisation in the laboratory

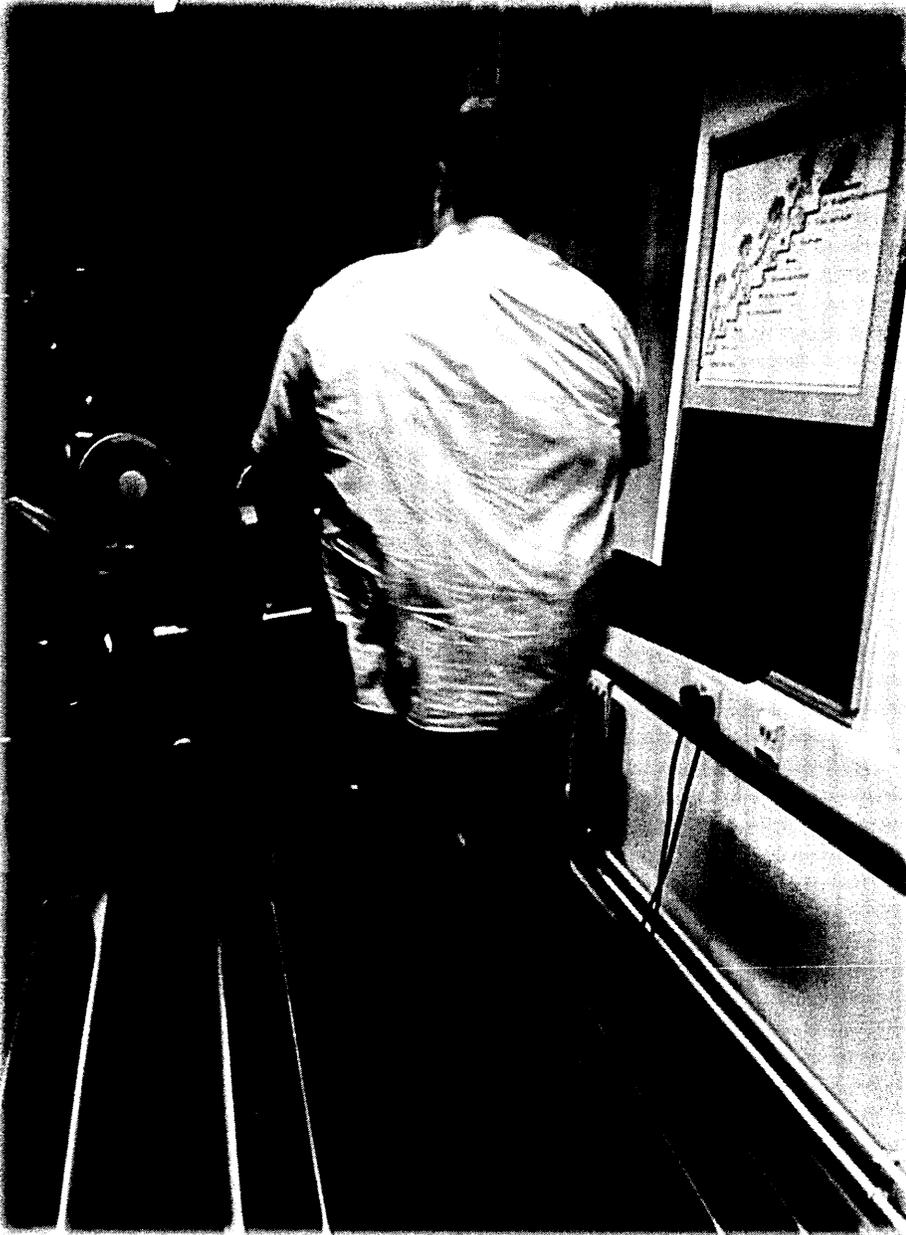


Figure 6.0 – Treadmill familiarisation in the gym at the university research facility

4.4.8.4.2 Questionnaire familiarisation

Questionnaires compiled into booklet form (Appendix 10) included Physical activity questionnaire for adolescents PAQ-A (Crocker et al., 1997); Paediatric health related quality of Life (Varni et al., 2001); Theory of planned behaviour (Ajzen, 1991); Affect (Ebbeck & Weiss., 1998); subscales of Physical self-worth (PSW) (Whitehead, 1995); Self-perceptions (Harter, 1995), with parents also completing the proxy measure of paediatric health related quality of life (Varni et al., 2001). The design and format of the questionnaires was carefully considered, aiming to be aesthetically pleasing, suitable for adolescents – all aimed at optimising the quality of responses without affecting questionnaire validity. The researcher sat with all families whilst they completed the questions and offered clarification if needed.



Figure 7.0 – Questionnaire assessment familiarisation

4.4.8.5 Additional biomedical outcomes*

Outcomes comparing change in biomedical data at the specific time points (baseline, following six months intra-gastric balloon insertion and 18 months post balloon removal) included:

- Difference in fasting glucose, fasting insulin glucose ratio and HOMA
- Difference in total cholesterol, HDL, LDL, triglycerides and atherogenic index.
- Difference in systolic and diastolic blood pressure standard deviation scores.
- Change in liver function tests
- Changes in Ghrelin, GLP-1 and GIP levels
- Changes in adipokines, osteokines, bone formation and turnover markers
- Changes in total fat mass, bone mineral content and bone density were assessed by DXA
- Changes in bone architecture assessed by high-resolution peripheral quantitative computed tomography (HR pQCT).

4.4.9 Statistical analysis

Based upon the small size ($n=12$) and the pilot nature of this data set, results will be expressed as means and standard deviations with the corresponding 95% confidence interval (95% CI). Effect sizes (Cohen's d) will be presented to highlight the magnitude of the change observed between groups, as recommended by Winter, Abt, and Nevill (2014). Cohen d is the difference in the two groups' means divided by the average of their standard deviations. If a control had been used, the standard deviation would be pooled. In the absence of a control like this study, the uncontaminated figure is used hence the baseline standard deviation. Cohen suggested that $d=0.2$ be considered a 'small' effect size (a real effect but careful study is needed to see it) 0.5 represents a 'medium' effect size and 0.8 a 'large' effect size (consistent effect, easily observed in the real world).

* The biomedical outcomes from this pilot study are beyond the scope of this thesis and are reported elsewhere led by Sheffield Children's Hospital

4.5 Results

4.5.1 Sample characteristics

Participants were recruited between October 2012 and July 2013 following a referral from paediatric consultants in the Yorkshire region. All balloon insertions and removals were completed by March 2014. The sample included 12 severely obese adolescents (7 females; average age 15 yrs; BMI >3.5 SD; puberty stage 4 or more) and their families. Baseline characteristics are displayed in table 7.0 as a group and split by gender. Ten families were from Caucasian descent with one black and one with mixed family origin. All were living in the Yorkshire and Humber region with 11 families living in areas of highest deprivation (Multiple deprivation quintiles 1 and 2) with 1 family living in quintile 3 (Indices of Multiple Deprivation, 2010). All agreed to travel to Sheffield for the lifestyle sessions, committing to participate in the study for 2 years.

Table 7.0 – Baseline anthropometric characteristics reported by group and gender (Mean ± SD)

	Both Mean ± SD (n=12)	Female Mean ± SD (n=7)	Male Mean ± SD (n=5)
Weight (kg)	138.45±23.97	131.5± 24.5	148.2± 21.7
%Excess Body Weight	73.6± 20.68	69.83 ±22.2	78.89 ± 19.3
BMI SDS	4.0 ± 0.29	4± 0.3	4± 0.2
Waist (cm)	128.25 ± 19.06	123.5± 21.04	135± 15.4
Hip (cm)	136.21 ± 13.38	135.8± 14.4	139.1± 13.3

4.5.2 Protocol adherence

All 12 participants recruited completed their 6-month assessments with nine participants (75%) attending their 12-month follow-up. Reasons for not attending; one withdrew from the project, one experienced a severe mental health episode, unrelated to the study requiring hospitalisation and one cancelled the appointment

resulting in it falling outside of the protocols specified time frame for data capture. Adherence with the weekly sessions delivered during the lifestyle programme ranged from baseline to 12 months varied amongst the participants, with a group average of 42% (16 sessions), ranging from 7% - 74% (3-29 sessions) adherence with the protocol. An average attendance of 14 sessions (46%), ranging from 3 to 25 sessions (10%-83%) occurred during intra-gastric balloon insertion, dropping markedly during the maintenance phase (two month) of the lifestyle programme, post balloon removal (average 2 sessions; 19%).

4.5.3 Primary outcome

A mean weight loss at 6 months (n=12), intra-gastric balloon removal, was 7.05 kg \pm 7.13; d= 0.3 and at 12-months (n=9) was 3.05 kg \pm 14.69; d=0.002. A BMI Z score (n=12) change of 0.2 SD; d=0.7, was observed at 6 months with a large effect, but was not sustained at 12-months (mean change 0.1 SD; d=0.3). A reduction in waist circumference at 6-months (n=9) of 13.78 cm \pm 11.95; d=0.6 was evident and at 12-months was (n=9), 10.47 cm \pm 17.46; d=0.5, although Hip circumference increased by 3.15 cm d= 0.2 at 12 months - higher than at baseline, see table 8.0.

4.5.4 Secondary outcomes

4.5.4.1 Health Related Quality of Life (HRQoL)

As seen in table 8.0, HRQoL scores improved across all domains from baseline to 12 months for the adolescents and their parents. Parental perceptions of their adolescents' scores were consistently lower than their adolescent scores. Largest change for adolescents was seen in the physical summary scores (mean difference 13.5; d=0.7) with parent's total HRQoL score (mean difference 16.16; d= 1.2).

4.5.4.2 Physical activity

As shown in table 8.0, self-reported physical activity questionnaires for adolescents (PAQ-A) scores, marginally decreased at 6-months (mean difference 0.19; d= 0.3), but returned to baseline at 12-months (mean difference 0.09; d=0.1).

4.5.4.3 Cardio - respiratory fitness

Cardio-respiratory fitness peaked at 6-months (mean difference 282.7; d= 1.9) with improvements maintained higher than baseline scores, at 12-months (167.2; d= 1.14).

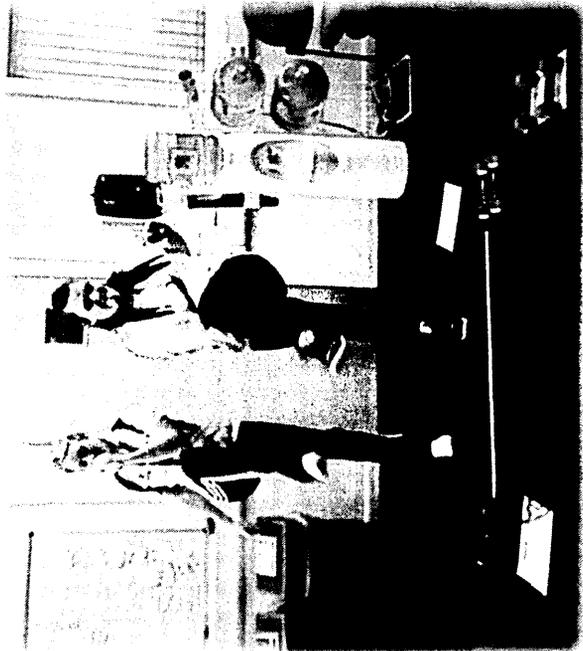
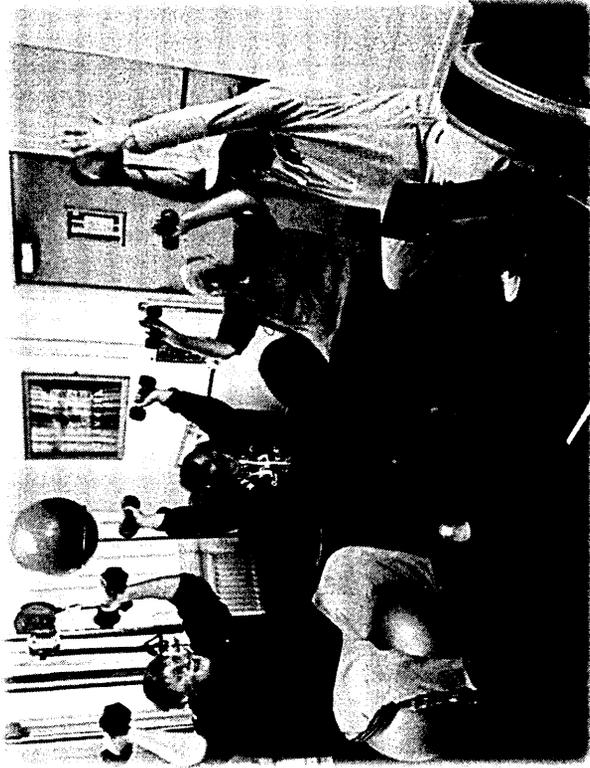


Figure 8.0 - Adolescents and their families participating in the lifestyle programme within the BOB study at the university research facility

Table 8.0 - All outcome variables expressed as Mean \pm Standard Deviation (95% confidence intervals) along with effect sizes for 6 month and 12 month follow-up

Anthropometrics	n=12		n=12		n=9	
	Baseline Mean \pm SD (95% CI* min-max)	6 months Mean \pm SD (95% CI min-max)	Effect size (cohen d) Baseline - 6 months	Effect size (cohen d) Baseline - 12 months	12 months Mean \pm SD (95% CI min-max)	Effect size (cohen d) Baseline - 12 months
Mass (kg)	138.45 \pm 23.97 (123.23 - 153.67)	131.43 \pm 23.10 (16.76-146.1)	0.2	0.2	138.4 \pm 21.85 (121.58-155.22)	0.0
%EBWL	-	9.55 \pm 9.16 (6.03-13.07)			2.29 \pm 16.47 (-1.94-6.52)	
BMI SDS	4.0 \pm 0.29 (3.82-4.18)	3.8 \pm 0.32 (3.6-4)	1.0	1.0	3.9 \pm 0.3 (3.64-4.16)	0.3
Waist (cm)	128.25 \pm 19.06 (116.15-140.35)	115.86 \pm 15.48 (105.59-126.13)	0.7	0.7	119.5 \pm 13.91 (108.79-130.21)	0.5
Hip (cm)	136.21 \pm 13.38 (127.72-144.7)	133.15 \pm 13.18 (124.41-141.89)	0.2	0.2	139.36 \pm 12.39 (129.82-148.9)	0.2

* Unless otherwise stated 95% confidence intervals are calculated using the t statistic and standard error due to the small sample size (Field, 2000).

Physical Activity and Cardio-respiratory fitness	Baseline Mean \pm SD (95% CI min-max)	6 Month Mean \pm SD (95% CI min-max)	Effect size (cohen <i>d</i>) Baseline – 6 months	12 Month Mean \pm SD (95%CI min-max)	Effect size (cohen <i>d</i>) Baseline – 12 months
	n=12	n=9	<i>d</i>	n=9	<i>d</i>
PAQ-A	1.94 \pm 0.66 (1.53 - 2.35)	1.75 \pm 0.59 (1.35 - 2.15)	0.2	1.85 \pm 0.86 (1.21 - 2.49)	0.1
	n=12	n=8		n=8	
Cardio-respiratory Fitness(Termination time secs)	353.7 \pm 146.98 (260.35 - 447.05)	636.45 \pm 268.22 (377.94 - 894.96)	1.9	520.95 \pm 234.07 (325.66 - 716.24)	1.1
Paediatric Quality of Life Peds QL - Adolescent	Baseline Mean \pm SD (95% CI min-max)	6 Month Mean \pm SD (95% CI min-max)	Effect size (cohen <i>d</i>) Baseline – 6 months	12 Month Mean \pm SD (95 %CI min-max)	Effect size (cohen <i>d</i>) Baseline – 12 months
	n=12	n=10	<i>d</i>	n=9	<i>d</i>
KIDS PedsQL Physical	56.2 \pm 17.2 (45.46 \pm 67.17)	70.3 \pm 12.8 (61.17 - 79.43)	0.8	69.79 \pm 9.63 (62.38 - 77.2)	0.7
KIDS PedsQL Emotional	63.75 \pm 25.9 (47.28 \pm 80.22)	66 \pm 31.86 (43.24 - 88.76)	0.1	70 \pm 27.61 (48.76 - 91.26)	0.2
KIDS PedsQL Social	67.08 \pm 22.6 (57.23 \pm 81.43)	74 \pm 22.21 (58.13 - 89.87)	0.3	71.11 \pm 29.76 (48.19 - 94.03)	0.2

KIDS PedsQL School	56.25 ±28.61 (38.07 ± 74.42)	57 ±27.6 (37.27 - 76.73)	0.0	66.11 ±33.98 (39.95 - 92.27)	0.3
KIDS PedsQL total	60.23 ±18.83 (48.27 ± 72.19)	67.28 ±18.37 (54.25 -80.41)	0.4	69.32 ±20.59 (53.46 - 85.17)	0.4
KIDS PedsQL Physical summary	56.25 ±17.27 (45.29 ± 67.21)	70.31 ±12.77 (61.68 - 79.44)	0.8	69.79 ±9.63 (62.38 - 77.2)	0.7
KIDS PedsQL Psychosocial summary	62.36 ±21.23 (48.88± 75.84)	65.66 ±23.78 (48.67 - 89.44)	0.1	69.07 ±27.79 (47.68 - 90.46)	0.3

Peds QoL - Parents	Baseline Mean ± SD (95% CI min-max)	6 Month Mean ± SD (95% CI min-max)	Effect size (cohen d) Baseline - 6 months	12 Month Mean ± SD (95 %CI min-max)	Effect size (cohen d) Baseline - 12 months
PedsQL Physical	53.12 ±13.71 (44.41 - 61.83)	60.41 ±25.33 (40.9 - 79.92)	0.5	71.87 ±14.82 (60.46 - 86.69)	1.4
PedsQL Emotional	55.83 ±18.4 (44.12 - 67.54)	53.33 ±20.76 (37.34 - 69.32)	0.1	71.11 ±19.96 (55.74 - 86.48)	0.8
PedsQL Social	50.41 ±20.38 (37.47 - 63.35)	57.77 ±28.51 (35.82 - 79.72)	0.3	67.77 ±20.69 (44.91 - 90.63)	0.8
PedsQL School	60 ±20.99 (46.67 - 73.33)	62.77 ±22.92 (45.12 - 80.42)	0.1	71.66 ±23.58 (53.6 - 89.82)	0.5
PedsQL total	54.61 ±12.73 (46.53 - 62.69)	58.81 ±21.93 (41.92 - 75.7)	0.3	70.77 ±18.31 (56.67 - 84.87)	1.2
PedsQL Physical summary	53.12 ±13.71 (44.41 - 61.83)	60.41 ±25.33 (40.9 - 79.92)	0.5	71.87 ±14.82 (60.46 - 83.28)	1.3

PedsQL Psychosocial summary	55.41 ±13.22 (47.02 - 63.8)	57.96 ±21.58 (41.35 - 74.57)	70.18 ±22.36 (52.96 - 87.4)	0.2	1.1
Theory of Planned Behaviour (Score range 1-7)	Baseline Mean ± SD (95% CI min-max)	6 Month Mean ± SD (95% CI min-max)	12 Month Mean ± SD (95% CI min-max)	Effect size (cohen d) Baseline – 6 months	Effect size (cohen d) Baseline – 12 months
	n=12	n=9	n=9	d	d
Perceived Behavioural Control	4.23±0.48 (3.9-4.56)	4.35±1.06 (3.55 - 5.15)	4.2±0.71 (3.67 - 4.73)	0.3	0.1
Subjective Norm	2.22±0.79 (1.67 - 2.77)	2.55±1.49 (1.4 - 3.7)	2.62±1.11 (1.77 - 3.47)	0.4	0.5
Intent	2.86±0.92 (2.23 - 3.49)	2.62±0.5 (2.37 - 2.87)	2.59±0.54 (2.18 - 3)	0.3	0.3
Attitude	1.77±0.75 (1.27 - 2.27)	1.2±1.41 (0.12-2.28)	1.15±1.3 (0.16 - 2.14)	0.8	0.8
Affect (Score range 1-5)	Baseline Mean ± SD (95% CI min-max)	6 Month Mean ± SD (95% CI min-max)	12 Month Mean ± SD (95% CI min-max)	Effect size (cohen d) Baseline – 6 months	Effect size (cohen d) Baseline – 12 months
	n= 12	n=10	n=9		
Positive affect	2.95±0.86 (2.4 - 3.5)	3.16±1.05 (2.42 - 3.9)	2.47±1.25 (1.44 - 3.5)	0.2	0.6
Negative affect	2.02±0.72 (1.56 - 2.48)	2.07±0.95 (1.4 - 2.74)	1.93±1.16 (0.99 - 2.87)	0.1	0.1

Physical Self-Perceptions (Score range 1-4)	Baseline Mean \pm SD (95% CI min-max)		6 Month Mean \pm SD (95% CI min-max)		Effect size (Cohen <i>d</i>) Baseline – 6 months		12 Month Mean \pm SD (95% CI min-max)		Effect size (Cohen <i>d</i>) Baseline – 12 months	
	n=12	d	n=12	d	n=9	d	n=9	d		
Sport competence	2.86 \pm 0.265 (2.09 - 6.52)		2.793 \pm 0.32 (1.98 - 3.6)	0.2	2.5 \pm 0.21 (0.86 - 4.14)		2.63 \pm 0.22 (0.88 - 4.38)		1.3	
Conditioning Competence	2.79 \pm 0.207 (2.11 - 3.47)		2.63 \pm 0.31 (1.86 - 3.4)	0.8	2.6 \pm 0.24 (2.37 - 2.83)		2.63 \pm 0.22 (0.88 - 4.38)		0.8	
Attractive body adequacy	2.24 \pm 0.165 (1.65 - 2.83)		2.2 \pm 0.21 (1.57 - 2.83)	0.3	2.44 \pm 0.22 (0.7 - 4.14)		2.58 \pm 0.36 (1.82 - 3.34)		3.6	
Strength competence	2.62 \pm 0.677 (1.81 - 3.43)		3.13 \pm 1.49 (2.25 - 4.01)	0.8	2.55 \pm 0.40 (2.23 - 2.87)		2.55 \pm 0.40 (2.23 - 2.87)		0.3	
Physical self-worth	2.47 \pm 0.425 (1.79 - 3.15)		2.46 \pm 0.188 (1.76 - 3.16)	0.1	2.44 \pm 0.22 (0.7 - 4.14)		2.55 \pm 0.40 (2.23 - 2.87)		0.0	
Global self-worth	2.65 \pm 0.31 (2.4 - 2.9)		2.36 \pm 0.43 (2.02 - 2.71)	1.0	2.55 \pm 0.40 (2.23 - 2.87)		2.55 \pm 0.40 (2.23 - 2.87)		0.9	
Self-perceptions (score range 1-4)	Baseline Mean \pm SD (95% CI min-max)		6 Month Mean \pm SD (95% CI min-max)	Effect size (Cohen <i>d</i>) Baseline – 6 months	12 Month Mean \pm SD (95% CI min-max)		Effect size (Cohen <i>d</i>) Baseline – 12 months		d	
Social	2.7 \pm 0.23 (2.52 - 2.88)		2.51 \pm 0.42 (2.19 - 2.83)	0.9	2.42 \pm 0.35 (2.17 - 2.67)		2.4 \pm 0.40 (2.1 - 2.7)		1.4	
Scholastic	2.5 \pm 0.21 (2.34 - 2.66)		2.53 \pm 0.51 (2.14 - 2.92)	0.2	2.4 \pm 0.40 (2.1 - 2.7)		2.4 \pm 0.40 (2.1 - 2.7)		0.5	

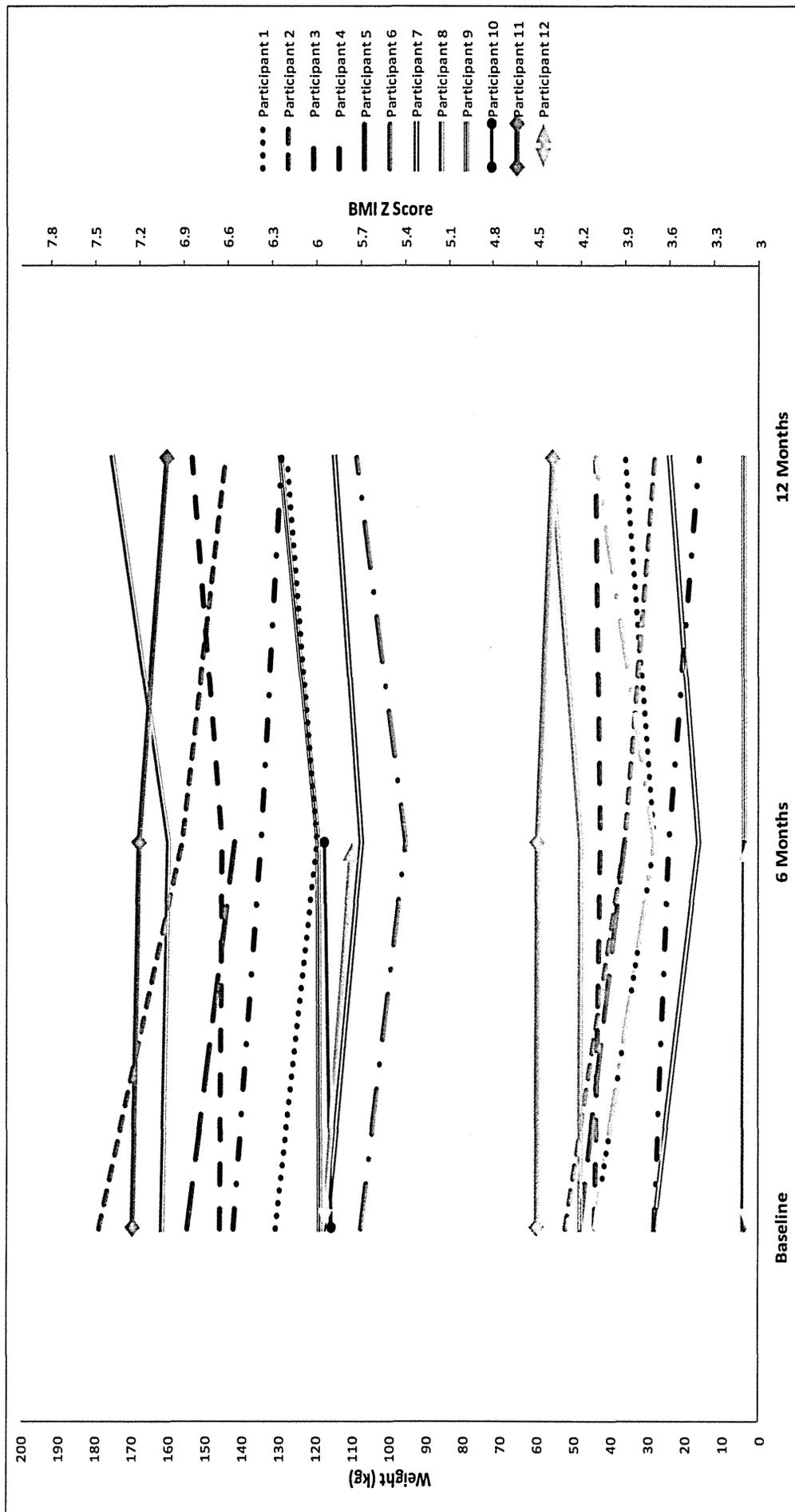


Figure 9.0 – Individual weight and BMI Z Score at Baseline, 6 months and 12 months

4.6 Discussion

The majority of previous studies have combined obese children and adolescents, failing to identify adolescents as a specific age group. Thereby making it difficult to determine adolescent-specific outcomes (Steinbeck, et al., 2009). Combine this with an increased recognition of the long-term health risks associated with severe obesity in adolescents (Kelly et al., 2013) the need to focus on effective treatments tailored specifically for severely obese adolescents is heightened. To the best of our knowledge, this is the first study focusing on the treatment of severe obesity tailored to adolescent's need that adopts a novel approach of combining an intra-gastric balloon (relatively untested in adolescents) with an intense, age appropriate, lifestyle programme delivered over a 12 month period.

This unique holistic treatment demonstrates its safety and acceptability in a small pilot of severely obese adolescents. The intra-gastric balloon was well tolerated with all participants experiencing minimal side effects and living with the balloon for the full 6-month period. Obesity treatment programmes are commonly associated with high attrition and dropout rates (Luttikhuis et al., 2009). In this study, 75% of participants and families remained in the study at 12 months and attended their follow-up appointment. Adherence with the lifestyle protocol varied significantly, ranging from 7% - 74% - a finding similar to previous studies (Skelton and Beech, 2010). Whilst there is a need for effective treatment, identifying the variables associated with attrition could have a direct implication on enhancing adherence rates, thereby potentially enhancing effectiveness (Jelalien et al., 2008). No criteria was set for distance to travel for this intervention, resulting in participants from across the Yorkshire and Humber region being recruited, which could have affected adherence rates in this study. This could be explored in more detail in the qualitative interviews analysed in Chapter 5.

Intra-gastric balloon treatment is temporary, placing great importance on weight maintenance post balloon removal. Previous evidence in adults (Dumonceau 2008; Imaz, Martinez-Cervell, Garcia-Alvarez, Sendra-Gutierrez, Gonzalez-Enriquez 2008) infers weight loss at treatment completion was not only sufficient to obtain health benefits, but was of higher efficacy estimations than for alternative treatments

including Orlistat (Li, Maglione, Tu et al., 2005). However, available follow-up data shows the majority of weight lost was regained one-year post treatment (Dumonceau, 2008). The results from this pilot study appear to support the short term effects observed in adults, with adolescents achieving a BMI Z-score reduction of 0.2 SD at 6-months offering health benefits (Ford, Hunt, Cooper and Shield, 2010), yet it was not maintained at 12 months. It is recommended to incorporate strategies on weight loss maintenance and relapse prevention for weight regain into treatment approaches (Luttikhuis et al., 2009). Despite, a structured eight-week maintenance phase built into the BOB study design, uptake from participants and families was poor (average attendance 1.5; ranging from 1 -8) following removal of the intra-gastric balloon. Information collated through the qualitative interviews could offer additional insight into the reasons for this, which is explored in more detail in Chapter 5. Additional research into the effective strategies for adolescents at this time is needed to optimise treatment success and prevent weight regains post treatment (Altman and Wilfely., 2015).

Overweight and obese young people who have a higher cardiorespiratory fitness have been associated with a lower overall total adiposity (Ortega, Ruiz, Castillo, Sjostrom 2008). Waist circumference (a measure of adiposity) was lower at 12-months and highlighted a large effect in this sample, inferring the potential added benefit of combining an intra-gastric balloon with a lifestyle programme promoting a physically active lifestyle. Linking this with qualitative feedback on how the young people phrased their goals on weight loss, such as 'dropping a dress size', infers the focus on specific numbers for weight loss within practice is not aligned with how the adolescents consider weight. This could be an important finding to inform future studies and practice working with adolescents.

Mean self-reported physical activity scores at 12 month demonstrated an insufficiently active score when compared with normative values (> 2.9 boys and > 2.7 girls) presented in this population (Voss et al., 2013). Whilst only modest changes were self-reported on the physical activity questionnaire in the 7 days prior to conducting the assessment(s), improvements in cardio-respiratory fitness were observed and maintained at 12-months. Coupled with maximal efforts stated using the pictorial children's effort rating table for children (Yelling et al., 2002), demonstrates not only

the adolescents ability to work to perceived maximum effort, but the importance of including an objective measure of fitness alongside a self-reported physical activity measure. There could be several reasons for the differences between self-reported and objective measures; adolescents could have underestimated the level of daily activity they were doing or when placed in an environment where they push themselves on a given activity they found they could actually do more than they thought or enjoy to do, day to day. Linked with subscales of the theory of planned behaviour specifically attitude, (Ajzen, 1991) it is inferred that many associate physical activity negatively and choose day to day to avoid it.

Health-related quality of life is a comprehensive and multidimensional construct that includes physical, emotional, social, and school functioning – all influential when working with adolescents (Varni, Seid and Kurtin 2005). Obese adolescents reportedly have lower health related quality of life scores than their healthy weight counterparts (Buttitta, Iliescu, Rousseau, Guerrien., 2014). A previous study found obese children and adolescents reported significant impairment not only in total scale score (mean score was 67.0 for obese children and adolescents compared with 83.0 for healthy children and adolescents), but also across all domains—physical, psychosocial, emotional, social, and school functioning—in comparison with healthy children and adolescents (Schwimmer, Burwinkle and Varni 2003). Noticeably in this study, child self-report baseline scores (table 8.0) across all domains (physical, emotional, social, and school) were low when compared with other studies in overweight and obese adolescents, inferring health related quality of life worsens with the degree of obesity (Burke et al., 2015). Changes in total score; physical summary score and psychosocial summary score between baseline and 12 months all exceeded the minimally important clinical difference criterion expressed by Varni, Burwinkle, Seid and Skarr (2003). Of interest, scores remained higher at 12-months from baseline across all domains irrespective of the pattern of weight regain, suggesting other variables, such as treatment approach and physical activity, could have independent effects on improving quality of life (Tsiros et al., 2009; Morrison et al., 2015).

Parental proxy measures reported here (mean total score of 54.61 at baseline), were low when compared with the parents of obese children and adolescents (mean total score of 63.3) and parents of healthy weight children (mean total score of 87.6)

(Schwimmer, Burwinkle and Varni 2003). All change values exceeded the minimal clinical important difference specified (Varni, Burwinkle, Seid and Skarr (2003). In addition, Parents throughout this study consistently perceived a worse quality of life for their child in line with previous findings (Zeller and Modi 2006). The reason for this discrepancy is unknown, but not unique to obesity (Tsiros et al., 2009). A possibility could be parent's catastrophise the situation or lack understanding of their child's lived experience (Tsiros et al., 2009). Given the role parents play in seeking obesity treatment, it is critical that their perspective is captured. Further research is needed to elicit the degree of weight change needed to influence quality of life scores and to explore mediators of this relationship.

Strong evidence has shown the theory of planned behaviour (Ajzen, 1991) to predict the likelihood of a given behaviour, yet the intention to achieve this is heavily influenced by perceived behavioural control, attitude and subjective norms (Ajzen, 1991). Findings here, in the main, are consistent across the time points limiting the conclusions that can be drawn. A stark finding is the low level of scores reported by the severely obese adolescents when compared with overweight and obese adolescents involved with an exercise therapy trial (Daley et al., 2006). This reinforces, that the perceived competence and self-esteem of adolescents worsens with extreme obesity (Steinbeck., 2014), which could affect the design of future studies, which requires further exploration.

Albeit in contrast, scores from the other constructs namely affect, physical and self-perceptions were similar in severely obese adolescents to scores reported by overweight and obese counterparts (Daley et al., 2006). What remains is that obese adolescents have lower self-esteem than healthy weight counterparts but the way they view and feel about their bodies is likely to be heavily implicated in the development and continuing presence of more-serious psychopathologic conditions (Daley et al., 2006). With this in mind, positive changes observed and maintained across 6 month and 12 month follow-up period within the physical self-perception domain (general feelings of satisfaction and confidence regarding the self in the physical domain) and body attractiveness scale (attractiveness of their bodies and how confident they feel about their appearance), in addition to a large effect within the strength domain at 6 months (perception of strength and muscle development), infers

participation in a tailored physical activity and lifestyle intervention enables severely obese adolescents to view themselves and their bodies more favorably in the short term.

Another possible explanation is that the utilisation of behavioural change techniques (see table 6.0) enabled adolescents to self-reflect within a safe environment. The positive reinforcement continually offered throughout the programme, the praise given for the achievement of goals (Abraham and Michie., 2011) and the innate feelings of reward felt by adolescents themselves reinforced the mastery experience. For example when completing, self-selected competitive tasks that the adolescents originally thought they could never achieve such as a 1000m row on the rowing machine, helped the adolescents begin to change the way they viewed themselves and their bodies.

Combined with modest increments in objective physical fitness, the increased capability of adolescents to be more physically active and have an increased awareness of themselves has potential to influence self-esteem in the longer-term (Crocker, Eklund and Kowalski., 2000). Albeit no real changes in global self-esteem measures were seen here, the use of the self-perception profile for adolescents (Wichstrom, 1995; Harter, 1988), which includes additional scales; romantic appeal, job competence and close friendships, could have offered greater insight into the way severely obese adolescents feel about themselves, view their bodies within their social environment. The large effects and positive changes observed in the physical, emotional and social subscales within the pediatric health related quality of life measure (Varni, 2006), alongside the qualitative experience captured from adolescents and their families (explored in more detail in Chapter 5), warrants further research. This is to not only understand the psychosocial profile of severely obese adolescents, but also understand the factors that influence self-esteem and what role a study or treatment has on mediating such factors.

4.7 Study limitations

This study is one of the first to specifically design and tailor a treatment approach for severely obese adolescents and their families. Findings contribute to the existing literature on the safety and acceptability of an intra-gastric balloon alongside a lifestyle

support programme, to induce short-term weight loss, producing clinically important improvements in health related quality of life and modest changes in cardio-respiratory fitness.

These results must however be interpreted with several limitations in mind. Firstly, this is a pilot study with a relatively small sample and therefore effectiveness cannot be reported. In light of this, a conscious choice not to run statistical null hypothesis testing was made to avoid a reliance on an inaccurate P value (Winter, Abt, Nevill 2014). Instead the alternative metric of meaningfulness (Winter, Abt, Nevill 2014), effect size (Cohen 1992) with the presentation of 95% confidence intervals were used to allow a meaningful interpretation of the data set, thereby strengthening this study. Secondly, the inclusion of adolescent specific measures such as self-perception profile for adolescents (Harter, 1988) or Rosenberg's self-esteem measure (Robins et al. 2007) could have offered additional consideration insight during the discrete period of adolescence. Thirdly, the lifestyle programme was delivered within a university research environment, reinforcing a key challenge for obesity treatment observed in existing literature (Watson et al., 2014) - the transition from a supportive intervention within a controlled environment to longer-term behaviour change at home. The use of a dietary specific measure or appetite measure could have also offered additional insight into dietary habits or how the adolescent's perceived hunger and feelings of satiety, especially during the time the intra-gastric balloon was inserted would have been beneficial. With all this in mind, the inclusion of a data collection point at 9 month (completion of the maintenance phase of the lifestyle programme) could have helped to differentiate changes between the intra-gastric balloon and lifestyle programme, as well as offering feedback on the maintenance phase of the study. In line with findings from Chapter 2 and Chapter 3, and as only three families requested home based support throughout this study, further work is needed to explore the integration of families' real world environment within intervention programmes in order to support long-term behavioural change.

4.8 Chapter summary

This Chapter details the design, implementation and outcomes from a pilot study assessing the use of an intra-gastric balloon alongside a lifestyle programme to promote weight loss and lifestyle behaviour change in severely obesity adolescents, 12

months from baseline. The Chapter gives careful consideration to the theoretical underpinning of the behaviour change intervention with the content delivered from the lifestyle programme explicitly mapped onto the taxonomy of behaviour change techniques (Abraham and Michie., 2011). Anthropometric, physical activity and cardiorespiratory fitness, along with psychosocial outcomes were recorded and interpreted within the context of the current literature.

To complete this interpretation and offer a holistic view of the journey undertaken by the severely obese adolescents and their families involved in the programme, the next Chapter (Chapter 5) offers a detailed analysis of their experiences during and post intervention captured through qualitative interviews and session notes recorded by the lead researcher.

CHAPTER 5: BEYOND WEIGHT LOSS: PARTICIPANT EXPERIENCES OF THE BOB PROGRAMME THROUGH A QUALITATIVE STUDY (STUDY 3)

5.0 Introduction

Chapter 3 offered insights into the complex, lived experience of obese adolescents, and a critique of the current evidence base on what constitutes effective treatment for severely obese adolescents. Collectively, this provided a strong rationale for the design and delivery of the novel pilot study implemented in Chapter 4, which used an intra-gastric balloon and a lifestyle support programme to facilitate weight loss. This Chapter will now detail the in-depth experiences of the 12 adolescents and their families participating in the BOB programme through a longitudinal qualitative study.

5.1 Study rationale

A growing body of evidence advocates a multidisciplinary, family-focused approach to treatment (NICE, 2007; 2103; Watson et al., 2011) but little is known about severely obese adolescents experiences in relation to such lifestyle and physical activity interventions (Dahl et al., 2014; Gronning et al., 2013). Qualitative research, which focuses on the individuals' experiences during and after participation in obesity treatment, offers a unique opportunity to explore the acceptability of the intervention and its impact on the lives of the participants (Daniellsson et al., 2015). Research on the effects of child and adolescent obesity treatment has shown that short-term weight loss is often not sustained long-term (Luttikuis et al., 2009). Successful treatment is typically associated with sustained weight loss outcomes, but we know much less about the broader psychosocial context surrounding participants including the experiences of individuals seeking to lose weight (Bryan et al., 2014). There is also only limited evidence regarding which individuals are most likely to benefit from a given treatment (Braet, 2012; Shalitin et al., 2015). A better understanding of the predictors of change and the mediating factors influencing successful or unsuccessful behavioural change (Nuutinen and Knip., 1992) could facilitate the effective tailoring of treatment to adolescent participant characteristics (Braet., 2012).

5.2 Study aims

This study aimed to explore the experiences of severely obese adolescents and their families who participated in a novel obesity treatment programme (the insertion of an intra-gastric balloon coupled with a family lifestyle behavioural support programme). Data has been synthesised from session notes and qualitative interviews conducted before and after participation in the study.

5.3 Method

5.3.1 Ethical considerations

The qualitative component of the study was covered under the National Health Service (NHS) ethics approval and written consent granted for the BOB study (Chapter 4).

5.3.2 Participants

All participants enrolled on the BOB pilot study (Chapter 4) were invited to be interviewed as part of their weekly attendance at the lifestyle programme at the university research facility, at 3 months, (half way through having the intra-gastric balloon in) and at 12 months follow-up (6 months post intra-gastric balloon removal, 3 months post lifestyle intervention). Interviews were held with an independent researcher at 3 months (n=11) and the lead researcher (LR) at 12 months (n=9). Only one participant chose to be interviewed alone, all others had family or friends with them. Reasons for not participating in the interviews included; not wishing to be audio recorded (n=2); failure to attend appointment (n=1) and an adverse event (unrelated to study delivery) resulting in a hospital admission (n=1).

5.3.3 Study design

Interviews lasted between 35 – 60 minutes. An interview guide containing eight open questions (see Appendix 11 for the topic guide) was used in conjunction with an analogy of a hot air balloon (see Figure 10.0) for both interviews. The open questions provided a framework, where topics were identified from previous reviews of childhood and adolescent obesity treatment interventions along with consultations with key stakeholders involved in obesity management (Luttikhuis et al., 2009; Staniford et al., 2011). Key topics within the guide included questions that focused on the expectations of the intervention, successful and unsuccessful changes, unanticipated setbacks, acceptability of the programme and future goals. Adhering to

this guide for all interviews ensured consistency, whilst remaining flexible enough to adapt to the emerging accounts of the young people. The script, along with the flip chart paper, was used to support reflection and interaction, offering additional prompts to help the young people think carefully about their experiences. Appreciating that these adolescents had very low self-esteem and were not necessarily confident about talking frankly and openly within an interview situation, the session was interactive allowing for responses to be written on coloured post it notes with creative artwork encouraged.

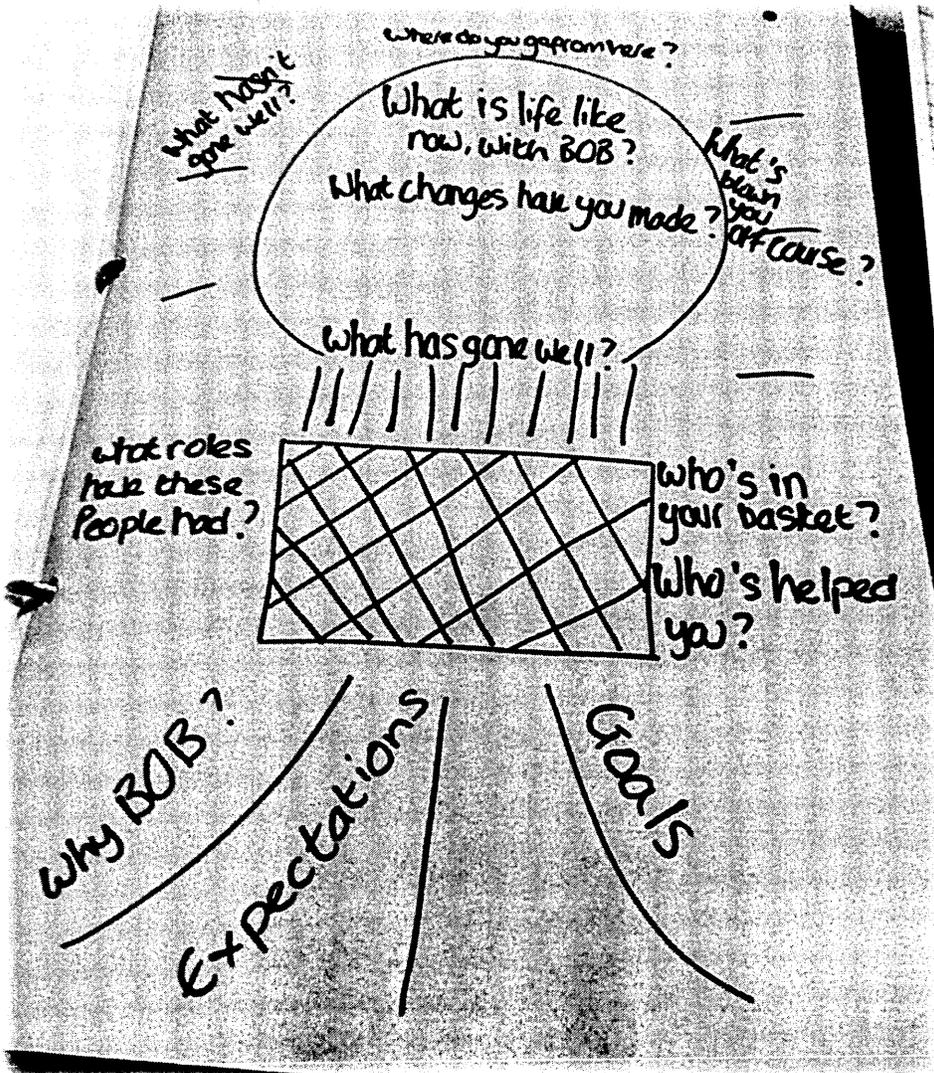


Figure 10.0 – Focus group topic guide for adolescents and their families

5.3.4 Data sources

In addition to the data captured during the semi-structured interviews, session notes were recorded at every contact with each participant (n=12) and after each session of the lifestyle programme. The rationale for this was to ensure the researcher tailored each session to the needs of the adolescent/ family as well as being kept as a record for discussions later. Throughout the programme, the lead researcher focused on building rapport with the adolescents and their families, through the use of an empathic approach to communication in order to encourage all families to share personal information and past experiences. She also sought to create a non-judgemental, and friendly environment. Some participants talked in these sessions about being bullied at school, whilst others talked about their coping strategies, which included emotional eating, and social isolation. Some talked generally about their relationships at home, school/college and/or any worries they might have had during that particular week. Keeping a record of informal discussions occurring during sessions enabled not only a deeper insight into the participants lives, but ensured sessions were responsive to cope with the needs of the individual at a given time.

5.3.5 Qualitative analysis

Framework analysis was used to analyse the data. Framework analysis was deemed an appropriate approach to analyse qualitative data due to the systematic nature of the approach (Murtagh et al. 2006; see Chapter 2 and 3). Details of the five distinct, phases of the systematic framework approach can be found in Chapter 3 (Table 2.0; Chapter 3; Ritchie & Spencer, 1994). Briefly here; the researcher firstly identified appropriate themes and associated sub themes that emerged from the data. Charts were then laid out on a thematic basis, which allowed identification of patterns, differences and similarities at each time point. Finally, diagrams were used to aid the final interpretation phase of the analysis. To counter bias and ensure the trustworthiness of the data, peer consultation took place between the researcher and two other colleagues on the development of the thematic framework, charting and mapping data, with final interpretations agreed. The qualitative analysis, explicitly outlining the process undertaken by Gale et al. (2004) can be found in Appendix 12.

5.4 Results

The qualitative findings from the focus groups will be discussed with the data presented as a group at 3 months and 12 months. Prior to this however, the characteristics of the BOB participants and their families are presented through the informal use of pen portraits.

5.4.1 Pen portraits for each BOB participant

An informal description called a 'pen portrait' for each of 12 BOB participants and their family characteristics are presented in table 9.0. These have been written from the lead researcher's perspective from the insight gained from the programme delivery. The pen portraits offer information on the demographics, family characteristics and the home environment along with weight outcomes at 6 and 12 months from the BOB programme. The pen portraits offer essential information on the biographical and familial context of the participants, which is deemed essential when attempting to understand and interpret the qualitative accounts of the participant's experiences of the BOB study (Gale et al., 2004).

Two families out of the 12 consisted of birth parents and siblings. Of the remaining ten, one participant was adopted, one father had died and the remaining seven lived within a single parent family. Many of the families described and were observed having frequent disagreements, limited communication and trust issues. BOB 11 mother admitted to finding it challenging in terms of maintaining parental control over her daughter, struggling to set boundaries and as a result went on a parenting course to try and help her relationship with her daughter. BOB 4 frequently attended sessions that resulted in confrontation and arguments amongst the family. BOB 9 and BOB 10 were carers for their disabled mothers, with BOB 9 not allowing her mum to be involved with any sessions during the programme, forcing her to stay in the car. BOB 3 mother was clearly very close and protective of her son following the loss of his father, and BOB 2 was extremely close and affectionate with his family, especially his mother. Amongst the young people and their parents, reports of alcohol and drug dependency were discussed, succumbing to peer pressure from friends and a desire to fit in. Several BOB participants had a history of physical and sexual abuse. One of the participants attempted suicide during the study resulting in psychiatric support,

medication and a multi-agency approach, which resulted in all professionals that supported her to meet regularly to discuss her care plan. Bullying was a recurring theme discussed by the young people during the lifestyle sessions with some reporting weekly episodes of name calling and teasing at school. Other accounts from participants were more extreme, with reports of physical abuse occurring during school time and an incident involving a knife in a public place experienced by another participant. The use of social media was described as a source of stress by many, with feelings of isolation when school friends did not want to be friends with them online or when humiliating photographs of them being bullied at school were posted on the internet. BOB 12 had a very complex home environment with the family receiving social care input.

In summary, families involved in the BOB study had challenging home lives with accounts including evidence of abuse, alcohol dependency, criminal backgrounds, disability, health issues and welfare issues, all of which reinforced the challenge of promoting weight loss and positive behavioural change within a complex family environment for these severely obese adolescents.

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
1 White, Female 16yrs	South Yorkshire. Lives with mum and her brother (Dad left when young). Attended sessions with her mum. Mum works as admin assistant. Mum overweight. Came with friends occasionally. Attended frequently whilst balloon in, didn't attend maintenance.	Attended college and at project end has a job working as a carer. Aspirations for university. Confident, outgoing young lady who from the outset was clear the balloon wouldn't change her personality. Fairly happy with the way she is – just wants to weigh less. Has lots of friends, very sociable.	Positive tone. Initial side effects of BOB frustrating but motivated after initial weight loss. Behavioural changes 1) increased awareness of food choices 2) improved attitude towards PA 3) increased PA – more walking. Goals – shopping and clothes focused.	- 11.1 kg	Frustrated tone. Frustrated with lack of significant weight loss. Felt just getting into a routine when balloon came out. Relied on balloon – not intrinsically motivated. Wanted more support maintenance phase – keen to get free gym pass. Limited evidence of behaviour change. Would have balloon again.	-2.9 kg
2 White, Male 16 yrs	South Yorkshire. Lives with mum dad, 2 sisters and brother who were all overweight. Family	Dropped out of school due to bullying. Initially very shy character wouldn't make eye contact and had hair in front of his eyes. Significant	Very positive. Mum still talks for BOB 2, but BOB 2 growing in confidence and appears to be developing autonomy regarding decisions. Describes	-22.6 kg	Extremely positive and describes significant lifestyle changes for him and his family – project	-34.4 kg

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
	<p>unemployed. Attended sessions with immediate and extended family who took part. Rarely missed a session. Conducted sessions in their home and local park (upon family request) to aid walking and family activity.</p>	<p>improvements in confidence weekly during project. Mum frequently speaks for him, At the end of the project was looking at apprenticeships, had started night school to get GCSE, opened his own bank a/c. Got engaged in 2015.</p>	<p>sustained changes. Adopts a whole family approach. Mum speaks of it bringing family back together. Family also describe weight loss and improved mobility especially for the mum (first session attended in a wheelchair now walks more than 2 flights of stairs). Recognises that this is just the start.</p>		<p>has been life changing! Whole family approach. Believes it worked because he hit rock bottom and he was ready. No longer sits on X box, now goes out to see friends. Evidence of previous stigma and negative attitudes – “Lindsey treated me like a human being and listened.” Talks of confidence and determination – absolute determination he will never go back.</p>	+7.8 kg
3	<p>West Yorkshire lives with mum (dad died when early</p>	<p>Very quiet pleasant young lad. Mum did the majority of the talking. Mum has had</p>	<p>Expected the balloon for do it for him. Explicitly admits he relied on the balloon at this</p>	-0.5 kg	<p>No sense of commitment for behavioural change.</p>	

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
White, Male 15yrs	teenager). Attended programme with his mum sporadically (mainly for hospital appointments).Mum is an osteopath. Mum had bariatric surgery. Didn't attend maintenance.	surgery herself. Enjoying college and has secured a place at Leeds uni Sep 2015.	stage. Believed the balloon would do more. Frustrated with weight loss. Overall tone, a little lethargic, sense of boredom, felt people are looking at him. Mum very protective.		Also a sense they are telling me what they felt they should say. Expressed it as a learning curve and that if change is going to happen it is down to him. Mum still very protective and doing much of the talking for him. Sometimes a sense she doesn't listen to her son. Is exploring bariatric surgery as an option.	
4 White, Male 15yrs	Greater Manchester lives with adoptive family mum dad and sister. Attended sessions with his mum and on his own. A tense relationship with	Several sessions were difficult due to aggression between the mum and him. Many session's involved fallouts and tears – this improved throughout project duration. Attending college training to be a	Open to help and support. Recognition its early days with the balloon. Emotionally feels happier but slight sense of unhappiness – a wanting to be accepted. Comes across quite a deep character and very thoughtful. Wants to be	-7.40 kg	A real sense of realisation that if change is going to happen it is going to be down to him. Significant lifestyle changes. Fear of stigma – worried that	-12.7 kg

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
	mum throughout. Attendance sporadic. Parents are academics.	chef, which is thoroughly enjoying. Has made contact with his natural parents. Came out as a homosexual. Has gym equipment at home for him to use which he uses. Significant lifestyle improvements and family relationships throughout the project. Struggled with alcohol addiction- now seeking help. Experiences of bullying and peer pressure.	accepted by peers with evidence of bullying. Want's to look like everyone else. Aspirational talk about attending college and university.		people look and judge. Moved beyond just the physical – comments emotionally, appeared to open up a little more. A mature account of his feelings. Balloon helped as a kick-start to get him on the right track. Reflected he had a point of despair pre BOB. Research study has prompted broader changes e.g. sought help for his alcoholism.	
5 White, Male	Lincolnshire, lives with mum dad and brother. Mum a cleaner and Dad a	Never really engaged with the programme despite initial interest. Distance definitely an issue but	-	-12.90 kg	-	

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
15yrs	truck driver. Didn't attend lifestyle prog – when he attended assessments he came with his Dad.	didn't seem open for change. Always Dad telling you what you wanted to hear. Dad has started paying for him to attend the gym.				
6 White, Female 14yrs	South Yorkshire, parents divorced but on good terms, lives with mum and 2 sisters. Dad brought her to sessions with his second wife. Mum has had bariatric surgery. Mum attended with Dad for assessments. Frequently attended sessions, with parents involved in physical activity and enjoying	Very committed from the start. Mum keen to look after longer-term health. BOB 6 a very quiet, shy, lovely character. Extremely low self esteem, always felt a burden on others, emotionally ate – reports hiding crisp packets in her room. Thinks she is ugly. Saw a psychiatrist and was taking anti-depressants. Suffered severe bullying throughout the project with reports of physical abuse. Attends a special school several days a week. Focus	Very shy character, quiet and fear of being judged. Avoids social situations and rarely opens up to people. Whole family approach. Weight focused, not convinced of longer-term success. Enjoying lifestyle sessions with her dad and stepmom. Feels supported and appears really engaged for the study.	-11.90 kg	Sad, quiet, very emotional young lady. Very reserved. Continues taking anti-depressants. Still being severely bullied. Struggling with school and grades are failing. Evidence of weight regain. Felt it was a shame the project is ending.	+1.4 kg

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
7	<p>South Yorkshire. Lives with mum (dad in prison), and younger brother. Attended weekly on her own, her friend or her mum. Mum is a carer working shifts and of healthy weight.</p>	<p>(2015) on GCSE's. LR worked closely with the school through the use of a common assessment framework (CAF) to ensure holistic support across all health and social care professionals. Visited the family at home on 3 occasions to support home based changes.</p> <p>A mature, well-mannered quite charming young lady. Engaged from the start, very honest and felt a good rapport was established early on. Attended college and recently got a job at the hospital (left MacDonald's). Mum now has a frequent shift pattern which helps with meal times.</p>	<p>Positive. Thought balloon would be worse – surprised experienced no side effects. Finds the exercise enjoyable especially when she came with her friends. Focus on smaller portions. Aware of coping strategies. Very mature, coherent interview. Really pleasant. Attributes success of healthy changes to balloon.</p>	-9.3 kg	<p>Recognition balloon is just one part of it. Blames herself for undoing the hard work post balloon. Old habits crept back in – focus on maintenance. Welcomed the opportunity – valued the frequent support.</p>	-1.8 kg

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
8 White, Female 15yrs	South Yorkshire. Lives with her disabled, obese mum. Attended sessions, not weekly but still came sporadically. Mum was never allowed out of the car.	Aspirational now talking about travelling and university. At last appointment she had bought herself a designer handbag after saving her wages and treating herself. Disappointed for her weight loss but has totally changed her lifestyle in terms of physical activity and food and her attitude each day.	Very resistant. Feeling really pressurised. One-word answers. Not thinking about future weight loss. No sign of behavioural changes.	-1.7 kg	Consistent with 3 mth. No evidence of engagement. No sign of behavioural change. Aggressive / assertive tone. Too busy to attend sessions / juggling sessions.	+13.8 kg

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
9	South Yorkshire. Lives with mum and dad. Attended frequently to the programme with various family members including	<p>equally, and being treated like a friend and not getting at her! Resistant to change although clearly not happy with how she is. Responds to situations she didn't like with anger.</p> <p>Always got the sense she's taking part because she has been told to. Adamant she will make changes on her terms when she is ready – a stubborn character for sure! Dropped out of college as not enjoying the course.</p>	<p>Focus on fitness. Already made significant physical activity changes. Gets positive reinforcement from beating his sister. When he actually put effort in he was easily de-motivated. Reliance on</p>	+0.5 kg	<p>Parent and child relationship – interesting dynamic. Mum very focused on social and emotional rather than health impact. Mum</p>	+10.7 kg

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
	sister . Main goal/focus was on physical fitness and socialising with friends.	overcome. Difficult to engage and interact with as very quiet and responded with frequent grunts or I don't know. Seemed embarrassed when parents talked to LR.	balloon. Parent more focused on social and attitude rather than weight loss. Mum keen but dad wasn't on being involved with the study. Fairly positive overall.		dismissive of BOB9 – “sticks out like a sore thumb”. BOB9 reliance on balloon. Now feels ready and prepared once completed. Parents not committed to change – some slight references inferring change. Disappointing weight loss which affected motivation – focus on fitness and confidence.	
10 Black, Female 16yrs	West Yorkshire lives with disabled overweight mum. Didn't engage with the programme but did attend assessments.	Excellent A* student academically with aspirations for university. An ambassador for her black community and a mentor for many. A very polite, charming young lady who always	Talks about some evidence of behavioural changes. Experienced negative side effects of the balloon. Not much weight loss. Not very enthusiastic.	+2 kg	Balloon made her feel worse – guilty almost for taking part. Honest open account. Just wasn't for her. Fear of being bullied. Fear of not fitting in and being judged.	

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
		<p>talked about wanting to lose weight but sadly the balloon didn't seem for her so didn't engage with the project. At times, very teary during sessions because she felt people were laughing at her and judging. On the outside very confident and determined, but on the inside really low self-esteem. Always got the impression she would lose weight when she was ready – just was never convinced this was the right time for her. Mum very poorly and happily talks about her issues.</p>			<p>Talks of feeling depressed. Strong acceptance that weight loss and the experience of BOB wasn't easy hence reason for not attending. Mum forced her to keep balloon in – doesn't really talk about family change. A lot on her shoulders – puts pressure on herself. Emotional – cried during interview. A life changing experience as it has changed her outlook and has a sense of realisation it is up to her.</p>	
11	South Yorkshire,	A dysfunctional family who	Seemed to agree as felt it was	-1.8 kg	Didn't lose much	-9.4 kg

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
White, Female 15yrs	lives with Mum and Dad. Always attended, when she chose too on random occasions, with her Dad. Mum never engaged in the study.	receive lots of social care input. Difficult to really get a clear idea of the home environment. Parents frequently fined for BOB11 lack of attendance at school. BOB11 was difficult to engage with sessions however loved music and singing. Using songs to express emotions because a useful component of sessions – e.g. tell me a song that you listen to when you are happy/sad. Bouts of exercise effort also lasted for song duration.	the easy option. On one hand values the opportunity to be involved and the other, values people believing in her. Mum doesn't feel she can do it. Upset and emotional on the day.		weight but feels project inspired her. First time she has lost weight in 12 years. Found the experience fun and has helped with her confidence. Reflects that the exercise is really hard. Old habits crept back in, including increased portions, lack of activity, when the balloon was removed.	
12 White, Female 13yrs	South Yorkshire, lives with her mum and brother. Attended sessions with her mum, brother joined	A lovely young lady, with behavioural difficulties, who was always very energetic with her sessions. At times a tense relationship with her Mum	Determination. individual sense of commitment to make it work. Healthy aspirations re: weight loss. Desire to fit in and be accepted socially in public. Changes already happening –	-7.40 kg	-	-9.4 kg

Table 9.0 – Pen portraits written from the researcher perspective for each of the BOB participants

BOB ID	Family characteristics	Background	Qualitative summary (3 months)	Weight change 6 m	Qualitative summary (12 months)	Weight change 12 m
	occasionally.	<p>– issues boundary setting. Mum attended parenting classes. History of abuse yet no specific details given, resulted in issues around men. Suffered psychotic episodes resulting in residential admission for a mental health home. Currently on weekend family visits at home.</p>	<p>increased socialising with friends walking dog, doing more. Found balloon painful initially. Established a real rapport with LR.</p>			

5.5 Key findings

Narrative discussions of the qualitative results are now presented with themes for 3 months and 12 months discussed in detail.

5.5.1 Experiences at 3 months

5.5.1.1 Reasons for engaging in BOB

To initiate conversation, all participants and their families were asked to introduce themselves with a general discussion around hobbies and interests. The independent researcher who was conducting the interviews also introduced themselves and explained the aims and purpose of the session.

Participants were asked about their reasons for participating in the BOB study and what they hoped to get out of the programme. All the young people (n=11) offered clear reasons which included the desire to lose weight (n=5), drop a dress size (n=3) or fit in (n=6); to improve confidence (n=6), to become happier in themselves (n=2) and for increased fitness to allow them to 'do more' (n=2). Some perceived the project as a last resort, with some reporting that they had hit 'rock bottom' and were at the point of despair and believed this programme represented their final opportunity to lose weight.

"I wanted to lose weight and feel better in myself because right now I'm not feeling too good" [BOB 8 participant girl aged 15yrs]

"I really wanted to improve my fitness because I thought I was really unfit and I was really fat. So I just wanted to obviously get a bit slimmer and get my fitness up" [BOB 9 participant boy aged 14yrs]

In all of the interviews where families were present (n=11), participants recalled previous weight loss attempts, and reported that they felt they had exhausted all available treatment options including community weight management groups and obesity medication. These failed attempts at weight loss were associated with feelings of guilt and disappointment. Not only was there an overwhelming sense of unhappiness with their weight status, there was also a high level of frustration both

with themselves and with what was felt to be a lack of support and treatment available to them.

“We’ve done all sorts haven’t we before, and BOB used to get really disheartened because he’d lose weight and then it would go back on again and the he’d exercise. Then he’d be weighed on different scales and it was really getting him down, he missed a good two years of school because he just didn’t want to be around people” [Mother BOB 2 participant]

“I’ve been overweight since I was little. I’ve tried tablets, I went to Shine. Nothing really worked. It was like doctors always said your resort’s surgery but I didn’t want permanent surgery” [BOB 1 participant girl aged 16yrs]

With this in mind, the final decision to participate appeared not an easy one with families reporting taking time to discuss the decision. Two families reported disagreement, as some relatives did not think they should have it done. Others were nervous about the insertion of the intra-gastric balloon itself; reporting searching for video clips on the Internet, or some had specific fears over the general anaesthetic or hospital stay.

“At first I was very nervous, but then I read in to it. I was nervous about dying in the operation” [BOB 11 participant girl aged 15 yrs]

The negative emotions and difficulties experienced by family members living with obesity reinforced willingness for their son/daughter to seek help in an attempt to prevent the ill health and negative experiences they had had.

“I’ve suffered all my life, it’s been hard, I don’t want that for my child, she deserves better.” [Mother 6 BOB participant]

Others (n=2) likened the study to bariatric surgery affecting their expectations about the degree of weight loss that could be achieved, shaping their decisions to take part in the study.

“It was just the fact that you hear all these stories of people having these gastric whatever they are and stuff like that, and they lose all this weight. So I’ll try it sort of thing because it should work. And it has up to now”[Mother 7 BOB participant]

5.5.1.2 BOB experiences

At 3 months, participants were asked to recount their early experiences of participating in the BOB study. Accounts predominantly focused on living with the intra-gastric balloon with immediate attention on the negative side effects initially experienced post insertion.

“It’s to be honest I don’t really notice it a lot, but most of the time it’s – it don’t really do much for me, like when I’m – I get weird like feelings in my stomach. Like when you, like when you, you can’t lay on your stomach on it because it feels like there’s a balloon in your stomach obviously, but you get random stomach rumblings, other than that I don’t not feel anything else” [BOB 7 participant girl aged 16 yrs]

Although all participants described not physically feeling the intra-gastric balloon on a day-to-day basis, its impact on eating behaviours varied. References to the type of food eaten and the restricted volume of food they could eat were common with some also comparing what they ate now to pre- balloon.

“I felt sick for quite a while, for like a week. But it felt quite weird because I felt like if I had a sandwich normally before I would have wanted something else. But if I just had that sandwich then I’m quite full and I didn’t really want anything else which seemed quite weird” [BOB 3 participant boy aged 15yrs]

“Well before I would normally skip breakfast. Then I’d have something at school, I’d probably have toast or a sausage sandwich. Then I’d have dinner at school but a main meal like fish and chips, or just some chips from the chip shop. Then I’d get home and I’d have like another sausage sandwich, then another big meal my mum cooked. And then I’d have crisps and chocolate and different sweets and lots of fizzy drinks. Now I’d have Weetabix with semi-skimmed milk and then an apple at 11. I have my dinner at one which would be pasta or sandwich then when I get home I’d have whatever my mum had cooked. The other night I had quiche and salad”[BOB 4 participant boy aged 15yrs]

Others focused on the psychological impact of knowing they had an intra-gastric balloon inserted and how this consciously influenced their decision making, particularly about what to eat.

“I think it’s the fact it’s [intra-gastric balloon] in there and you can sometimes feel it when you are eating. It just makes you actually take notice so you think about you’re doing and whether you’re eating or whatever. But before you’re eating and you don’t think” [BOB 4 participant boy aged 15 yrs]

Individuals and families (n=5) talked positively about engagement with the lifestyle programme, enjoying the gym based physical activity sessions and valuing the additional time to talk to someone.

“We’ve come and done all the gym sessions haven’t we, I mean I started in a wheelchair as I’ve fluid on the brain and I was ever so stuffed. There were only little bits I could do, like the leg push down, the first time I couldn’t do it and was just hoisting, I couldn’t move I couldn’t do it. Today I’ve done it, put my legs up and its totally different. My movements totally different, everything different” [Mother 2 BOB participant]

All of the young people talked positively about attempting lifestyle changes however their accounts varied in the degree to which these changes had been consistently implemented.

“I’m doing more, I’m actually walking to school. I’m walking a lot more , doing a lot more, eating less, changing my food and what I’m eating” [BOB 9 participant boy aged 14yrs]

5.5.1.3 Support

Participants were asked to identify key people who had supported them in their journey so far and how they had helped. Family, friends and members of the research team were all identified.

Peer support from friends was frequently mentioned but the extent to which they described their support was mixed with only a few (n=2) seemingly being able to honestly talk to their friends about their involvement with the study, whilst others (n=3) looked to internet friends for reassurance.

"I have some very supportive friends. My friends are always telling me to come out and we'll go for a walk and stuff like that. And they're walking the dog an' stuff" [BOB 12 participant girl aged 13yrs]

"I don't know, like some people answer like oh yeah we'll go out and do something and then other people would be oh yeah we'll get a KFC or something stupid like that and you're always battling between them" [BOB 3 participant boy aged 15yrs]

All adolescents perceived their family to be supportive but their accounts differed in the level of detail given when describing how they were being supportive. Some felt they were supported logistically, because their parents enabled them to attend the programme by driving them to appointments, as well as practically helping by buying healthy food in the house whilst others recalled their parents had consented allowing them to take part in the research in the first place (n=4).

"The positives outweigh the negatives definitely. Well, when people brought me here a lot like week in and week out, and obviously mum brought me" [BOB 6 participant girl aged 14yrs]

"My mum's helped me a lot because like if I say oh don't bring that into the house she'll stop bringing it in the house. So if I ask her to get me some more water she'll go shopping and get me some more water" [BOB 4 participant boy aged 15yrs]

The perceived emotional support from families seemed important to the adolescents, with many reporting their families helped motivate them, particularly on bad days, offering regular encouragement to keep up with lifestyle changes.

"I couldn't do it on my own because well I live with my mum and brother. If they were against it or anything like that I couldn't do it on my own. They're there to support me" [BOB 1 participant girl aged 16yrs]

"I just think when they're giving advice and like when, they basically tell you how it is. Because I wouldn't want them like tiptoe around me and just be easy, but when they just tell you how it is". [BOB 3 participant boy aged 15yrs]

Interviews also offered insight into the habits of the parents, particularly around dietary patterns, with many parents recognising the impact of their own habits on the capability of their son or daughter to make healthy lifestyle changes.

"I've been helping with food a bit more haven't I ? [Mother 12 BOB participant] Yeah, by not eating chocolate in front of me, or drinking loads of fizzy pop in front of you" [BOB 12 participant girl aged 13yrs]

Whilst all parents described a willingness to support their children to lose weight, for the majority of parents this did not involve making any changes to their own lifestyles or behaviours.

"Obviously we do try and support him definitely. So obviously we do try and have meals that fit around what he [BOB participant] should have, that sort of thing. But we work silly hours me and his Dad so obviously our eating habits are different" [Mother BOB 9 participant]

Only one mum described how in their family they implemented changes together with everyone acknowledging that they could all benefit from leading a healthy lifestyle.

The BOB participant within this family lost the most weight out of the cohort inferring that whole family support was crucial here.

"We all now eat low fat and skimmed milk, low fat spread, turkey rashers instead of bacon. Everything's changed hasn't it? We have Quorn meat instead – you know we are always looking for alternatives. Everything's fresh and like we'll sit and make our own kebabs but we do it together" [Mother 2 BOB participant]

The research team were involved in delivering the lifestyle programme and were perceived as supportive either as advice givers, sources of encouragement or as a friend with whom they could trust and talk to.

“That they believe that I can do it; like they support me , I support them and we support each other and they help, which is nice as some people don’t” [BOB 8 participant girl aged 15yrs]

5.5.1.4. Evidence of change

During this early phase of the intra-gastric balloon and lifestyle support programme, adolescents spoke clearly of how their lifestyles had changed compared to life prior to the study. Participants most commonly focused on dietary changes, making healthier food swaps or eating smaller portions.

“When she eats its like she’s having a snack. She’ll think about what she’s having but it’s also not as much as before. Whereas before it would have been a sandwich followed by a yogurt, followed by a chocolate bar followed by a biscuit followed by, she’d still be looking for something else, whereas now it could be yogurt and a biscuit or a piece of fruit and a biscuit” [BOB 7 participant girl aged 16yrs]

The reasons behind these changes did however vary. What was apparent across all participants was the awareness of the intra-gastric balloon and how often the adolescents thought about this. For some (n=3) the negative side effects of the intra-gastric balloon including stomach cramps and vomiting and diarrhoeas forced some of the dietary changes in the short term.

“You learn like some stuff you can eat and you’ll be fine, and other stuff you can’t eat and you’ll get horrible bellyache. Like hash browns, I thought I’d be alright and I weren’t. I had McDonalds, I had chips and chicken nuggets and just like after a month of having it done I was in pain for four days. You learn what you can and can’t have” [BOB 8 participant girl aged 16yrs]

Even at this early stage, many adolescents attributed changes in their behaviour directly to the intra-gastric balloon either because of the conscious awareness that they had an intra-gastric balloon inside them or as a result of the physical side effects impacting on their taste or cravings for specific foods.

“I think it’s the fact that it’s in there and you can feel it when you are eating. It makes you actually notice it, so you think about what you’re doing and whether you’re eating

or whatever you take note of it. Not before you're just eating and you don't think about it" [BOB 4 participant boy aged 15yrs]

"its put me off certain foods but not everything. I've lost a bit, can't remember how much" [BOB 8 participant girl aged 15yrs]

5.5.1.5 Challenges

All participants had described situations where they had found it difficult to manage their emotions in their day-to-day lives with frequent accounts of feeling upset and angry at their weight status. Commonly, those adolescents attending school (n=10) detailed negative experiences of bullying (n=8) or the stress of exams (n=4). They were reminded of the difficulty to achieve weight loss, even for those who had lost weight at this stage (n=8). Some thought weight loss would be easier with the intra-gastric balloon inserted and were left feeling disappointed when weight loss was less than expected (n=4).

"I was a bit disappointed because I had actually started trying. When you do these weight loss things and you give up halfway through, but then I actually started trying really hard and I put it back on, and I got a bit upset about it" [BOB 6 participant girl aged 15 yrs]

Reasons given for the weight measurements differed amongst those who had lost weight and those who hadn't. Where weight loss had occurred there was an acknowledgment of how changes in individual behaviours were supported by the intra-gastric balloon but importantly required their own volitional control.

"I eat less, because it makes you not feel hungry but I now eat healthier with more fruit and stuff. I still have to make sure I don't eat too much, say if I ate now like I used to before then I would I would weight on" [BOB 8 participant girl aged 15yrs]

Whilst in contrast, for those who had not lost weight, failure was attributed directly to the intra-gastric balloon inferring that they thought the balloon would lose weight for them.

“I mean I eat less but it [intra-gastric balloon] hasn’t worked as well as I thought it would because I still eat quite a bit of amount, its sort of a learning curve and to saying, I have to do it, not the balloon. It’s helped me more mentally instead of physically because I haven’t done a right deal of weight loss” [BOB 7 participant boy aged 16 yrs]

5.5.1.6 Looking ahead to the remainder of the programme

The predominant focus when looking ahead was on the removal of the intra-gastric balloon and their aspirations of weight loss and positive changes. For some, the focus was on maintaining what they were currently doing, attending the programme’s gym and lifestyle sessions (n=6) and aiming for steady weight loss (n=2).

“it’s made a difference, if I keep working on it then it will be a bigger difference” [BOB 3 participant boy aged 15 yrs]

Some spoke of aspirations to accomplish a challenge, for example to take part in a race for life or get in a certain dress size for a wedding (n=2). Whilst in contrast, others seemed anxious already about *“keeping the weight off longer-term”* (n=2).

“More weight loss, because you can get the ball rolling but it should just carry on” [BOB 3 participant boy aged 15 yrs]

5.5.1.7 Summary of 3-month findings

At three months, a desire to fit in amongst peers, improved confidence, health benefits and an opportunity to receive treatment prior to undertaking bariatric surgery, were the main reasons given by BOB participants for taking part in the study. All (n=11) had clear expectations of what they wanted from the programme including; increased confidence, weight loss, enhanced ability to fit in socially and avoid bullying alongside the opportunity to shop for new clothes on the high street. The initial negative side effects of the intra-gastric balloon were discussed, which for some (n=3) lasted longer causing distress (n=1). For others (n=5) this early phase was already associated with positive changes including an increased awareness of food choice, eating breakfast, increased physical activity levels along with a sense of commitment to maintain this momentum for further change. In contrast, others (n=3) expressed a sense of

frustration, as weight loss was slower than expected. An overwhelming theme was the reliance on the intra-gastric balloon and that it would make weight loss easier from both adolescents and parents. Whilst interviews offered an insight into the habits of parents the accounts inferred a complex process within the family dynamic that requires additional exploration in order to understand how to facilitate a whole family approach to change. That said parental accounts identified an awareness of the impact of their behaviours on their children albeit there was limited evidence of their implementation of behaviour change. Distance to travel for the study and study logistics such as car parking, were discussed as initial barriers.

5.5.2 12-month interview findings

The next section describes interviews from the BOB participants at 12-month follow-up from their baseline appointment (6 months post balloon removal and 3 months post lifestyle programme).

5.5.2.1 BOB experience and programme reflections

Overall the accounts reflected a sense that, irrespective of weight outcomes, all participants interviewed at 12 months had welcomed the opportunity to take part in the research and had enjoyed participation in the programme.

“Before the balloon was in I was just bad. I was putting on weight like two pounds every month and it was making me depressed which caused me to eat more. I wasn’t in an amazing place but going through the whole BOB trial it just makes me think about if I hadn’t done this what size would be now? Enormous” [BOB 4 participant boy aged 16yrs]

“I’ve spent so many years trying to do something, looking abroad at surgery and if it wasn’t for this research then I wouldn’t be in the position I am now” [BOB 1 participant girl aged 15 yrs]

Frequently families described the study as a learning opportunity. Many spoke (n=8) of how their initial impressions of the programme were that the intra-gastric balloon would offer a quick fix - firmly believing that weight loss would be easier with the intra-gastric balloon inserted. This was despite a 4-week preparatory phase with the multidisciplinary team of researchers who outlined the expectations for the study and

how the intra-gastric balloon worked, continually reinforcing that the study was to act as a 'kick start' to weight loss. The qualitative findings reinforce the importance of having this preparatory phase within a programme such as this, in order to ensure participants are psychological ready for the demands of the study and their expectations managed.

Some families reported doing their own research on the internet particularly around the intra-gastric balloon and were unclear about whether it would work or not, whilst others compared the study with bariatric surgery.

Generally, there was a sense of disappointment felt by the adolescents when asked how effective the intra-gastric balloon had been in helping them achieve weight loss compared with their initial expectations. For many, they felt they were just getting into a routine living with the intra-gastric balloon when it was removed and they then struggled to continue what they had been doing.

"Like I'd actually got really settled in and everything were going really really well and I were coming to the gym and doing all that lots but then it were time to come. And of course with other stuff going on in my life and it just too far to keep coming here . I know I'd asked about a gym membership"[BOB 1 participant girl aged 17yrs]

*"I lost it [weight] when it was in. yeah it gave me a kick start. But since the balloons out I put it back on. I'm back to less exercise and probably eating more of the wrong stuff"
[BOB participant 7 girl aged 16yrs]*

For one BOB participant however he described making meaningful changes throughout the programme and described feeling that he *"thought I was going back to square one and it would just undo itself. But actually my portion sizes are smaller and I don't feel hungry constantly like I used to. Before I would have gone back for seconds and thirds and they were just big. Now I have three standard meals a day and they're usually healthy as well. I wouldn't say I've achieved my goal though yet but I'm on the right path to reaching it."*

What was apparent throughout all the interviews was the psychological impact of the intra-gastric balloon. During its insertion, participants described how it acted as an

additional nudge, like “a little voice in my head” for motivation and encouragement as they consciously remembered it was there.

“it’s psychological you know the balloons in so you know you can’t eat more as it will make you feel sick or whatever” [BOB 8 participant girl aged 15yrs]

Whilst on reflection at 12 months, irrespective of their current weight status, all participants described how the intra-gastric balloon had been a learning tool, helping them realise that not only did they have to work with the intra-gastric balloon to lose more weight but that it was actually their own choices and lifestyle behaviours that would help them lose weight, not relying on the intra-gastric balloon to do it for them.

“It’s helped me mentally realise that this is not a quick fix and that I have to do it myself instead of looking for another way out” [BOB 3 participant boy aged 16yrs]

“I realised that it had come out and then it was a like OK I need to get my arse into gear now” [BOB 3 participant boy aged 15yrs]

“I don’t know but when it came out something just clicked, just changed and he thought no, I got to do this for myself” [mother 2 BOB participant]

5.5.2.2 Evidence of change

A strong theme emerging from the 12-month interviews was the time spent reflecting on changes made throughout the programme. Change meant different things for different individuals and their families. For some, changes were behavioural with one family talking about how they adopted change as a whole family with accounts focused on actions they had taken and were continuing to take.

“We’ve changed everything what we eat. We try to eat the same as what [BOB] does, so that nobody’s having anything different “ [Mother BOB 2 participant]

Other adolescents attributed all changes to the intra-gastric balloon whilst it was inserted diminishing their role in the weight loss process. Looking at the weight loss outcomes, those adolescents who solely relied on the intra-gastric balloon for weight loss were left more unsatisfied than those who did not rely on it solely for weight loss.

This attitude shifted however, once the intra-gastric balloon had been removed. There was an overwhelming feeling from the adolescents that if they had actually worked with the intra-gastric balloon by making lifestyle changes, such as eating healthily, reducing portion sizes and being physically active, increased weight loss would have been possible. It appears that going through this process, the group were beginning to accept their own role in achieving weight loss, attributing less to external factors such as an intra-gastric balloon.

“If you don’t work with the balloon, then it won’t work” [BOB 2 participant boy aged 16yrs]

“I thought it would be a lot more easier, I just thought the balloon would do it all for me. But I’ve realised that wasn’t the answer, it was just the kick start to keep things going but it was just partly to help me but I had to do the rest myself” [BOB 3 participant boy aged 16yrs]

All parents acknowledged that their son or daughters weight was an issue prior to commencing the programme and all parent’s welcomed the opportunity for their child to receive support, not only in an attempt to lose weight but to also improve their overall health and wellbeing. On reflection, some parents admitted that they had perceived larger amounts of weight loss with the intra-gastric balloon, with some feeling dissatisfied (n=4). Other parents focused on the broader changes observed in their son and daughter, their improved attitude to weight and the broader health and wellbeing benefits experienced.

“We were getting to the point of despair weren’t we, we had tried everything. I did look at a gastric band but I didn’t think that was quite the answer, although that would be the last resort , I knew he [BOB] was getting into this I’ll go somewhere and they will fix me mentally. I knew deep down he needed a balloon first and if that didn’t work then it would be a gastric band. There are other way around it and if you don’t understand and take ownership, even with a gastric band you need to manage calories..... so I wasn’t comfortable to start but its been more than I expected..... It’s gone beyond physical, if you do this the balloon will help you. Its gone beyond that to him realising well I’ve got to work at this otherwise it’s not going to happen. Otherwise after the balloon you go back to square one, and fortunately he hasn’t, so it’s been fantastic” [Mother BOB 2 participant]

Parental views differed to their child's when consideration was given to programme set up. Distance to travel to appointments and attending the two research sites were barriers to attending for families living outside of Sheffield with some travelling over an hour to attend sessions. Although sessions were offered on a flexible basis with times chosen by each family, several parents (n=5) reported a disturbance to their commitments, with some re-arranging work commitments and shift patterns, or booking annual leave so they could attend. Others had to negotiate the time off with schools and colleges which caused some disruption to school work, others had to organise childcare around the session whilst one parent alluded to the financial impact of attending with the timing of sessions dictated around when she got her benefit money so that she could put petrol in her car.

"A bit annoying at times. The actual balloon didn't work as well as I thought it might be have done, he obviously didn't lose as much weight as I thought he might have done. But all other aspects and everything put together its been fine, that what I wanted for him, to be more social, go out more and a bit more active and self-confident, and he has" [Mother BOB 3 participant]

There was an overwhelming sense from the BOB adolescents and their parents/families that further formal support was needed for the lifestyle programme post intra-gastric balloon removal. This was a consistent finding across the group irrespective of individual weight change. The protocol allowed for two-month support post balloon removal yet poor adherence was recorded for all families. Reasons for not attending included college and university work; social commitments; childcare and distance to travel.

The primary reason given for the need for further support was to encourage maintenance of lifestyle changes and to continue the support received from the researchers. Adolescents reported old habits creeping back in once the programme had finished which included sneaking crisps back to their bedroom and eating in secret, *"eating whatever I want"*, and the size of portions increasing along with eating regularly through the night.

"I thought well there's nowt telling me I can't eat, so can eat as much as I want now. So I'll just go back to as I were type of thing" BOB 10 participant girl aged 17yrs]

"I've been trying but it's been quite difficult, not as easy as when the balloon was in. you have to think about things even more" [BOB 10 participant girl aged 17yrs]

Irrespective of weight regain post balloon removal, many described themselves as more confident in the knowledge that they could now lose weight and took pride in this. This is reinforced by the increased quality of life scores reported in Chapter 4.

"It's just not necessary to eat so much, there's just no need for it. Maybe I used to use it as a way of coping emotionally but because I am now a lot happier that I'm not that weight I don't snack because of it" [BOB 4 participant boy aged 17yrs]

5.5.2.3 Relationships

Support networks identified by an individual are a crucial element when facilitating a successful behaviour change attempt (Lachal et al. 2013). At 12 months, the young people predominantly identified the research team and family as the main sources of support during the intervention. Adolescents reported the research team offered advice, regular support and continuous encouragement, whilst also offering emotional support, with some BOB participant's seeing the team like friends.

"The feeling you get from being here and doing, and we talk and we laugh and we find, you know bits. It's not like coming, its not a chore, it becomes, you want to come; its like coming to see a friend" [BOB 7 participant boy aged 17yrs]

Adolescents generally found describing how their family had supported them a challenge. Where examples were given, all focused on practical support, such as buying healthy food in the home, providing lifts to the university to attend the sessions or giving money for travel expenses. This for some (n=2) reinforced that their family cared.

"My mum especially as she's spent all these years and she found this, She didn't have to, most parents wouldn't but she is always there, saying if I put too much on plate and stuff like that" [BOB 4 participant boy aged 16yrs]

Across this group of adolescents, relationships with peers appeared inconsistent and somewhat complex. Some described having supportive friends who attended sessions of the BOB programme with them (n=2). Some adolescents(n=4) chose not to tell their friends about the procedure for fear of being judged whilst two of the participants reported being bullied throughout the BOB programme at school.

“Don’t even talk to me about friends. Don’t even talk about them. I don’t know who my friends are. Yeah but the only people I have at school now is Georgia Annabel Antonia and Page and its like they don’t even want to be my friends anymore. Because they don’t talk to me. I’m like the third wheel with them. It hard, it like it can’t speak to them about it though because they get all defensive and say it’s my fault. It just always puts me down” [BOB 6 participant girl aged 15yrs]

A couple of the male adolescents (n=2) did allude to having *“actual friends now rather than virtual ones through my Xbox”* reinforcing a tendency to socialise with peers in these cases. The social impact requires further exploration, as this was not explicitly detailed in the qualitative data analysed here.

5.5.2.4 Life events

Several of the adolescents, particularly the older adolescents, alluded to life events influencing their participation in the intervention. This included transitions from school to college and to university, getting a job, learning to drive and generally turning 18 years old. Some factors were perceived as negative for example, exam periods, whilst others were positive such as learning to drive and having their own car which enabled them to be independent.

“I’ve started college now which means I’m going out more, walking more and just more independence which is good” [BOB 2 participant boy aged 16yrs]

5.5.2.5 Summary of 12-month findings

The 12-month interview gave the opportunity for adolescents and their families to reflect on the overall programme experience. Perceived effectiveness of the programme was strongly influenced by the degree of weight loss experienced. Families who perceived the study a quick fix and relied on the intra-gastric balloon felt

disappointed with weight loss. The majority however acknowledged that it had been a learning opportunity.

A consistent view held by all of the participants and their families was the need for longer-term support post intra-gastric balloon removal, to encourage the maintenance of lifestyle behaviours. This is despite being offered a two month maintenance period which none of the families attended consistently. Parents empathised with the challenge of weight loss experienced by their children yet the level of engagement observed from parents, in terms of attending the programmes and making lifestyle changes themselves, differed amongst the group. This reinforces the importance, albeit complex, of integrating the family and home environment within the delivery of obesity treatment for severely obese adolescents.

5.5.3 Case studies of BOB participants

The aim of this qualitative enquiry was to understand the experiences of participating in the BOB programme, from the perspective of severely obese adolescents and their families, recognising very little is known about participant's actual experiences during and post treatment (Dahl et al., 2014). The qualitative experiences help to provide a context to begin to understand the variability of outcome data, highlighted in Chapter 4, across the pilot study of 12 adolescents at 6 months and 12 months. Beginning to unpack the mediators and barriers to weight loss could help identify individuals and families who are more likely to succeed within a treatment programme. A typology can do this by offering an informal description of an individual or group that displays certain traits and behaviours (Gale et al., 2014).

Building further on the qualitative findings, and in an attempt to understand the reasons behind the varied outcomes in the BOB participants (Chapter 4), a typology has been developed amalgamating qualitative interview data and session notes captured during the lifestyle sessions, for the following case studies:

Successful BOB participant who lost and maintained weight at 6 and 12 months and engaged with the BOB programme;

BOB participant who lost minimal weight at 6 months, gained weight at 12 months and did not engage with the BOB programme.

BOB participant, who lost weight at 6 months, re-gained at 12 months and attended the BOB programme regularly.

5.5.3.1 Case study 1:

BOB participant 2

Weight loss at 6 months = 22.6 kg

Weight loss at 12 months = 34.4 kg

Attendance with BOB programme = 76%

On entering the programme, BOB 2 had dropped out of school 2 years ago due to bullying, his weight was continually going up and he had tried all available treatments including lifestyle programmes in the community and medication. BOB 2 attended all sessions of the BOB programme with his Mum and at least always one sibling. From the first appointment with the research team, the whole family attended every appointment as a family and were committed to change together. They appeared ready for the intervention and reported researching details of the intra-gastric balloon on the internet, which had given them an idea of what to expect. All family members were overweight and/or obese but recognised that although the programme was focused on BOB 2, they could all benefit from the education, advice and lifestyle sessions throughout the programme. During the first session Mum arrived in a wheelchair only able to walk 100 m unaided with BOB 2 mute throughout the whole session, hiding behind a long fringe. He looked at the floor and did not respond verbally to any questions. It became apparent at this early stage that this was the last resort for this family, they were in an emotional low and they had acknowledged the need to respond and change to their common issues around weight and weight loss. BOB 2 defined success at the end of programme by drawing his ideal outfit, which we would not only wear, but have brought, from a high street shop.

At 3 months, the tone of the interview conducted was positive. There was a clear evidence of lifestyle change for the whole family – *“we’ve done everything together haven’t we?!”* They described sitting as a family to plan the weekly meals, writing a supermarket shopping list and adopting a different way of cooking. They talked openly about feeling they can move, going out as a family and visiting places, going to Rother Valley and playing rounder’s – *“he doesn’t sit in his bedroom all day, he’s now downstairs and out and about with us”*. This positive momentum continued into the 12-month interview with a strong appreciation of their involvement with study *“it was the best thing for him, he was ready, we had a bad time before it, crying all the time, seeing that change from him saying I don’t want to live anymore”* and a totally different young man – *“he head’s up, instead of walking looking at the floor he actually looks at people”* and *“I see him every day, and I can’t believe it’s my son walking around in his boxers, he totally changed”*. Recurring themes from conversations were the focus and implementation of lifestyle changes as a family, with less conversation focused on the intra-gastric balloon. There was never a sole reliance on the intra-gastric balloon, BOB 2 invested in making positive lifestyle choices throughout the programme, with a committed attitude to lose weight for him – *“it was the right time, it just clicked”*.

Towards the end of the programme, he had started an apprenticeship scheme at college, proposed to his girlfriend and opened a bank account. He also achieved his goal of wearing the outfit he drew in one of the familiarisation sessions to his last BOB session. The family commitment to engage with the programme and the changes at home were stark. BOB 2 and his family believed this programme was the answer and committed to not only attending the sessions from the outset, but also making changes within their home environment. They did a lot as a family and throughout BOB 2 attitude has changed. They described him as more confident, now walking with his head held high, not looking down at the floor all the time. The family saw this programme *“as a kick start, having the additional support to help and guide but it’s still left for us to do the work. It’s just what we needed, BOB 2 wouldn’t have survived otherwise, just brilliant”*.

The key themes to draw from BOB 2 case study is the impact that wholehearted commitment from the whole family can have on the ability to make lifestyle changes and adaptations within their home environment. BOB 2 also entered the study believing this was the right time, it was last resort and he firmly believed that he wanted, needed and would change *"it's been life changing"*.

5.5.3.2 Case study 2:

BOB participant 3

Weight loss at 6 months = 0.5 kg

Weight gain at 12 months = 7.8 kg

Attendance with BOB programme = 26%

BOB 3 entered the study during his GCSE year and lived an hour away from the research centre. It was apparent during the early sessions that the mother was protective of her son, talking for her son on numerous occasions, with BOB 3 having to be actively encouraged to contribute to the sessions. At times it was clear his Mum did not listen, as she would say the opposite to what her son had said moments before. BOB 3 explained that he never felt full and ate due to boredom most of the time, whilst admitting he was lazy. *"Because I've got nothing to do and I'm bored I just, I don't know, get something to eat; for something to waste time a bit because nothing else to do when I'm bored"*.

During the 3-month interview, BOB 3 described how he rarely felt the balloon, albeit a few weird sensations, and that he felt it hadn't done much for him. To the extent at times, *"that it's easy to get demotivated when I know I've got the balloon in because I know oh its not doing anything, what's the point of having it and that makes me get really demotivated"*. BOB 3 acknowledged he thought it was going to stop him eating a lot more than it actually did inferring he solely relied on the balloon to induce weight loss. His mother spoke openly about her bariatric surgery operation and the large amount of weight lost. It is possible that this influenced family expectations about the degree of weight loss achievable on this study. Once the balloon had been removed

BOB 3 described feeling more comfortable. His mother described dietary changes, a reduction in portions size and increased daily walking now that BOB 3 had started college. Reflecting on the BOB programme, BOB 3 described how it had been a learning curve and *“it’s helped me mentally realise that it’s not a quick fix and that I have to do it myself instead of looking for another way out”*. His mother describes the experience as *“yeah we did stay with the balloon and it didn’t work. To be honest, for those 6 months he did feel bloated, now whether or not he gives it a chance now to do it himself now and see how he gets on with that”*.

A theme demonstrating concordance within the data, is the apparent lack of a united approach. The mother’s language implies that she perceived her sons weight to be entirely his issue, placing the need for change solely on him – a direct contrast from Case study 1. Limited attention within the interviews was given to the lifestyle changes, or the home environment inferring an attitude of sole reliance on the intra-gastric balloon, thereby feeling dissatisfied with the weight outcome.

5.5.3.3 Case study 3:

BOB participant 6

Weight loss at 6 months = 11.9 kg

Weight loss at 12 months = 1.4 kg

Attendance with BOB programme = 73%

BOB 6 and her family took the decision to participate in the study after they had tried all available treatment options with limited effectiveness. Although her parents are divorced, she lives with mother but sees her Dad regularly. She attended the lifestyle sessions primarily with her Dad. She talked during the sessions about being bullied at school and how the bullying involved recent episodes of physical and verbal abuse. This began to impact on schoolwork and even resulted in a care plan being jointly devised between multiple agencies including the BOB research team and child and adolescent mental health services (CAHMS). BOB 6 was also diagnosed with depression and given medication following a suicide attempt. At 3 months, BOB 6 had lost weight and was enjoying the sessions with a visible improvement in physical fitness levels.

Evidence of change was detailed as regularly eating breakfast, eating less and walking more, including walking to school. BOB 6 was very reserved and very quiet particularly during the qualitative interviews, even telling the lead researcher she did not enjoy being audio recorded. At 12 months, BOB 6 reported regaining all of the weight she had lost during the programme, describing old habits creeping back in. The bullying had persisted at school to an extent she now attended a different school a couple of days a week. Her father attributed weight changes to the intra-gastric balloon, with BOB 6 admitting she relied on the programme for routine and was just getting used to it and then when it stopped was not able to keep the momentum going. This outlines that whilst attending the programme BOB 6 felt supported yet when this stopped, she was unable to maintain the behaviours back within her home environment. Integrating the home and family environment within the treatment programme could help with this, along with supporting the young person to have the skills and strategies to apply within their own environment.

The key theme to draw from BOB 6 is the complexity of severe obesity and the depth of emotional and psychological issues experienced, which shaped her ability and willingness to engage in the programme. She also had very low self-esteem "*I'm just worthless*", most likely due to her bullying experiences, identified through the PedsQL scores (Chapter 4), with evidence of emotional eating and negative health behaviours that although were not helpful for weight loss, helped her cope with the emotional situations. Whilst receiving support during the programme, "*I just focus on one day at a time as its easier that way*". This did not go as far as to tackle the root cause of her obesity. As a result, once the intra-gastric balloon was removed and the lifestyle sessions had stopped she defaulted back into the coping strategies she had adopted previously, leading to weight re-gain. This case study also reinforces the need for a multi-agency approach for individuals who have greater psychological needs, which, with an absence of professional guidance on how to manage to young people on care plans within obesity management, is a particular challenge for practitioners and researchers (Nobles and Sharman., 2016).

5.6 Discussion

The aim of this qualitative study was to explore the experiences of the BOB intervention, intra-gastric balloon and lifestyle programme, from a participant and family perspective during and post-treatment. The discussion has been structured around a number of key themes, which emerged from the findings.

5.6.1 Perception of the intervention (Reliance on balloon, “its down to me”)

All of the BOB participants had exhausted all available treatment options resulting in the perception that this study was a final opportunity, prior to considering bariatric surgery. Many alluded to feelings of desperation, following a history of failed weight loss attempts, and a sense of hope that this study would be effective in helping them lose weight. There was, initially, an overwhelming reliance on the intra-gastric balloon, with the majority of adolescents admitting that they believed the intra-gastric balloon would lose weight for them in the 6 months it was inserted. The adolescents believed that it would tell them when to stop eating therefore making weight loss much easier. Once the negative side effects had subsided after several days, many were surprised at how little they could feel the intra-gastric balloon and how ‘normal’ they felt. At 12-months there was an apparent realisation by the group that they had to work with the intra-gastric balloon in order to optimise weight loss.

Frequently, the families confused the study with bariatric surgery resulting in unrealistic expectations regarding the expected degree of weight loss in the 6-month period. Unrealistic goals and treatment expectations have been identified as a characteristic amongst adults seeking obesity treatment (Morinder et al., 2011), yet whether this is consistent with obese adolescents is unknown. What was found here, was that considering the perceived criterion for evaluating treatment success was weight loss; many of the participants saw the process as disappointing

5.6.2 Longer-term strategies

The goal of multidisciplinary obesity treatment for adolescents is long-term weight change. Relapse after treatment is common amongst children and adolescents (Wilfley et al., 2000) although obesity treatments that are theoretically underpinned and use behavioural change strategies are more likely to promote longer-term successes

(Hardeman et al., 2000; Mitchie et al., 2011). In addition, a programme that focuses on building self-esteem and personal empowerment will foster individuals who are more likely to engage in health related activities (Bandura, 2004). Collectively, this evidence provided the rationale for including a two-month post intervention phase within the BOB study design. Despite this, adolescents and parents perceived support ceased when the intra-gastric balloon was removed at 6-months, with poor attendance at the 'maintenance phase' of the study. When questioned during the focus groups, all participants emphasised a need for further support post-balloon removal. Previous research exploring the needs of obese adolescents has highlighted ambivalence between personal motivations and their motives for treatment (Morinder et al., 2011) highlighting a potential characteristic of this adolescent age group. That said, effective behaviour change strategies that prevent weight re-gain in severely obese adolescents post interventions are needed.

5.6.3 Environmental barriers

Multidisciplinary interventions that incorporate families into treatment are considered the 'gold standard' for treating obesity in children and adolescents (Luttikhuis et al., 2009) yet there is limited research on how to engage family members within treatment in order to optimise outcomes (McLean et al., 2013). Despite all of the families actively seeking treatment this was not necessarily an indicator of family motivation during treatment, a finding consistent with previous research (Stewart et al., 2008). Involvement and attendance of family members within the structured sessions differed significantly. One family consistently attended together, with all family members taking an active role in discussions and physical activity sessions, one adolescent forced her mother to stay in the car, whilst others attended with their family but the attention was predominantly on the adolescents behaviour. The adolescent whose whole family attended did in fact lose the most weight, yet weight outcomes were variable and further research is needed to determine the specific role families play within treatment with severely obese adolescents.

All families raised similar barriers to attending the intervention, including travel time and/or distance to travel, along with the lack of time to commit to the weekly lifestyle

sessions. When consideration was given to the implementation of behavioural change, all participants referred to a sense of chaos – a lifestyle characterised by conflicting priorities. Chaos alluded to parents juggling shift patterns at work, a perceived lack of control over their son or daughter’s behaviour, financial worries and a perceived lack of time. Whilst the young people talked about caring for a disabled mother or looking after siblings, spending nights of the week between the mother and father’s house, school and relationship issues with friends and family, all affected their ability to successfully implement their lifestyle goals.

Parental behaviours, both self-reported by parents and observed by the adolescent have been associated with an increased consumption of fruit and vegetables (Berge et al. 2014) and frequent physical activity (Erkelenz et al., 2014), which not only predicted adolescent behaviour but also reduced BMI (Zarachtya et al., 2016). Verbal pressure from parents, such as restriction of certain foods, or verbal messages to eat less and exercise more - an observation within the interviews conducted here, has been associated with negative results (Zarachtya et al., 2016). In this pilot study in four cases of weight gain at 12 months, some form of verbal pressure was identified or perceived by the young person during the qualitative interview. Whilst in comparison the participant who lost the most weight at 12 months had full engagement from the family members with all family members making lifestyle changes too. This suggests that perceived parental modelling, and not perceived parental social pressure, could be an effective way of helping adolescents to reduce their weight.

5.7 Limitations

The open-ended nature of this qualitative approach means it is possible that the researcher’s own views, conflicts and prejudices might have influenced the themes that were subsequently identified. The close rapport established between the lead researcher and the families could also have influenced the development of the informal pen portraits. On reflection, the independent researcher conducting the 3-month interviews affected the depth and quality of the interviews due to a perceived lack of rapport or trust from study participants. To resolve this, the lead researcher conducted the 12-month interviews. As identified in one of the in-depth case studies,

the audio-recorded nature of the interviews did not suit some of the participants, as they remained quiet during the interview, not detailing many of the issues, which had arisen during the informal lifestyle sessions. Having parents and families present during the interviews could have also affected the responses given by the adolescents. Therefore an alternative method of collecting the qualitative data could have been implemented along with adolescent only interviews.

5.8 Chapter conclusion

This qualitative study aimed to provide in-depth experiences of participating in the BOB programme from the adolescent and family perspective. The use of pen portraits illustrated the characteristics of the participants involved giving a context for the qualitative analysis. It also began to explore, through case studies, reasons behind the large variations in weight outcomes. The lifestyles described by the severely obese adolescents were challenging with difficult family circumstances reported including; parental divorce, parental death, disability and alcohol dependency, as well as bullying at school. The process of weight loss for severely obese adolescents also appears complex. Treatment programmes must be aimed, not just at the individual behaviour level, but also at the environment with which they live. Whilst the extent to which family inclusion in treatment influences effectiveness remains unknown (Upton et al. 2013), it appears the home based environment and the role of parent and families own lifestyle behaviours must be taken into account when designing adolescent treatment programmes.

This chapter contributes to the limited evidence base of the lived experience of severely obese adolescents and their families participating in obesity treatments. Further qualitative work should be conducted from the participant perspective to improve the effectiveness of obesity treatment programmes for severely obese adolescents and their families.

6.0 Purpose

Adolescent obesity is a significant public health issue (Baur et al. 2011). Amongst obese adolescents, a third are severely obese classified above the 99.6th centile or a BMI Z score greater than 3.5 SD (Cole, 1997). Severe obesity is associated with significant physical morbidity, with evidence of obesity related complications including type 2 diabetes, fatty liver and respiratory failure, all developing whilst still in adolescence (Kelly et al., 2013). Research interventions have predominantly focused on young people as a whole with little differentiation of treatment and outcomes by age and severity of obesity. Although this allows for general conclusions to be drawn, it does however make it challenging to identify any findings that are specific to the adolescent age group (Steinbeck et al. 2009).

A review of the efficacy of a range of interventions designed to treat obesity in children and adolescents (Luuthkhis et al., 2009) identified the importance of a combined diet, physical activity and behavioural component and parental involvement. That said data fails to identify a specific treatment programme, with interventions in the main failing to initiate and sustain significant weight loss (Luttikhuis et al., 2009). The few studies that have focused on the treatment of severely obese adolescents have predominantly involved bariatric surgery (Black et al., 2013) with a lack of consistency in the design and delivery of lifestyle behaviour interventions – a finding identified in the scoping review (Chapter 2). Bariatric surgery in adolescence is however under researched with limited data on the long-term health and psychological impact (Sachdev et al., 2014). In addition, reluctance from health professionals to consider permanent bariatric surgery for adolescents (Woolford et al., 2010) reinforces the need for research that bridges this treatment gap.

The aim of this thesis was to advance understanding on the treatment of severe obesity amongst adolescents and their families. To achieve this, the thesis considered the following research objectives: 1) Better understand the unique characteristics and needs of adolescents as a distinct population and explore how this knowledge can be

used to inform the design of treatment programmes 2) Determine the current effective treatments that specifically focus on severe obesity amongst adolescents and establish how current evidence can be used to inform novel and effective treatments going forwards 3) Enhance the quality and reporting of the detail of programmes that intend to treat obesity in adolescents 4) Pilot the use of an intra-gastric balloon alongside a multidisciplinary lifestyle support programme to promote weight loss and behaviour change in severely obese adolescents 5) Explore the adolescent experience of engaging in treatment to inform future work.

The purpose of this final Chapter is four-fold: 1) Provide a synthesis of the key findings from the studies throughout this thesis 2) Discuss the implications for future research 3) present a reflection on the research process throughout undertaking the PhD and 4) conclude the thesis.

6.1 Synthesis of the key thesis findings

Collectively, the obese and severely obese adolescents involved in this thesis provided detailed and coherent accounts of their experiences living with obesity. The young people offered negative, emotional accounts detailing how obesity affects all aspects of their lives including physical health, mental and emotional wellbeing, and social situations. Low self-esteem was a recurring theme along with an inability to make friends and foster social relationships – collectively acting, as catalyst's to promote behaviour change. Bullying was frequently described as debilitating, and was associated with behaviours that promoted weight gain including emotional eating and social isolation, reinforcing feelings of low self-worth and low self-esteem.

To bridge the treatment gap between ineffective multidisciplinary lifestyle treatments and invasive bariatric surgery (Chapter 2), Chapter 4 detailed the design and implementation of a novel treatment approach for severely obese adolescents and their families (Study 2). Chapter 4 demonstrates the acceptability of a multidisciplinary lifestyle programme (incorporating diet, physical activity and a theoretically underpinned behavioural component) alongside an intra-gastric balloon delivered over a 12-month period within a pilot sample of severely obese adolescents and their

families. This study demonstrated the ability to produce short-term reductions in BMI Z score, which is known to have beneficial impact on health and wellbeing later in life (Kelly and Kelly, 2013). Results also exceeded the minimal clinical important differences in all domains of health related quality of life, with improvements sustained at 12 months whilst modest improvements were also observed in cardio-respiratory fitness. Furthermore, the detailed reporting on the lifestyle programmes content (Reece et al. 2014), in line with conclusions drawn in Chapter 2, provides pragmatic information to assist researchers and practitioners in the design and implementation of future programmes.

The qualitative study exploring the experience of participating in the BOB study (Chapter 5; Study 3) offered a unique insight into a population group, which thus far have remained largely ignored (Steinbeck, 2011). The qualitative findings in BOB were consistent with the conclusions drawn from Study 1 - that the lives of severely obese adolescents were associated with low self-esteem involving difficult life circumstances including parental divorce, parental death, disability and alcohol dependency, as well as bullying at school. The process of weight loss for severely obese adolescents appears somewhat complex with individual, family, environmental and social factors all influencing adolescent behaviours. Adolescents involved in this thesis frequently perceived parents as a critical source of support when seeking treatment, but recognised they were also crucial in the successful implementation of lifestyle changes longer-term (Study 1). For adolescents participating in the BOB study (Study 2; Chapter 4), family habits, parental behaviours and the capacity of the family unit to make changes, all influenced weight loss outcomes along with dietary and physical activity patterns. Obese adolescents (Study 1) associated their weight gain with their own behaviours, attributing self-blame and responsibility for being obese internally to themselves. Yet the adolescents externally perceived the treatment as the primary responsibility for the solution, which potentially diminishes their engagement with the weight loss process. It also undermines the development of self-worth and self-esteem. This finding was further reinforced through the BOB study as the majority of severely obese adolescents entering the study relied on the intra-gastric balloon to

lose weight for them. Only during the 12-month interviews did adolescents and their families acknowledge the difficulty in achieving weight loss hence, not the quick fix perhaps expected. A strong theme at 12 months was the acknowledgement that there was a need to change their own behaviours alongside the intra-gastric balloon in order to maximise weight loss outcomes. The case story of the successful adolescent (Chapter 5) showed the whole family supported the BOB participant, with clear strategies adopted in the home and family environment that allowed the successful implementation of behaviour change. Examples included the family writing the supermarket list together and planning meals in advance as well as going out on day trips, walking and being active as a family. For the majority though, the focus remained on intentions to change individual behaviour, with varying levels of parental and family engagement and successful implementation of change.

To enhance an individual's capability to manage their environments to enable healthy behaviour changes, interventions must utilise behaviour change techniques (Mitchie et al., 2011; NICE, 2014). That said, the thesis findings not only reinforce the need for further research into the effective delivery of long-term weight management strategies, but also a focus on the explicit reporting of the active ingredients within treatment programmes to ensure the treatment addresses the *'how'* rather than the *'what'* of behaviour change. This would offer opportunities for comparison between studies as well as aiding further understanding into the mechanisms behind long-term change - even when combined with more invasive treatment options including bariatric surgery.

Adolescents require support to develop a skillset that enhances their ability to cope and manage emotional choices and situations if they are to develop a healthy pattern of lifestyle behaviours – merely educating on energy balance alone could be counter-productive. Consideration therefore, must be given to tackling the root cause of an adolescent's obesity, identifying and understanding the adolescent's drivers for change (Watts et al., 2015). The role of the family and the optimal level of engagement from

parents, along with how to integrate the home environment within treatment, in order to positively impact on weight loss, requires further exploration.

6.1.1 Theoretical interpretation of findings

The design, delivery and evaluation of Study 2 reinforces the importance of developing theoretically underpinned behavioural interventions, with content mapped to an evidence based framework, to not only promote consistency but begin to understand the mechanisms for change. Although it was not a main of this study, it is useful to consider how the behaviour change techniques delivered throughout the intervention related back to the programmes theoretical underpinning – the theory of planned behaviour (Ajzen, 1991) and the TTM (Prochaska and DiClemente, 1983). The lifestyle intervention delivered in study 2 aimed to increase physical activity, enhance an individuals perceived behavioural control and support individuals social structures to influence social norm. Figure 2.0 attempted to map the techniques delivered throughout the programme, to the components of the theory of planned behaviour they could influence. Despite the majority of these potentially influencing perceived behavioural control, quantitative data collected through the questionnaire illustrated a fairly constant response for this domain. Likewise, subjective norm showed moderate change whilst scores actually reduced in the attitude domain. This discrepancy in findings illustrates a need for further research to explore the mechanisms of action for behaviour change techniques used in treatment programmes.

Delivery of the programme was underpinned by the processes of change within the TTM (Procaska and DiClemente, 1983) to influence an individuals movement between the stages of change. One way this was achieved was through the inclusions of a pre-intervention phase, prior to the intra-gastric balloon insertion. For example, initial sessions of the intervention focused on the cognitive elements of change involving, consciousness raising (talking with the adolescents and their families in depth about their current situation) and dramatic relief (exploring what life would be like if the adolescents and their families stayed the way they were).

Based upon the results from study 2 and the qualitative accounts from the BOB participants, it appears that individuals moved through the stages of change at varying paces. BOB 2 continued through to maintenance at the 12-month assessment as his account talking about maintaining positive changes for several months. In comparison, BOB 8 appeared to stay in preparation phase throughout the programme with marginal weight change and a lack of interest in goal setting and action planning. Whilst this is largely anecdotal at this stage, it reinforces the need for research to consider how the role of different behavioural change techniques in influencing change and consider the practical solutions for delivering theoretically underpinned interventions.

6.2 Implications for practice

Adolescents can be challenging to engage and with little pragmatic evidence or guidelines on how best to work with severely obese adolescents (Steinbeck, 2011), the findings from this thesis might be of particular interest to health professionals, weight management teams and exercise specialists tasked with treating this population. A number of key implications for practice have emerged;

- 1. Programmes must be age specific treating adolescents as a discrete population. Delivery must remain flexible yet remain tailored to the specific needs of adolescents and their families.*

Adolescence has been deemed a 'critical period' not just in the development of obesity but also in the opportunities it presents to intervene and influence behaviours (Steinbeck, 2011). That said, adolescence is however associated with characteristics of turbulence and stress. Early adolescence is associated with body image changes whilst during adolescence there is typically powerful drive for independence and peer association (Wills et al. 2006). Older adolescents typically seek greater autonomy over their own behaviours. The dynamic nature of this lifestyle is reinforced by the qualitative accounts recorded throughout this thesis. Collectively, to engage adolescents in treatment programmes, practitioners need to empathise with adolescents, aim to tackle the root cause of the adolescent's obesity and be responsive

to tailor intervention to specific needs. Further research is needed to enhance knowledge on adolescent health and what drives their motives to influence health status whilst also informing the design of treatment services.

2. *All practitioners should be encouraged to assess the adolescents and parent's outcome expectations and willingness to change in an orientation or pre-treatment phase (Germann et al., 2006).*

Although there was a one-month preparation phase built into the BOB protocol, the qualitative findings highlight that there was an unrealistic perception about the degree of the weight loss expected from the intra-gastric balloon, with some comparing it with bariatric surgery. There was also a perception that weight loss would be easier with the intra-gastric balloon inserted, with many focusing their attention to the intra-gastric balloon rather than their individual behaviours. Further research assessing the extent to which the inclusion of a pre-treatment phase optimises weight outcomes is needed.

3. *Interventions must include a multidimensional psychological assessment as an integral part of the screening process for treatments and in routine care of severely obese adolescents. In addition, a multidisciplinary team should be involved with clear mechanisms for signposting to broader agencies for support if required.*

Throughout the delivery of the BOB study it became increasingly apparent that a large proportion of participants experienced complex psychological and psychiatric issues. These included clinically significant depressive symptoms, histories of abuse and addiction in addition to those reported in their medical records. Collectively, this reinforces the importance of working closely with families prior to treatment to understand their needs, expectations and willingness and suitability for treatment.

4. *Practitioners must utilise behavioural change strategies (Mitchie et al., 2011) creating an atmosphere that promotes the adolescents and families confidence*

and autonomy to initiate and sustain behavioural changes and weight related outcomes, particularly in the long term.

A strength of this study was the explicit mapping of the intervention content onto the taxonomy of behaviour change (Mitchie et al., 2011). That said, without a control, the extent to which its inclusion influenced weight and behavioural outcomes can't be determined. Further research is therefore needed. The maintenance of lifestyle behaviours post obesity interventions is challenging (Luttikhuis et al., 2009). In an attempt to resolve this, the BOB protocol offered eight weeks of support post intra-gastric balloon removal aimed at maintaining the momentum and encouragement for change but with reduced support. None of the BOB participants attended yet all reinforced the challenge of maintaining weight loss and positive behaviour change post the BOB programme during the qualitative interviews at 12 months.

5. Practitioners must consider the context of the home environment within treatment

The role of environmental and interpersonal factors in influencing adolescent health behaviours is clear (Story et al., 2008), with the home environment and parental behaviours key in shaping adolescent lifestyle habits (Watts et al., 2015). Although the specific role of the families within treatment programmes remains unclear, all adolescents involved in this thesis emphasised how crucial parents were in seeking support and in influencing longer-term success. An enhanced understanding of the family dynamics and characteristics of the home environment during the BOB intervention, supplemented perhaps with a home visit, would have helped integrate the home environment formally within the BOB treatment programme potentially supporting positive change. Further research into the ability of the home environment within and post treatment programmes to influence longer-term behavioural change requires further research.

6. One-to-one contact appeared central to establishing and maintaining a meaningful relationship between researcher and participant, building trust to

facilitate open and honest discussions around potential areas of behaviour change

The delivery of the lifestyle programme was family focused yet the majority of adolescents often attended on their own, on a one to one basis. From the researcher's perspective, it seemed the majority of adolescents preferred to discuss sensitive topics such as bullying at school, friendships and body image without their parents present. Delivering the intervention on an individual and family basis was however logistically time consuming for the researcher and goes above and beyond the current resource within weight management and health teams. A cost effectiveness element might be considered for future research to determine the costs and efficacy of individual vs. group based interventions. An alternative could be the integration of adolescents and families to deliver group based lifestyle sessions, however the complex nature of their severe obesity and the psychopathology is a crucial consideration. This reiterates the need for practitioners to remain flexible in their style of delivery responding to the needs of individual adolescents and their families.

6.3 Implications for research

This thesis addressed a number of important research questions; however it has also uncovered several issues that require consideration for future research. This discussion will be structured around these areas.

Qualitative findings from Study 1 identified the needs of obese adolescents. This must be used in future research to inform the design and implementation of obesity treatment programmes in order to ensure they are tailored to the adolescent age group. The scoping review (Chapter 2) reinforced how more intervention research which is well designed, controlled and involve large samples of severe obese adolescents are needed to understand what treatments are effective in positive behaviour change and weight related outcomes. Chapter 3 detailed the BOB study, which fulfilled the purposes of a pilot study (Barownoski et al., 2008) – to assess safety and acceptability of an intra-gastric balloon alongside a lifestyle programme to promote weight loss amongst severely obese adolescents. However further pilot work

on a larger scale involving a control group is needed in light of the variability of results. Although the lifestyle programme explicitly detailed the active ingredients within the lifestyle programme content, against the taxonomy of behaviour change (Mitchie et al., 2011), further research assessing the fidelity of the intervention must be considered (Bellg et al., 2004). In addition, further work is needed to explore how the behaviour techniques applied relate back to behaviour change theory. Attempts were made in study 2 to do this, but further research is needed to enhance understanding of the role behaviour change techniques play in behaviour change. Learning from this study infers the importance of incorporating a pre – treatment and maintenance phase within the design of research protocols, further research must however test the extent it can reduce attrition and improve treatment outcomes. Whilst the qualitative accounts of the BOB participants (Chapter 5) begin to explore the reasons behind the outcomes, further qualitative work with families and adolescents participating in treatment programmes are needed to understand the mechanisms to optimise engagement and promote behavioural change. Diverse samples including populations at increased risk of obesity including Asian ethnic groups and low socioeconomic status are warranted to identify the needs in order to tailor obesity treatment programmes to diverse cultural needs (Barlow et al., 2008; NICE, 2014).

The pilot study (Chapter 3) demonstrated the ability of the intra-gastric balloon and lifestyle programme to induce short-term weight loss and produce clinically important improvements in health related quality of life and cardio-respiratory fitness when led by experts in a university setting. Further research to test the effectiveness of the intervention embedding the home and family environment within the intervention design, drawing on resources within local communities, in order to promote sustainability. High quality research that considers the psychosocial determinants for behaviour change, strategies to improve clinician-family interaction and an analysis of cost effectiveness are required.

Future research questions that require attention include:

- Which level of obesity and age is the most appropriate and effective to use with an intra-gastric balloon and lifestyle support programme in light of its acceptability and short-term effectiveness in the severely obese adolescent in this thesis?
- Further research assessing the extent to which the inclusion of a structured pre and post intervention programme (multidisciplinary lifestyle programmes) has potential to improve the weight loss and behavioural outcomes following the use of an intra-gastric balloon or broader obesity treatment in severely obese adolescents?
- What are the individual and family characteristics that promote successful weight loss and behaviour change in severely obese adolescents and families?
- To what extent do social, environmental and psychological factors including low self-esteem and family capacity to change behaviour, influence the effectiveness of treatment for severely obese adolescents?
- How can the home context and environmental factors become embedded within obesity treatment programmes to promote longer-term weight loss and positive behavioural outcomes?
- Which behavioural change techniques are most effective in influencing behaviour change in severely obese adolescents and how do these relate back to the theoretical underpinning to inform future obesity interventions?

6.4 Limitations of this thesis

The specific limitations of each of the studies have been considered within each Chapter, this section will therefore consider the limitations to the research as a whole. All participants involved in study 1 were aged 11 – 16 yrs from South Yorkshire limiting the application of these findings. The uncontrolled pilot nature of the BOB study with 12 families makes not only generalising the findings difficult, but also drawing conclusions on treatment effectiveness implausible. Further research with larger diverse samples involving a control arm is needed. An experienced researcher within a university environment delivered the multidisciplinary lifestyle programme, therefore

considerations on how the programme could be pragmatically delivered in local communities with local workforces is needed. Further research on the role of the family and how to integrate a participant's home environment within the delivery of the programme is also warranted.

6.5 Critical self-reflection of the research process

Reflection can be defined as thinking about something after an event whilst reflexivity in contrast involves a dynamic more immediate assessment of self-awareness (Finlay and Gough, 2002). Critical self-reflection is used here to hopefully capture elements of reflection and reflexivity. The importance of reflexivity especially in social qualitative research has been highlighted (Finlay and Gough., 2002) with researchers frequently keen to acknowledge the nature of their research and demonstrate the trustworthiness of findings. Disclosing factors such as a researcher's position, perspective and presence can demonstrate how they have influenced research choices and credibility of the research (Krupey et al., 2008). The purpose of this section is to offer an insight into my experiences of undertaking this research including the positives, the challenges and dilemmas I encountered and overall what I have learnt from the research process.

Without question, the most enjoyable element of this research process has been meeting and working with all of the study participants and their families. As the lead researcher I conducted all participant interviews detailed in the qualitative studies (Study 1 and Study 3). I also designed, delivered and evaluated the lifestyle programme, which ran alongside the intra-gastric balloon (BOB Study Chapter 4) at the university research facility. I worked closely with all families throughout the 12-month intervention, which arguably could have compromised 'neutrality' of the research. On reflection however, I believe that the rapport I developed with each of the participants proved invaluable. It allowed me to develop a close rapport with the adolescents and their families, enabling them to talk openly about private and sensitive issues including body image, bullying and peer relationships. Frequently during the recorded qualitative interviews, the BOB participants remained quiet and shy drawing into debate the most appropriate research tool to capture the experiences of the

adolescent age group. That said, having the close relationship with the families and understanding the context with which they were talking, enabled me to tailor the questions and interpret the responses appropriately.

At times, I honestly found sessions difficult due to the distressing nature of the topics being discussed. Listening to the challenges many of the BOB participants experienced was difficult whilst also managing the complex family dynamics and relationships that, proved difficult at times. Drawing on research colleagues and support from the medical teams at Sheffield Children's Hospital enabled me to continually look after my own health and wellbeing throughout. Collectively though, the experience of working with the severely obese adolescents and their families taught me an incredible amount. Enhancing my empathy of their needs and increasing my knowledge of how to work with them and build rapport. Overall, the research has given me a unique insight into the complex lives of severely obese adolescents, and crucially, has enhanced my skillset and ability to deliver interventions like this in future. With the hindsight of delivering this intervention I am now more prepared to deliver it all over again than when I began. Working closely with the paediatricians at Sheffield Children's Hospital was enjoyable and essential in helping me understand the clinical processes and challenges faced with delivering care for obese adolescents. I also never envisaged the difficulties we would face seeking ethical approval for the BOB study and the extent to which the research teams would be scrutinised due to emotive nature of the topic area. From my perspective, the shift in emotional responses to one of general acceptance now in 2016 regarding the use of the intra-gastric balloon is remarkable, considering the relatively short time frame to conduct this research.

Overall, the research process has been a learning curve from the outset with the practical experience gained from undertaking mixed method research instrumental in my development as a researcher. During the write up phase I learnt to not take criticism personally which has helped me become a more resilient academic. I also embraced the opportunity to learn and be mentored by a team of expert academics in the field. My understanding of research methods including qualitative and quantitative

techniques has increased, alongside my knowledge on the effectiveness of obesity treatment strategies for severely obese adolescents. I also have an increased understanding on how to utilise behaviour change techniques to deliver adolescent specific and family focused treatments, along with an appreciation of the needs of this unique population.

6.6 Thesis conclusions

This thesis advances understanding of the needs of severely obese adolescents, contributing to the evidence base on effective treatment strategies for this population and their families. The following conclusions can be drawn:

- This thesis makes a unique contribution to obesity treatment as it identifies adolescents as a discrete population and responds to the increasing prevalence of severe obesity amongst adolescents (Ells 2015) by designing and delivering a novel treatment approach to promote weight loss and behaviour change.
- Severe adolescent obesity is a complex condition encompassing social, emotional, behavioural and cultural issues characterised by low self-esteem.
- Multidisciplinary lifestyle programme's must be appropriate to the adolescent age group and aim to tackle the root cause of an adolescents obesity, identifying and understanding their drivers for change.
- Findings illustrate the importance of a supportive home environment and family involvement in the initiation and maintenance of physical activity, healthy eating and weight related outcomes. In addition, adolescents need support to develop a skillset that enhances their ability to cope and manage emotional choices and situations if they are to develop a healthy pattern of lifestyle behaviours. To do this, the integration of key messages and practices within their home environment are recommended.
- The intra-gastric balloon was a safe and well-tolerated procedure associated with limited side effects in severely obese adolescents.
- The pilot study (BOB Chapter 4) combining the use of an intra-gastric balloon and lifestyle programme demonstrated its ability to promote short-term weight

loss and clinically meaningful BMI Z score reductions (Sachdev et al., 2014; Wright and Wales, 2016) in a sample of severely obese adolescents.

- In light of the complex psychological issues expressed by the severely obese adolescents in this thesis, a thorough assessment of an adolescent's psychopathology is recommended prior to treatment.
- Future interventions involving the use of an invasive procedure, including an intra-gastric balloon, should consider the use of a structured pre-treatment phase aimed at managing an individual and family expectations regarding treatment along with a maintenance period to promote positive changes in the longer-term.
- The explicit reporting of behaviour change content aligned to a theoretical framework in BOB design was a unique feature of the study that strengthened the programme delivery. That said, treatment fidelity (Belg et al., 2004) needs to be addressed in future interventions to not only enhance the strength of the conclusions drawn, but to allow for accurate replication in future studies.
- Further research must assess and identify the active ingredients within treatment programmes, in order to support adolescents to manage their weight in the long-term, as well as enabling study comparisons to be made (Mitchie et al., 2011).
- Establishing and maintaining a meaningful and empathetic relationship between researcher/health professional and adolescent participant is crucial for building rapport and enabling open and honest discussions.
- Short bouts of moderate intensity physical activity involving a range of modalities including rowing, walking and dancing are appropriate for severely obese adolescents and should be encouraged. The activities must be enjoyable, involve a competitive element for some, with positive reinforcement and praise a crucial component for all participants helping to build self-esteem and an increased likelihood of long-term maintenance.

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APPENDICES

- Appendix 1 Study 1 qualitative ethics approval
- Appendix 2 Informed consent participant study 1
- Appendix 3 Interview schedule study 1
- Appendix 4 Qualitative analysis study 1
- Appendix 5 Commonly used theories in health behaviour change programmes
- Appendix 6 BOB ethics approval
- Appendix 7 BOB participant informed consent
- Appendix 8 Child growth chart boys
- Appendix 9 BOB risk assessment
- Appendix 10 BOB questionnaire booklet
- Appendix 11 BOB interview schedule
- Appendix 12 Qualitative analysis BOB experience

Appendix 1 - Study 1: Ethics approval



NRES Committee North West - Lancaster

HRA NRES Centre - Manchester
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7818
Fax: 0161 625 7299

22 October 2012

Miss Lindsey Jane Reece
Exercise Science Officer
Sheffield Hallam University
A124 Collegiate Hall
Collegiate Crescent Campus
S10 2BP

Dear Miss Reece

Study title: A qualitative study to assess stakeholder beliefs about obesity and obesity treatment options in adolescents.
REC reference: 12/NW/0487
IRAS reference: 64456
Amendment number: 1
Amendment date: 02 October 2012

Change to student study.

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The Committee requested that the Participant Information Sheets be revised to include the fact that the study is being done for a PhD and you complied with this request.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
REC application	3.4 revised	15 June 2012
covering email		02 October 2012

Notice of Substantial Amendment (non-CTIMPs)	1	02 October 2012
Investigator CV	Reece	
Participant Information Sheet: Child 13-18	3	15 October 2012
Participant Information Sheet: Professionals	2	15 October 2012
Participant Information Sheet: Parents/Guardian	2	15 October 2012

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

12/NW/0487;

Please quote this number on all correspondence

Yours sincerely



Dr Lisa Booth
Chair

E-mail: nrescommittee.northwest-preston@nhs.net

Enclosures: List of names and professions of members who took part in the review

*Copy to: Mrs Wendy Swann, Sheffield Children's Hospital
Brian Littlejohn, Sheffield Hallam University*

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

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12/NW/0487:

Please quote this number on all correspondence

Yours sincerely


LB

Dr Lisa Booth
Chair

E-mail: nrescommittee.northwest-preston@nhs.net

Enclosures: List of names and professions of members who took part in the review

*Copy to: Mrs Wendy Swann, Sheffield Children's Hospital
Brian Littlejohn, Sheffield Hallam University*

Participant Consent Form

Title of Project: Assessing stakeholder beliefs about obesity and obesity treatment options

Name of Researcher: Lindsey Reece

Please initial box

1. I confirm that I have read and understand the information sheet for the above project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

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

3. I understand that my details and participation with the study, will be shared with my GP.

4. I understand that interviews will be audio recorded and I give permission for this to be used for education and research purposes. I understand that all names shall be anonymised however direct quotes will be used.

5. I understand that data collected during the study, may be looked at by individuals from Sheffield Hallam University, or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for the data collected to be used for education and research purposes.

6. I understand that the information/data I give will remain confidential.

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

Name of Participant _____

Signature _____ **Date** ___/___/___

Name of Person _____

Signature _____ **taking consent** **Date** ___/___/___

Topic guide 1.0 - Adolescents and families

Question	Prompts
Firstly, Tell me a little bit about you?	<i>School, friends, home life, social life, likes/dislikes, emotions, image</i>
Tell me about your experiences of being overweight?	<i>Diet, types of food, portions, physical activity, family, emotions)</i> <i>Invite families comments also.</i>
When did you first seek support? Where did you go?	GP, commercial weight loss group, dietician <i>In your opinion, how does your GP explain your overweight? was this what you wanted?</i>
Tell about the advice, if any, have you been given about your weight?	Yes / positive response <i>Could you expand on this please?</i> <i>Timescale? advice given, referral/signposting?</i> No/can't remember/negative response <i>How do you feel about this? Do you think you would/should have any? Families view on this</i>
Are you aware of any services/programs that are available to help you lose weight/lead a healthier lifestyle?	<i>If this was mentioned in response to previous question, expand on this to capture experience of the service, success, timescale, learnt from it</i> Positive response/recognition of some <i>Could you explain further? Do you know there names? Have you tried any? Have</i>

	<p><i>you thought of attending?</i></p> <p>Negative response/ no awareness</p>
NICE guidance (2006)	
Tell me what you know about obesity medication?	<p><i>(Name? brand? what it does? advertising? Know anyone? Cost)</i></p> <p><i>Invite families' opinion</i></p>
Has this treatment option been discussed as a possibility with you?	<p>Yes</p> <p><i>Have you tried it, if so how long, which one? Experience? side effects? lose weight?</i></p> <p>No - Do you think it would be a possible option for you?</p> <p><i>How do you feel about this? Alternatives?</i></p>
When I say the phrase "Bariatric surgery" what comes to mind?	<p><i>(Describe the picture, types of surgery, stories, cost, side effects)</i></p> <p><i>Invite family's opinion</i></p>
Has this treatment option been discussed as a possibility for you? If so, please tell me more	<p><i>Invite family's opinion</i></p> <p>Yes</p> <p><i>Have you had surgery? Which procedure? Experience? side effects? lose weight? stories, media</i></p> <p>No - Do you think it would be a possible option for you?</p> <p><i>How do you feel about this? Alternatives? Stories, media</i></p>
Where do you go from here?	
What is the most helpful thing health services/weight management programs	

can do to help someone like you who is overweight?

If you could give one piece of advice to someone in a similar position to you, what would it be?

Conclusion of interview

Appendix 4 - Qualitative study analysis Study 1

QUALITATIVE FINDINGS FROM STUDY 1

STAGE 1: TRANSCRIPTION AND FAMILIARISATION WITH THE INTERVIEWS

All transcripts were transcribed verbatim and double-checked for errors by listening back to the audio recording and reading the transcripts simultaneously. All members of the research team read transcripts and listened to audio recordings to become familiar with the data set as a whole. Notes were recorded in the margins to capture initial thoughts and impressions.

STAGE 2: DRAFT THEMATIC FRAMEWORK

Transcripts were then read repeatedly with interesting segments of the text underlined and notes made in the margins. This can range from a few words to full sentences and paragraphs. When completed, these interesting sections begin to form a draft-coding framework.

Table 6.0 Qualitative analysis stage 2: Draft theoretical framework

Initial theme	Definition
Reasons for being overweight	Child talking about things they believe contributed to weight gain
Health messages	Pre-existing knowledge or information about weight management and ways to lose weight
Bullying	Experience of, feelings, reasons for being bullied

Barriers to losing weight	Failed attempted to lose weight / what has stopped them from losing weight , what the child finds difficult,
Social norms	Comparison to other people their age, sense they can't do what others are doing, they look and feel different to their peers.
Treatment	Experiences of previous treatment, outcomes from treatment, knowledge of or lack of knowledge of treatment and perceptions about specific treatments.
Support	Relationships (Family and friends) and services/health professionals. Comments around people, services that have positively influenced their weight management.anyone or group or community who has played a role in their weight management experience
Motivations	Discussion about reasons for losing weight, weight stops them from doing things they want to do, they want aspire to be a certain way or do a certain job.

STAGE 3: (APPLYING) WORKING ANALYTIC FRAMEWORK(LR, RC, PB)

The thematic framework developed through the initial stages was then systematically applied to interview transcripts.

Code (definition)	Sub codes	Description
Determinants of obesity (Influencing factor; causes of weight gain)	Bullying	General experience, feelings, reasons for being bullied
	Emotional eating	Expressions of any feelings affecting food consumption, emotions influencing food choices
	Eating patterns / Food habits	Discussion of any food related topics such as portions sizes, cooking...

<p>Reasons for change (Triggers, motivation's to lose weight, reasons why)</p>	<p>Fit in / be normal (Social norms)</p> <p>Improve health</p> <p>Avoidance of bullying (motivation)</p> <p>Supportive relationships (family and friends / supportive)</p> <p>Supportive services / health professionals</p>	<p>Comparison with others, discussion of activities they want to do, perceived judgement by others</p> <p>Clear reasons for losing weight, benefits gained from losing weight that all relate to physical / psychological elements of health</p> <p>A need for bullying to stop, reinforces emotional consequences, impact of bullying.</p> <p>Clear individuals who have helped in attempt to lose weight</p> <p>Description of services or professional support received which have helped in weight management experience</p>
<p>Experiences of losing weight (Description of what is was like when trying to lose weight)</p>		
<p>Outcomes of treatment (Factors associated with being involved in treatment and post treatment)</p>	<p>Barriers</p> <p>Knowledge about losing weight</p> <p>Attribution of success</p>	<p>Any challenges experienced to weight management</p> <p>Describing things learnt about weight management</p> <p>Where individual places success when they have achieved weight loss. Reasons for success</p>
<p>Alternative treatment options (Any factor associated with additional treatment options for managing weight)</p>	<p>Creates Dependence</p> <p>Awareness of treatment options</p> <p>Attitude towards alternative treatment</p>	<p>Benefits of support received, reflective account of support</p> <p>General awareness of any alternative treatment options</p> <p>When alternative treatments known, their attitude about this, their opinion</p>

STAGE 4: CHARTING DATA INTO THE FRAMEWORK MATRIX

Once all the data had been coded it was then laid out in a thematic basis throughout the data. This can be seen below.

Table 8.0 – Qualitative analysis stage 4: Charting data into the framework

Code	Sub codes	Quote [transcript details]
Determinants of obesity	<u>Bullying</u>	<p>"Sad and upset, but that makes me more determined to lose weight because then they'll stop calling me names".</p> <p>"I've been bullied a bit....makes me really upset".</p> <p>"I used to get bullied a lot, and then when I got bullied I didn't eat, so then I put more, even more weight on. And then....[unclear] and then I don't get bullied"</p> <p>"I used to get bullied because of my weight, and I want to do something about it but I used to kind of like eat because I was getting bullied, like I used to eat because I was either wanting comfort food and that kind of like made it worse because that made me bigger, which made me like get bullied.</p>
	<u>Emotional Eating</u>	<p>"Usually if I'm upset, then sometimes I'll have chocolate".</p> <p>"It's just basically boredom, but when I'm out with my friends I don't really eat."</p> <p>"I think one of the reasons why I probably, I comfort eat a lot and there's like stuff going on, well used to be stuff going on at home which kind of like used to upset me a lot, and I just used to comfort eat".</p> <p>"I just used to comfort eat and then like or I didn't eat at all, and then my energy levels went down so I didn't have any energy".</p>

	<p><u>Food Consumption/Patterns of eating</u></p>	<p>"I just like started eating a lot more than I usually do.I just got bigger".</p> <p>"I probably put a little bit on because of my food and portion sizes"</p> <p>Well I don't cook my own food so I don't know how much my mum cooks sometimes.So I've started making my own food".</p> <p>"Just like, well I prefer to go out with me mates quite a lot, and basically what it is with me is I, it's not what I eat, it's the amount of what I eat.I'll have my tea or something and I'll go in the fridge and get yoghurt or something after, or a bag of crisps or something".</p> <p>"Play with your friends and not get out of breath, and the same as everyone else".</p> <p>"To come to SHINE because it's really good, you can make friends, they help you, they support you and give you tips, like if you're like going back to how you were they can like support you and stuff, it's good".</p> <p>"They don't judge you like everyone else does".</p>
<p>Reasons for change</p>	<p><u>To fit in / be normal</u></p>	<p>"Get fit, because I want to be a police officer but I can't be a police officer if I'm not fit".</p> <p>"I want to lose weight for her bridesmaid"</p> <p>"To lose weight and feel better and look better".</p> <p>"And it doesn't affect your life when you're older, like with all health problems and that"</p>
<p><u>Improve health</u></p>		

		<p>"My weight doesn't bother me but I'd like to lose some weight."</p> <p>"Because I'm not exactly happy with my appearance, and also because of health issues. I don't want to die of something to do with my weight, and I want to live like a nice long life basically"</p>
	<p><u>Appearance, body image</u></p>	<p>"I'm not exactly happy with my appearance, and also because of health issues. I don't want to die of something to do with my weight and I want to live a nice long life basically"</p>
	<p><u>Motivation Avoidance of bullying</u></p>	<p>"I just don't want to get bullied anymore, and then like I cannot get picked on and then I can just do a normal life without getting stared at or something".</p> <p>"Sad and upset, but that makes me more determined to lose weight because then they'll stop calling me names".</p> <p>"I just don't want to get bullied anymore, and then like I cannot get picked on and then I can just do a normal life without getting stared at or something".</p>

<p>Experiences of seeking treatment to lose weight</p>	<p>Supportive: <u>Relationships (family/friends)</u></p> <p>Positive experience from treatment</p>	<p>"my dad and my sister and my mum, my step dad, have been dieting with me".</p> <p>"But my mum and dad support me, and all my friends at school".</p> <p>"Well my mum helps me, and my sister does because she's losing weight as well for when she gets married this year"</p> <p>"Just family and friends".</p> <p>"From like family and friends, but not really, this [weight management group] has been like my main support."</p> <p>"It helps you like your portion sizes, your sports and your five a day and stuff like that".</p> <p>"it's just brilliant"</p> <p>"its all been good and its all helped, they've taught us everything we need to know and then it's just like us going out and doing it for ourselves"</p> <p>"We just, my mum just saw it in newspaper and then we decided to go, and then we got on really well with them all, they were all like really nice and supportive and then we carried on going and just carried on going. And now that's what I want to do when I'm older".</p> <p>"Oh no sorry, it were paper, that were it, yeah, saw it in paper, but it's like getting the help and finding</p>

the help, you know, and once you've got the help or once you find that stick at it and keep going. You know, not to give in just keep going."

"Definitely, oh definitely, yeah because she still comes every month now to get weighed don't you, so it like that just, you know, makes her think oh I'm going to get weighed so, you know what I mean. I think if you just leave it I think that when you fall by the wayside. I think you've got to keep coming on a regular basis so that you're, you know, you're thinking about it all the time."

"Yeah, last year, and what happened were, is me mum said do you want to lose some weight and I said yeah, and we found MoreLife which is like who put us into touch with RIO and it were like all activities and stuff like trying to get you active, trying to change your food portions, swap like junk food for fruit and stuff like that".

"Like you meet new people so it's easier to get along with it. We're all different sizes and shapes. Everyone just treats us the same. Yeah you all bond like a big family."

"To come to SHINE because it's really good, you can make friends, they help you, they support you and give you tips, like if you're like going back to how you were they can like support you and stuff, it's good".

"Well before I started coming to Carnegie and everything I weren't too happy with the way I were, but then I came here and it were alright and I got better".

"It gives you knowledge to know what you need to eat and stuff like that, but it's just boring".

		<p>But yeah, I think coming here [SHINE] has like helped me a lot because I've lost weight and I don't get bullied any more so".</p> <p>"he were a big lad but it's harder in winter, you know"</p> <p>"I haven't been able to do as much as I could do with weather being as bad as it is".</p> <p>"I mean they've got a dog, but our Nicola won't let him take him for walks....Because it's a bit of a rough area".</p> <p>"You know, it's not safe to let him out unless you all go with him".</p> <p>"I would definitely seek help, but it's just finding out about these services.I mean we didn't realise, we only saw it at the doctors didn't we".</p> <p>"Yeah, because you want to change and as much as people were being horrible to you it's like, I don't know it's just, it was hard, I didn't really know how to deal with it.I don't think my mum did either, because I used to be quite close to her and she really wanted to help me.But I think it's hard for everyone who's trying to lose weight because you want to lose as much weight as you can but it's like an on- going process".</p> <p>"Try and get more active, try not to eat as much as you would, like cut down a bit, and just try and enjoy doing, like try to enjoy losing weight because if you don't lose it, if you've not go the enthusiasm to do like activities and eat smaller, whereas if you do you're more like focused to do it".</p> <p>"Well about how much exercise to do and how many calories to intake in a day, and that's the most important things".</p>
<p>Outcomes engaging Treatment</p>	<p><u>Knowledge about how to</u> <u>lose weight</u></p>	

		<p>"I've learnt that from there, because what it was really was I'd have whatever were cooked and whatever were left my stepdad would go, 'go on finish that off for me.' But instead, now it's more like portion size so stuff that's suitable for me and it's more fruit".</p> <p>"Yeah, I didn't used to do nowt and now I've took GCSE PE, and like tonight that's where I've been stopping behind for PE, doing trampolining and doing all different sports. My week's like proper full of sports".</p>
	<p><u>Attribution of success to the programme</u></p>	<p>"Like with my weight and like how I looked, and then I came here and then it like changed everything round".</p> <p>"Well before I started coming to Carnegie and everything I weren't too happy with the way I were, but then I came here and it were alright and I got better".</p>
	<p><u>Creates Dependence</u></p>	<p>"Sometimes I regret like not working as hard as I could have because then I would have lost more, but like if I went back again then I would push myself harder to lose more".</p> <p>"I think if you just leave it I think that when you fall by the wayside. I think you've got to keep coming on a regular basis so that you're, you know, you're thinking about it all the time".</p> <p>"Yeah, but then because it [weight management service] stops after a bit doesn't it, then I just like fell back into what I was doing before, because it were only like, I can't remember how long it were but it were short and I just fell back into what I were doing before"</p>

<p>Alternative weight management treatments</p>	<p><u>Awareness of treatment options</u></p>	<p>"I don't think there's really is anything, I've not really seen anything. I mean obviously at the schools and that, they encourage sports at schools and activities but it's not the same as like going and getting weighed at a place, you know, because obviously they used to get weighed every week and that used to help them, and obviously they would talk to all the other children. But no, I don't think there is anything really for them to, you know, join into and, you know, there's no support there really at all."</p> <p>"Not really. Not for like people our age, maybe older like Weight Watchers and stuff like that, but not for young people."</p> <p>"Yeah dieting tablets."</p>
	<p><u>Attitudes towards alternative treatment</u></p>	<p>"Dieting tablets, but it's a waste of money as well."</p> <p>"Too young, and I think me mum did try like taking the slimming tablets but saw no results. I would [take medication or have surgery] but I haven't. If it made me lose weight then yeah."</p> <p>"I would have something like ...[unclear] but I don't think I'd like a gastric band. Like say for example I want to go to my normal friend's, he had a McDonald's ...[unclear] it would just affect me in that way. Is it like gastric band or something like that?"</p> <p>"I wouldn't do it. If you're going to lose weight you might as well do it to yourself not for other people. It's just cheating yourself."</p>

"Sometimes they don't work so there's no point in taking them. I'd rather do the work for myself so be proud of myself than taking tablets."

"I think she's had to like to get to a point where it's like you can't go back yourself and people do sometimes need surgery."

STAGE 5: MAPPING AND INTERPRETATION

Themes are generated within the data and through making connections between participants. These were explored in detail with the research supervisors and were refined upon the basis of discussion. This was influenced but the research objective and guided by the semi structured interview topic guide, which was based upon current evidence base. The results from this study will now be explored

Appendix 5 - Brief summary of commonly used theories in health related behaviour change interventions

Theory	Author (s) and Date	Key Components
<p>Transtheoretical Model of behavioural change (TTM)</p>	<p>Prochaska and Diclemente, (1982)</p>	<p>The TTM determines behaviour change as a process rather than a single event and offers practical suggestions for how individuals can change behaviour. The TTM was originally designed within the field of addictive behaviours, such as to stop smoking in adults, with more recent support for the tool to increase exercise adoption and adherence in adults. The TTM consists of five constructs: stages of change, processes of change, decisional balance, temptation and self-efficacy.</p> <p>The Stages of change has received most attention and proposes behaviour change occurs in five sequential stages;</p> <p>Precontemplation (<i>not planning to change in 6 months</i>) Contemplation (<i>thinking about change in the next 6 months</i>) Preparation (<i>taking steps towards change in the next month</i>) Action (<i>attempting change</i>) Maintenance (<i>have changed for at least 6 months</i>)</p> <p>Although the model is described as sequential it is also possible to skip stages and move forwards and backwards as appropriate as it recognizes that most people relapse especially on their first attempt.</p> <p>Ten processes of change offer a structured method to help facilitate intervention programs (<i>Conscious raising, dramatic relief, environmental reevaluation, self evaluation, self liberation, helping relationships, counter relationships, stimulus control, reinforcement management,</i></p>

		<p><i>social liberation</i>) that are associated with individuals stages of change facilitate and stimulate movement through the process.</p> <p>Decisional balance, essentially the pros and cons of change, and self-efficacy, a person's belief about their ability to carry out a given change in a given situation, also support this model process of change (Prochaska et al. 1992).</p>
Theory of Planned Behaviour (TpB)	Ajzen (1991)	<p>Is an extension of an earlier theory, the theory of reasoned action, and emphasizes the importance of beliefs in driving behaviour. The model demonstrates that intentions are the direct precursors of behaviour, which are influenced by attitudes, subjective norm and perceived behavioural control (Ajzen, 1991). <i>Subjective norm</i> is defined as a person perception on whether people important to them believe they should carry on that behaviour. <i>Perceived behavioural control</i> is the extent to which a person feels they can perform that behaviour and essentially behavioural intention refers to the motivation to perform the behaviour, willingness to try to perform the behaviour and how much effort they plan to perform that behaviour. Intentions are directly determined by attitudes.</p>
Social Cognitive theory (SCT)	Bandura (1986)	<p>This theory aims to offer a framework to understand human thought and behaviour, proposing that the environment, behaviour and personal and cognitive factors all interact as determinants of each other. It is then defined through capabilities including <i>symbolizing capability</i>; transforming experiences into mental models that guide behaviour adding meaning to experience, <i>Forethought capability</i> ability to regulate behaviour on the basis of future; <i>Vicarious capability</i>, ability to learn through observation, self regulatory capability,</p>

		<p>ability to regulate own behaviour on personal standards and evaluations and <i>self reflective capability</i>, ability to analyze and reflect on our own experiences. (Bandura 1986).</p>
<p>Self-determination theory</p>	<p>Deci and Ryan (2000)</p>	<p>Based upon the key premise that motivation to perform a behaviour varies according to the degree with which a behaviour is self determined.</p> <p><i>External regulation</i> is the most controlling form of motivation and refers to individuals performing behaviour to gain a reward or punishment; <i>Introjected regulation</i> involves performing a behaviour due to internal pressures; <i>Identified regulation</i> entails people to identify with the value of behaviour not necessarily the activity; <i>Integrated regulation</i> involves accepting behaviours as congruent with personal values and interests; <i>Intrinsic motivation</i> is the prototypical form of self-determined motivation and involves engaging in activities due to inherent interest and motivation.</p> <p>A primary objective in addressing behaviour change is therefore to promote the internalization of regulations such that individuals behaviours are reinforced internally.</p>



Health Research Authority

National Research Ethics Service

NRES Committee Yorkshire & The Humber - Sheffield

HRA NRES Centre Manchester
Barlow House
3rd Floor
4 Market Street
Manchester
M1 3BZ

Tel: 0161 625 7832

Fax: 0161 625 7289

15 July 2014

Chris Small
Research Support Assistant
Children's Clinical Research Facility
D Floor, Stephenson Wing
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
S10 2TH

Dear Mr Small

Study title: A feasibility study of the acceptability and efficacy of intra-gastric balloons for the treatment of severe adolescent obesity and the metabolic and psychosocial effects of weight loss – (Balloons in Obesity) BOB study

REC reference: 11/YH/0421

Amendment number: 1

Amendment date: 27 May 2014

IRAS project ID: 69138

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

Approval was sought to carry out focus groups 3 months into the insertion phase and 6 months post balloon removal. Approval was also sought to pay young people to attend follow up appointments.

The Committee queried whether recruitment to the study had finished. Dr Wright advised that recruitment had finished and all participants are now in the support/maintenance phase of the study.

The Committee queried how participants would be approached again about the focus group. Dr Wright explained that participants are still engaged in the intervention which included a lifestyle intervention package running both in parallel with the balloon whilst it was in situ and continuing after it was removed. All participants are scheduled for follow up sessions, therefore discussion and consent would be taken as part of these routine consultations.

The Committee queried whether participants would be re-consented. Dr Wright explained that participants would be re consented. At this juncture they would also ask participants for their consent to use case notes from discussions with families and feedback from professionals that has been assembled as part of the delivery of the intervention. The purpose of this would be to enhance the understanding of the acceptability of the programme as well as enhancing our understanding of the needs of this population to inform policy and future practice. This would therefore become a formal part of the research hence the request here. The individual needs of each family have been very different and feedback on how the project was going for each participant was informally identified and their needs met as the project went on. It was retrospectively suggested that this be incorporated in a more formal qualitative manner, (with the families consent) using the data collected.

The Committee queried how, if all participants have had their balloon removed they could take part in the 3 month focus group. Dr Wright advised that due to a delay in getting this amendment to the ethics committee obviously a 3 month group is now no longer possible and this should have been amended prior to submission.

Dr Wright advised that they would re phrase the Participant Information Sheet to read *you will be asked if you and your family would like to take part*.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Interview schedules or topic guides for participants (interview script for focus group at 12 months)	1.0	27 May 2014
Notice of Substantial Amendment (non-CTMP)	1	27 May 2014
Participant consent form (Parents/Legal Guardians)	5.0	27 May 2014
Participant information sheet (PIS) (for young people)	5.0	27 May 2014
Participant information sheet (PIS) (for carers)	5.0	27 May 2014
Research protocol or project proposal	5.0	27 May 2014

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

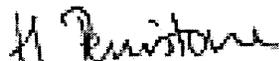
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

11/YH/0421:

Please quote this number on all correspondence

Yours sincerely



On behalf of
Professor Basil Shamack
Chair

E-mail: nrescommittee.yorkandhumber-sheffield@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Neil Wright,
Sheffield Children's NHS Foundation Trust

Wendy Swann
Sheffield Children's NHS Foundation Trust

Appendix 7 - BOB participant informed consent

Sheffield Teaching Hospitals
NHS Foundation Trust



Sheffield Children's
NHS Foundation Trust



**Sheffield
Hallam
University**

Centre for Sport
and Exercise
Science

Patient study number:

PARENT/LEGAL GUARDIAN CONSENT FORM

Title of project: A feasibility study of the acceptability and efficacy of intra-gastric balloons for the treatment of severe adolescent obesity and the metabolic and psychosocial effects of weight loss- BOB study or the Balloons in Obesity Study

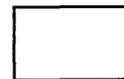
1 copy for parent; 1 copy for researcher; 1 copy to be kept with hospital notes

Names of researchers: Pooja Sachdev, Jerry Wales, Neil Wright, Lindsey Reece

Please initial box

1. I confirm that I have read and understand the information sheet dated 13/09/2013 (version 5.0) 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 child's medical care or legal rights being affected.
3. I understand that relevant sections of any of my child's medical notes may be looked at by researchers and those involved in the running and supervision of the study from Sheffield Children's NHS Foundation Trust or from regulatory authorities, where it is relevant to my child taking part in research. I give permission for these individuals to have access to my child's records.
4. I agree to my child's GP being informed of participation in this study.
5. I agree to my child taking part in the above study.
6. I agree to my child's school attendance records being looked at by researchers
7. I agree to allow the researchers to look at my child's national reference exams results

8. I agree for me and my child to take part in two family focus groups to provide feedback on project progress and share our experiences.



Name of Parent/Guardian

Date

Signature

Name of Person taking consent
from researcher) _____

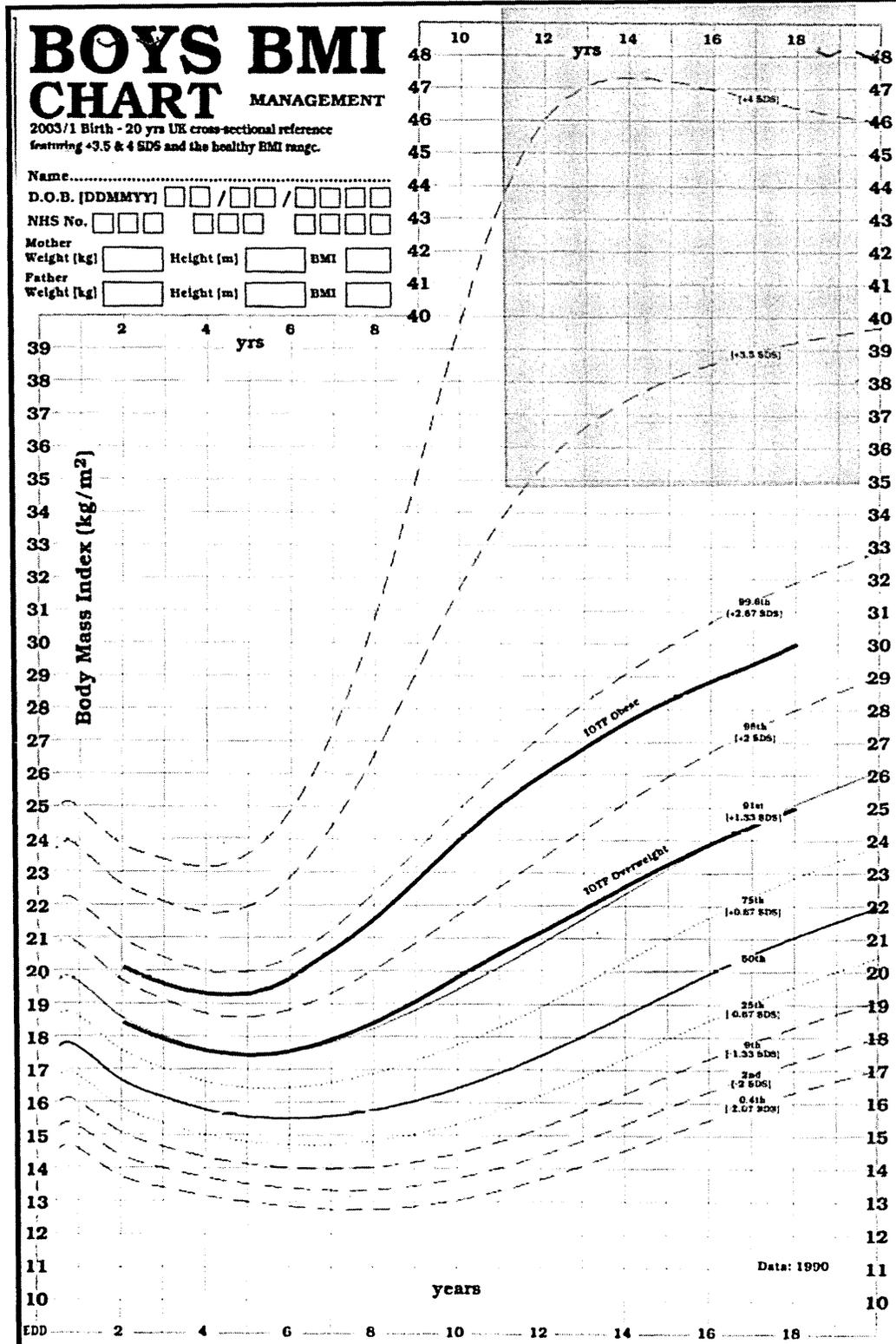
Date

Signature (if different

Researcher

Date

Signature





Sheffield Hallam University

Faculty of Health and Wellbeing Research Ethics Committee
Sport and Exercise Research Ethics Review Group

Risk Assessment Pro Forma

****Please ensure that you read the accompanying
Risk Assessment Risk Ranking document before completing this form****

Title of research	A feasibility study of the acceptability and efficacy of intra-gastric balloons for the treatment of severe adolescent obesity and the metabolic and psychosocial effects of weight loss – (Balloons in Obesity) BOB study.
--------------------------	---

Date Assessed	10/10/2012
----------------------	------------

Assessed by (Principal Investigator)	Lindsey Reece
---	---------------

Signed	Position
	Principal Investigator

Activity	Risks	Control Measures
Put in this box the activity which may cause harm.	Risk of [<i>place in here the harm that may be caused</i>] caused by [<i>put in the hazard (source of danger) here</i>]. Risk = consequence x likelihood. Identify risk category Low Medium or High	Place here what you would do to minimise the risk

<p>Submaximal exercise on a motorised treadmill. Subjects walks on treadmill at a speed of 5.6km-1, increasing elevation by 2% every 2 minutes, from 6% to a maximum of 22%.</p>	<p>Risk of musculoskeletal injury caused by extra demand placed on musculoskeletal system when performing physical activity. (C2XL1=R2) LOW RISK</p> <p>Risk of Cardiovascular complications caused by extra strain placed on the cardiovascular system when exercising (C3XL1=R3) MEDIUM RISK</p> <p>Risk of participant fainting or feeling nauseous caused by the extra demands of being physically active. (C2XL2=R4) MEDIUM RISK</p> <p>Risk of participant vomiting caused by exercising (C2XL2=R4) MEDIUM RISK</p> <p>Risk of participant stumbling on the treadmill and/or falling off. (C2XL1=R2)</p>	<p>Pre-screening questionnaire, appropriate warm up prior to commencing the test.</p> <p>Pre-screening questionnaire to assess the subject's current fitness level and health status. At all times, at least one first aider will be present during the test. Heart rate and rate of perceived exertion will monitored throughout the test.</p> <p>Continuous monitoring throughout the test. If the participant feels faint the test will be terminated.</p> <p>Continuous monitoring throughout. A bowl and spillage kit will always be present to collect any vomit and clean up any spillages.</p> <p>All participants will undergo a familiarisation trial before the exercise test. The exercise specialist will be present at all times.</p>
--	--	---

<p>Risk Evaluation (Overall)</p>
<p>Medium Risk</p>

General Control Measures
Is a pre-screen medical questionnaire required? Yes [<input checked="" type="checkbox"/>] No [<input type="checkbox"/>]

Emergency Procedures
<p>Emergency first aid, resus and defibrillation kits are available if the subject faints or experiences cardiovascular complications.</p> <p>A spillage kit is always present to swab up sweat, saliva and/or vomit.</p> <p>A cool room with a fan and water cooler will be set up for the participant when required.</p>

Monitoring Procedures
Continuously monitor the participants responses throughout and after test

Review Period	Annually
----------------------	----------

Reviewed By (Supervisor)	Date
R Copeland	12.10.12

PedsQL™

Paediatric Quality of Life Inventory

Version 4.0 – UK English

TEENAGER REPORT (ages 13-18)

The PedsQL™ asks you questions about how you feel and what you think about your health. It is not a test, and there are no right or wrong answers. It takes about

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 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 MONTH**, how much of a **problem** has this been for you ...

About My Health and Activities (<i>problems with...</i>)	Never	Almost Never	Some- times	Often	Almost Always
1.It is hard for me to walk more than a couple of streets (about 100	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 activities or exercise	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 do chores around the house	0	1	2	3	4
7.I have aches and pains	0	1	2	3	4
8.I feel tired	0	1	2	3	4

About My Feelings (<i>problems with...</i>)	Never	Almost Never	Some- times	Often	Almost Always
1.I feel afraid or scared	0	1	2	3	4
2.I feel sad	0	1	2	3	4
3.I feel angry	0	1	2	3	4
4.I have trouble sleeping	0	1	2	3	4
5.I worry about what will happen to me	0	1	2	3	4

How I Get On with Others (<i>problems with...</i>)	Never	Almost Never	Some- times	Often	Almost Always
1.I have trouble getting on with other teenagers	0	1	2	3	4
2.Other teenagers do not want to be my friend	0	1	2	3	4
3.Other teenagers tease me	0	1	2	3	4
4.I cannot do things that other teenagers my age can do	0	1	2	3	4

5.It is hard to keep up with other teenagers my age	0	1	2	3	4
---	---	---	---	---	---

About School / College (<i>problems with...</i>)	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 school / college work	0	1	2	3	4
4.I miss school / college because of not feeling well	0	1	2	3	4
5.I miss school / college to go to the doctor or hospital	0	1	2	3	4

Physical Activity Questionnaire for Adolescents

Name: _____

Age _____

Sex: M _____ F _____

We are trying to find out your level of physical activity from the **last 7 days** (in the last week). These includes sports or dance that make you sweat or make your legs feel tired, or games that make you breathe hard, like tick/tag, skipping, running, climbing and others.

Remember:

- a There are no right and wrong answers - this is not a test
- b Please answer all the questions as honestly and accurately as you can - this is very important

1 Physical activity in your spare time:

Have you done any of the following activities in the past 7 days (last week)?
If yes, how many times? **(Tick only one box per row)**

	No	1-2	3-4	5-6	7+
Skipping	<input type="checkbox"/>				
Rowing/Canoeing	<input type="checkbox"/>				
Roller Bladeing/Skating	<input type="checkbox"/>				
Tick/Tag	<input type="checkbox"/>				
Walking for Exercise	<input type="checkbox"/>				
Cycling	<input type="checkbox"/>				
Jogging or Running	<input type="checkbox"/>				
Aerobics	<input type="checkbox"/>				
Swimming	<input type="checkbox"/>				
Rounders	<input type="checkbox"/>				
Dancing	<input type="checkbox"/>				
American Football	<input type="checkbox"/>				
Badminton	<input type="checkbox"/>				
Skateboarding	<input type="checkbox"/>				
Football	<input type="checkbox"/>				
Hockey	<input type="checkbox"/>				
Volleyball	<input type="checkbox"/>				
Ice Skating	<input type="checkbox"/>				

Rugby

Tennis.

Other:

.....

2 In the last 7 days, during your physical education (PE) classes, how often were you very active (playing hard, running jumping throwing)? **(Tick one only)**

I don't do PE

Hardly ever

Sometimes

Quite often

Always

3 In the last 7 days, what did you normally **do at lunchtime** (besides eat lunch)? **(Tick one only)**

Sat down (talking, reading, doing schoolwork)

Stood around or walked around

Ran or played a little bit

Ran or played quite a lot

Ran or played hard most of the time

4 In the last 7 days, on how many days **right after school**, did you play sport, dance or play games in which you were very active **(Tick one only)**

None

Once last week

Twice or three times last week

4 times last week

5 times last week

5 In the last 7 days, on how many **evenings**, did you play sport, dance or play games in which you were very active **(Tick one only)**

None

Once last week

2 or 3 times last week

4 times last week

6 or 7 times last week

6 On your **last weekend** how many times, did you play sport, dance or play games in which you were very active **(Tick one only)**

None

Once

2-3 times

4-5times
 6 or more times

7 Which one of the following describes you best for the last 7 days?
 Read **all five** statements before deciding on the **one** answer that describes you best

- a All or most of my free time was spent doing things that involve little physical effort
- b I sometimes (1-2 times last week) did physical things in my free time (eg played sport, went running, swimming, cycling, did aerobics).
- c I often (3-4 times last week) did physical things in my free time
- d I quite often (5-6 times last week) did physical things in my free time
- e I very often (7 or more times last week) did physical things in my free time

8 Mark how often you did physical activity (e.g. played sport, games, danced, or any other physical activity) for each day last week. **(Tick only one box per row)**

	None	Little bit	Medium	Often	Very Often
Monday	<input type="checkbox"/>				
Tuesday	<input type="checkbox"/>				
Wednesday	<input type="checkbox"/>				
Thursday	<input type="checkbox"/>				
Friday	<input type="checkbox"/>				
Saturday	<input type="checkbox"/>				
Sunday	<input type="checkbox"/>				

9 Were you ill last week, or did you do anything other than doing your normal physical activities?
(Tick one only)

Yes
 No

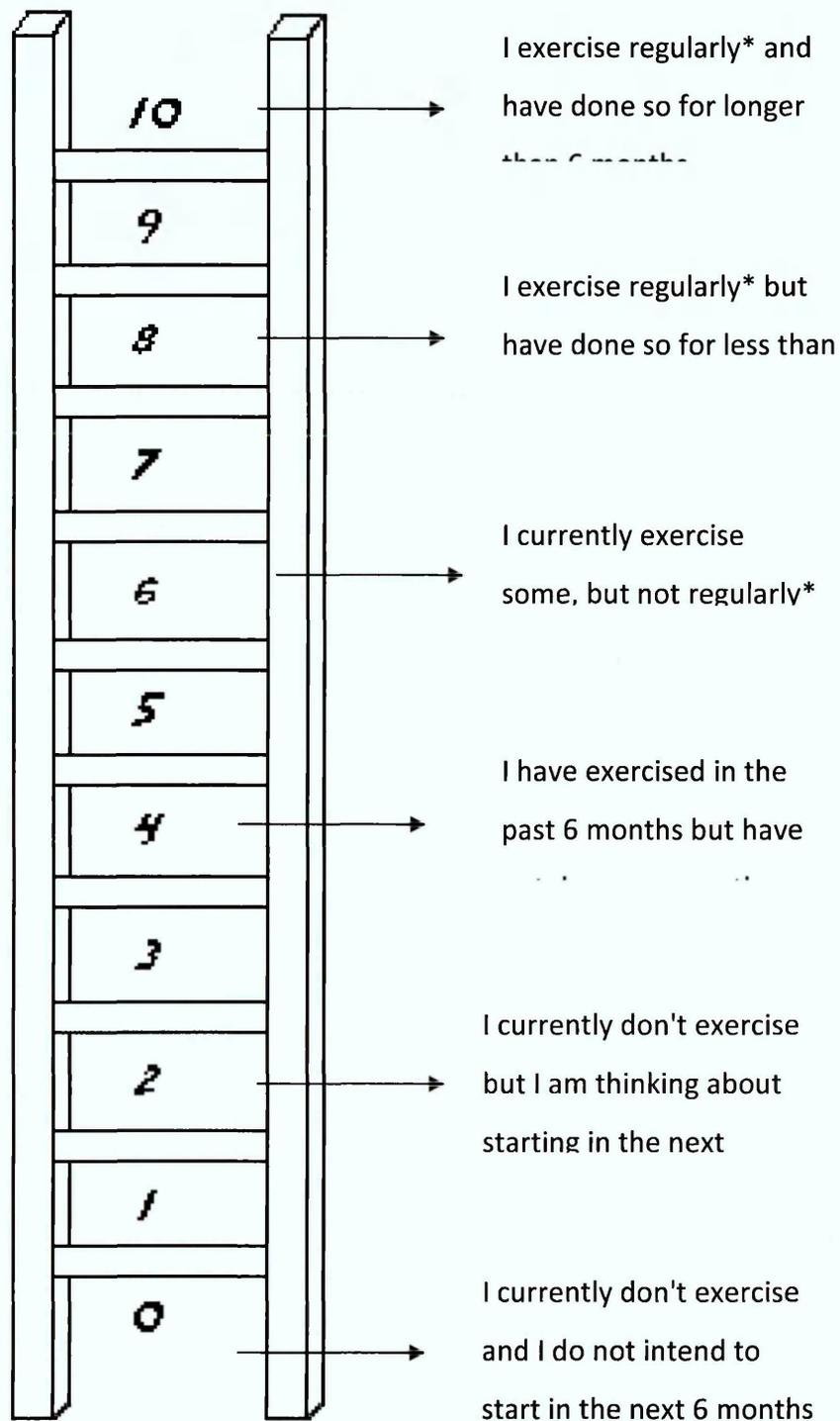
If yes, what prevented you?

.....

Physical Activity Questionnaire

Please let us know what exercise you do and how you feel about exercise. A lot of young people do not participate in much exercise and would like to participate in more. This is not a test. We would just like to find out how physically active you are

*Regular exercise = three or more times per week for 20 minutes or longer of moderate exercise e.g. walking briskly or cycling, swimming.



Below you will see a number of words that describe different feelings and emotions. Read each item and then mark the appropriate number in the box next to that word. Indicate to what extent you have felt this way over the past week.

1
Very slightly or
not at all

2
A little

3
Moderately

4
Quite a bit

5
Extremely

Proud

Angry

Satisfied

Guilty

Happy

Unhappy

Excited

Nervous

Relaxed

Your Thoughts about Physical Exercise

Please indicate by circling a number, how much you agree or disagree with each of the sentences below. This is not a test. Please answer this question as honestly as

1. I would like to participate in physical activity at least 3 times per week every week

1 2 3 4 5 6 7
Strongly Agree Agree Neutral Disagree Strongly Disagree

2. I am going to take part in physical exercise as much as I can every week

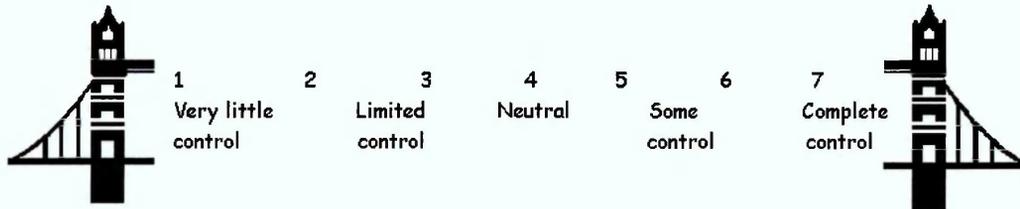
1 2 3 4 5 6 7
Strongly Agree Agree Neutral Disagree Strongly Disagree

3. I plan to take part in physical exercise at least ____ times per week.

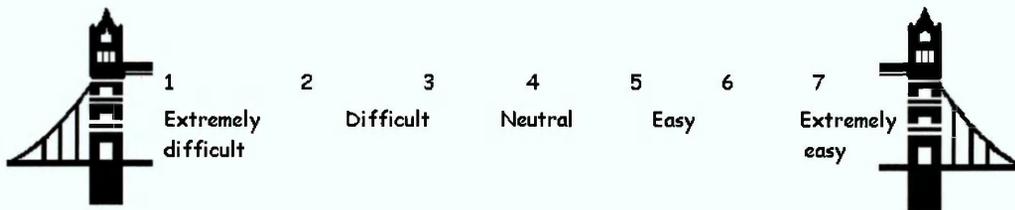
Please indicate by circling a number, the best answer to the following sentences below.

This is not a test. Please answer the questions as honestly as you can.

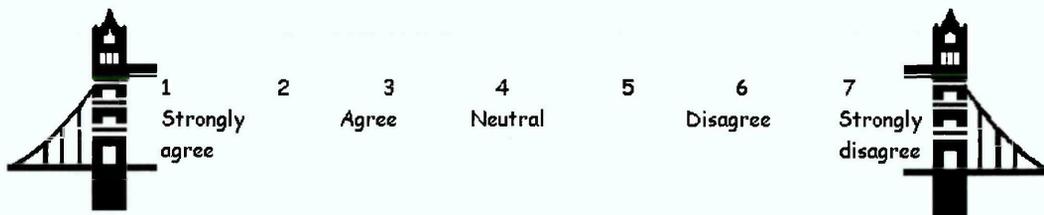
1. Is it always up to you when it comes to taking part in physical exercise...



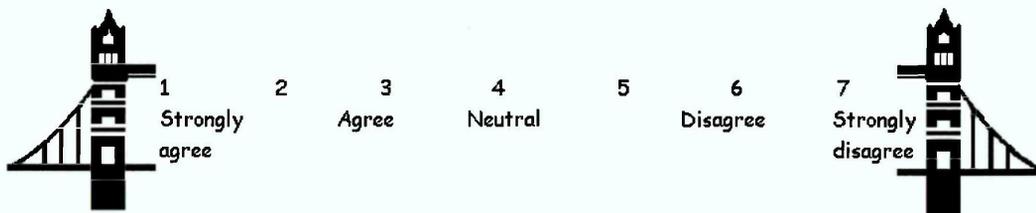
2. For you to take part in physical exercise is...



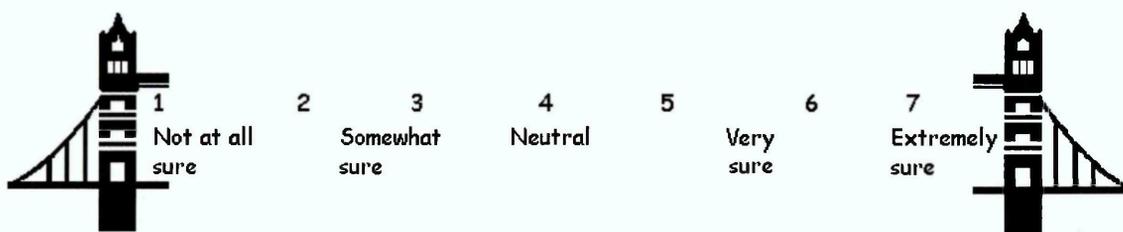
3. If I wanted to, I could easily take part in regular physical exercise...



4. How much physical exercise I take part in is completely up to me...

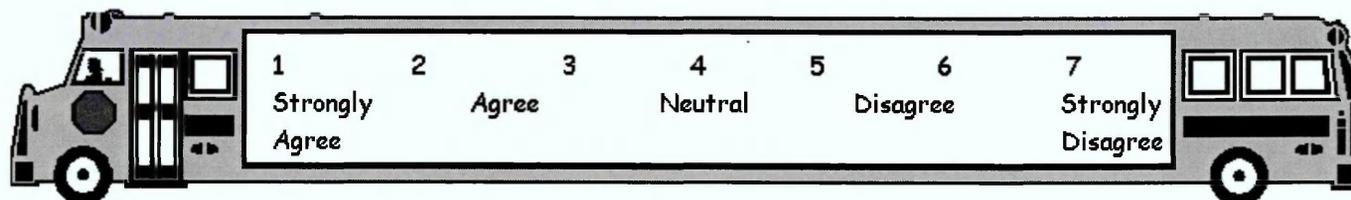


5. How sure are you that you are able to take part in regular physical exercise...

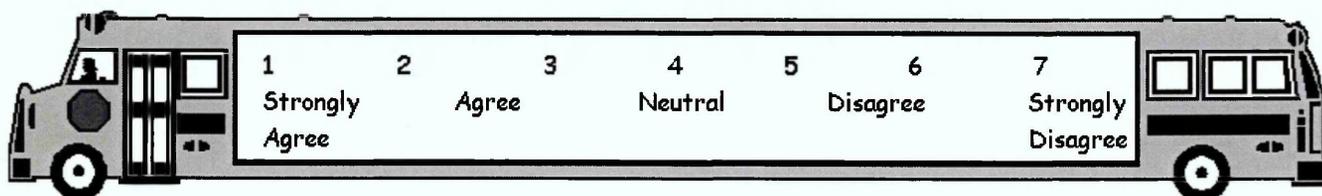


Please indicate by circling a number, how much you agree or disagree with the sentences below. This is not a test. Please answer the questions as honestly as you can.

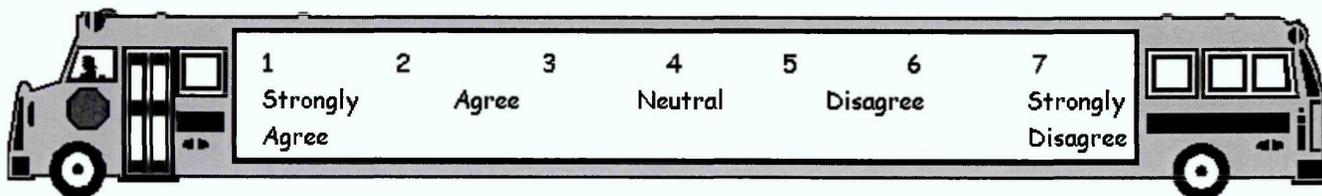
1. Most people who are important to me, think that I should take part in regular physical exercise



2. Most people who are important to me encourage me to participate in regular physical exercise



3. Most people who are important to me support me participating in regular physical exercise



Your Feelings about Exercise Participation

Please consider the statement below, then for each scale, choose one score that best describes your feelings about exercise participation;

STATEMENT: For me to participate in regular physical exercise is:

Useless

-3

-2

-1

0

+1

+2

Useful

+3

Write your score here _____

harmful

-3

-2

-1

0

+1

+2

beneficial

+3

Write your score here _____

foolish

-3

-2

-1

0

+1

+2

wise

+3

Write your score here _____

bad

-3

-2

-1

0

+1

+2

good

+3

Write your score here _____

**un-
enjoyable**

-3

-2

-1

0

+1

+2

enjoyable

+3

Write your score here _____

unpleasant

-3

-2

-1

0

+1

+2

pleasant

+3

Write your score here _____

stressful

-3

-2

-1

0

+1

+2

relaxing

+3

Write your score here _____

Please read each statement carefully and indicate one answer on each row which relates to you. Answer as honestly as you can,

	Really True for me	Sort of True for me	SAMPLE SENTENCE		Sort of True for me	Really True for me
a	<input type="checkbox"/>	<input type="checkbox"/>	Some kids would rather play outdoors in their spare time	BUT	Other kids would rather watch TV	
1	<input type="checkbox"/>	<input type="checkbox"/>	Some kids do very well at all kinds of sports	BUT	Other kids don't feel they are very good when it comes to sports	
2	<input type="checkbox"/>	<input type="checkbox"/>	Some kids feel uneasy when it comes to vigorous physical exercise	BUT	Other kids feel confident when it comes to vigorous physical exercise	
3	<input type="checkbox"/>	<input type="checkbox"/>	Some kids feel that they have a good looking (fit looking) body compared to other kids	BUT	Other kids feel that compared to most, their body doesn't look so good	
4	<input type="checkbox"/>	<input type="checkbox"/>	Some kids feel that they lack strength compared to other kids their age	BUT	Other kids feel that they are stronger than other kids their age	
5	<input type="checkbox"/>	<input type="checkbox"/>	Some kids are proud of themselves physically	BUT	Other kids don't have much to be proud of physically	
6	<input type="checkbox"/>	<input type="checkbox"/>	Some kids are often unhappy with themselves	BUT	Other kids are pretty pleased with themselves	
7	<input type="checkbox"/>	<input type="checkbox"/>	Some kids wish they could be a lot better at sports	BUT	Other kids feel that they are good enough at sports	
8	<input type="checkbox"/>	<input type="checkbox"/>	Some kids have a lot of physical stamina for vigorous physical exercise	BUT	Other kids soon get out of breath and have to slow down or quit	
9	<input type="checkbox"/>	<input type="checkbox"/>	Some kids find it difficult to keep their bodies looking good physically	BUT	Other kids find it easy to keep their bodies looking good physically	
10	<input type="checkbox"/>	<input type="checkbox"/>	Some kids think that they have stronger muscles than other kids their age	BUT	Other kids think that they have weaker muscles than other kids their age	
11	<input type="checkbox"/>	<input type="checkbox"/>	Some kids don't feel very confident about themselves physically	BUT	Other kids don't feel good about themselves physically	
12	<input type="checkbox"/>	<input type="checkbox"/>	Some kids are happy with themselves as a person	BUT	Other kids are often not happy with themselves as a person	

13	<input type="checkbox"/>	<input type="checkbox"/>	Some kids think they could do well at just about any new sports activity they haven't tried before	BUT	Other kids are afraid they might not do well at sports they haven't ever tried		
14	<input type="checkbox"/>	<input type="checkbox"/>	Some kids don't have much stamina and fitness	BUT	Other kids have lots of stamina and fitness		
15	<input type="checkbox"/>	<input type="checkbox"/>	Some kids are pleased with the appearance of their bodies	BUT	Other kids wish that their bodies looked in better shape physically		
16	<input type="checkbox"/>	<input type="checkbox"/>	Some kids lack confidence when it comes to strength activities	BUT	Other kids are very confident when it comes to strength activities		
	Really True for me	Sort of True for me				Sort of True for me	Really True for me
17	<input type="checkbox"/>	<input type="checkbox"/>	Some kids are very satisfied with themselves physically	BUT	Other kids are often dissatisfied with themselves physically		
18	<input type="checkbox"/>	<input type="checkbox"/>	Some kids don't like the way they are leading their life	BUT	Other kids do like the way they are leading their life		
19	<input type="checkbox"/>	<input type="checkbox"/>	In games and sports some kids usually watch instead	BUT	Other kids usually play rather than watch		
20	<input type="checkbox"/>	<input type="checkbox"/>	Some kids try to take part in energetic physical exercise when ever they can	BUT	Other kids try to avoid doing energetic exercise if they can		
21	<input type="checkbox"/>	<input type="checkbox"/>	Some kids feel that they are often admired for their good looking bodies	BUT	Other kids feel that they are seldom admired for the way their bodies look		
22	<input type="checkbox"/>	<input type="checkbox"/>	When strong muscles are needed, some kids are the first to step forward	BUT	Other kids are the last to step forward when strong muscles are needed		
23	<input type="checkbox"/>	<input type="checkbox"/>	Some kids are unhappy with how they are and what they can do physically	BUT	Other kids are happy with how they are and what then can do physically		
24	<input type="checkbox"/>	<input type="checkbox"/>	Some kids like the kind of person they are	BUT	Other kids often wish they were someone else		
25	<input type="checkbox"/>	<input type="checkbox"/>	Some kids feel that they are better then others their age at sports	BUT	Other kids don't feel they can play as well		
26	<input type="checkbox"/>	<input type="checkbox"/>	Some kids soon have to quit running and exercising because they get tired	BUT	Other kids can run and do exercises for a long time without getting tired		
27	<input type="checkbox"/>	<input type="checkbox"/>	Some kids are confident about how their bodies look	BUT	Other kids feel uneasy about how their bodies look physically		

physically

- | | | | | | |
|----|--------------------------|--------------------------|--|------------|--|
| 28 | <input type="checkbox"/> | <input type="checkbox"/> | Some kids feel that they are not as good as others when physical strength is needed | BUT | Other kids feel that they are among the best when physical strength is needed |
| 29 | <input type="checkbox"/> | <input type="checkbox"/> | Some kids have a positive feeling about themselves physically | BUT | Other kids feel somewhat negative about themselves physically |
| 30 | <input type="checkbox"/> | <input type="checkbox"/> | Some kids are very unhappy being the way they are | BUT | Other kids wish they were different |
| 31 | <input type="checkbox"/> | <input type="checkbox"/> | Some kids don't do well at new outdoor games | BUT | Other kids are good at new games right away |
| 32 | <input type="checkbox"/> | <input type="checkbox"/> | When it comes to activities like running, some kids are able to keep going | BUT | Other kids soon have to quit and rest |
| 33 | <input type="checkbox"/> | <input type="checkbox"/> | Some kids don't like how their bodies look physically | BUT | Other kids are pleased with how their bodies look physically |
| 34 | <input type="checkbox"/> | <input type="checkbox"/> | Some kids think that they are strong, and have good muscles compared to other kids their age | BUT | Other kids think that they are weaker and don't have such good muscles as other kids their age |
| 35 | <input type="checkbox"/> | <input type="checkbox"/> | Some kids wish that they could feel better about themselves physically | BUT | Other kids always seem to feel good about themselves physically |
| 36 | <input type="checkbox"/> | <input type="checkbox"/> | Some kids are not very happy with the way they do a lot of things | BUT | Other kids think the way they do things is fine |

	Really True for me	Sort of True for me		BUT		Sort of True for me	Really True for me
1	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers feel they are just as smart as others their age		Other teenagers aren't so sure and wonder if they are as smart		
2	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers find it hard to make friends		For other teenagers it's pretty easy		
3	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers are often disappointed with themselves		Other teenagers are pretty pleased with themselves		
4	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers are pretty slow in finishing their school work		Other teenagers can do their work more quickly		
5	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers have a lot of friends		Other teenagers don't have many friends		
6	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers don't like the way they are leading their life		Other teenagers do like the way they are leading their life		
7	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers do very well with their classwork		Other teenagers don't do very well with their classwork		
8	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers are kind of hard to like		Other teenagers are really easy to like		
9	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers are happy with themselves most of the time		Other teenagers are often not happy with themselves		
10	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers have trouble figuring out the answers in school		Other teenagers can almost always figure out the answers		
11	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers are popular with others their age		Other teenagers are not very popular		
12	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers like the kind of person they are		Other teenagers often wish they were someone else		
13	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers feel that they are pretty intelligent		Other teenagers question whether they are intelligent		
14	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers feel that they are socially accepted		Other teenagers wished that more people their age accepted them		
15	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers are very happy being the way they are		Other teenagers wish they were different		

ID# _____

Date: _____

PedsQLTM

Paediatric Quality of Life Inventory

Version 4.0 English (United Kingdom)

PARENT REPORT for TEENAGERS (ages 13-18)

INSTRUCTIONS

On the following page is a list of things that might be a problem for **your teenager**.

Please tell us **how much of a problem** each one has been for **your teenager** 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 teenager had with ...*

Physical Functioning (<i>problems with...</i>)	Never	Almost Never	Some-times	Often	Almost Always
1. Walking 100 metres	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activities or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having aches or pains	0	1	2	3	4
8. Feeling 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	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	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 teenagers	0	1	2	3	4
2. Other teenagers not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other teenagers	0	1	2	3	4
4. Not being able to do things that other teenagers his or her age can do	0	1	2	3	4
5. Keeping up with other teenagers	0	1	2	3	4

School Functioning (<i>problems with...</i>)	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. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

Appendix 11 - BOB 3 and 12 month interview schedule

Question	Prompts
<p>Expectations</p> <p><i>(Wind underneath the balloon basket)</i></p>	<p><i>Why BOB?</i></p> <p><i>Goals</i></p> <p><i>What did you want to get out of the project?</i></p> <p><i>What had happened to get this decision making point.</i></p>
<p>Who has helped you along the way?</p> <p><i>(People inside the balloon basket with you)</i></p>	<p><i>Key people</i></p> <p><i>What role have they played</i></p>
<p>What has gone well?</p> <p><i>(The fire)</i></p>	<p><i>School? Family? Lifestyle? Diet? Exercise?</i></p>
<p>What changes have you made so far?</p>	<p><i>Lifestyle? Diet? Exercise? Routine?</i></p>
<p>How does it feel living with the balloon?</p>	<p><i>Expected? Changed from before balloon?</i></p> <p><i>Travel? Project set up?</i></p>
<p>What hasn't worked well?</p> <p><i>(Balloon)</i></p>	<p><i>School? Family? Motivation? Weight loss?</i></p> <p><i>Program design? Balloon? Diet? Exercise?</i></p>
<p>Unexpected things which have knocked off course</p> <p><i>(Wind)</i></p>	<p><i>School? Friends? Family?</i></p>
<p>Where do you go from here?</p> <p><i>(Sky)</i></p>	<p><i>Goals? Weight loss? Clothes?</i></p>

Appendix 12 - Qualitative analysis BOB experience

Code (definition) 3 MONTH	Sub codes	Quote [transcript details]
Challenges	School Overcoming set-backs	<p><i>"its been hard because I have obviously had exams coming up, so its been up and down really"</i></p> <p><i>" I 'll be in bed and I'll just be watching TV and I will think to myself I could be doing exercise on the treadmill but I can't motivate myself. I don't know, its just the whole boring concept of it all" [BOB4]</i></p> <p><i>"Its hard, you still have one or two slip ups when you get depressed now and then" [BOB6 Dad]</i></p> <p><i>"it's hard as I felt disappointed as when I actually started trying. When you do all these things and you give up half way through but when I actually started trying really hard and I put the weight back on I got bit upset" [BOB9]</i></p>
Future directions	Future goals	<p><i>"Keep losing weight, eat healthy and keep going to the gym" [BOB2]</i></p> <p><i>"I want to be able to go into a shop, pick something up and buy it, rather than having to try it on and make sure it fits right" [BOB1]</i></p> <p><i>"I want to just carry on the same when the balloon comes out" [BOB6]</i></p> <p><i>[I want to go college and uni and become a teacher, so I need to be fitter and everything so I can do that" [BOB7]</i></p> <p><i>"I'll continue the same as when the balloon is in now but just gonna be harder because it stops like you eating"</i></p>

Why BOB?		portions. I will have nothing to stop it, I'll have to mentally think that I'm full" [BOB10]
	Bullying	<p>"it was really getting him down. He missed two years of school because he just didn't want to be around people" [BOB2 mum]</p> <p>"If I carry on I know my health will be affected but also its to feel more confident, because obviously I was bullied quite a bit before and I feel like if I lost weight then I can show them that's that's what I was then, but this is me now" [BOB4]</p> <p>"You wanted to be confident in yourself because you had that bullying in school which was getting you down" [BOB6 Dad]</p>
	Health and wellbeing	<p>"Lose weight and get my confidence back" [BOB2]</p> <p>"I wanted to improve my fitness because I was unfot and really fat" [BOB9]</p> <p>"I was putting on loads and loads of weight and it was affecting my health, that why I really wanted to change" [BOB4]</p> <p>"Because I have got diabetes so hopefully it will help that and my health, I've got polycystic ovaries, high lipia levels, high cholesterol which should help if I lose weight." [BOB5]</p> <p>"to get healthier and save my life. That night I went to a party and all I did was just scream and laugh as I was so excited by the opportunity of being involved with BOB as nothing else has helped" [BOB12]</p>

		<i>"I wanted to lose weight and feel better in myself, because right now im not feeling good" [BOB 11]</i>
	Social acceptance	<i>"it would be nice to similar to everyone and not stand out like a sore thumb. It would be nice to fit in and just be a good size" [BOB4]</i>
	Exhausted all available treatment	<i>"it was like doctors always said your last resort is surgery but I didn't want permanent surgery" [BOB1]</i>
Support	Research team	<i>"they know what they are talking about and they understand you, they help offer best solutions. I'd rather them involved because if I didn't I'd fall back into my old ways" [BOB4]</i> <i>"I just think it is their advice giving and like when, they basically just tell you how it is" [BOB4]</i> <i>"they (research team) believe I can do it; they support me , I support them, we support each other whereas some people aren't bothered [BOB11]</i> <i>'it's easier with their support as they phone regularly and text, which makes it easy to talk to them" [BOB 6]</i> <i>'cause you get weighed and measured but you don't get forced to do anything, you can come and talk and do what you want" [BOB7]</i> <i>"always giving advice, always prompting to go a little bit more. And then sometimes when I cant do it you still push a little bit more, but when I actually do it you support" [BOB 11]</i> <i>"my mums my biggest supporter as she brings me here [lifestyle program], helps make sure portion sizes are right and always there. My little brother keeps me running around too. Having their support makes it more fun too especially when they come to the sessions with me"</i>
	Family	

Evidence of change	Internet	<p>"I've got a friend, he's on the internet so have never met him, I just talk to him, I don't know he just keeps saying you're doing really well, keep it up, stuff like that" [BOB1]</p> <p>"I feel happier, I know I've still got a long way to go though" [BOB4]</p>
	Individual	<p>"I am more active and I am eating more healthily, I have even started having breakfast" [BOB6]</p> <p>"I'd have days where I would eat loads, then the next eat nothing at all but now I eat regular" [BOB7]</p> <p>"I am actually moving more, I actually walk to school and have changed what I am eating" [BOB11]</p> <p>"I feel now I can get out of bed in a morning instead of feeling right tired and lazy and doesn't matter. I get out of bed on a morning now and I'll go downstairs and get my breakfast" [BOB9]</p>
	Family	<p>"It's low fat spread and skimmed milk, turkey instead of bacon. Everything's changed hasn't it? We all sit there planning and doing" [BOB2 mum]</p> <p>"he was horizontal most of the time so seeing him vertical and moving around is a surprise" [BOB 4 mum]</p> <p>"we walked on new years eve, we all walked to and from our aunties when normally we would take the car, which was far" [BOB 11 mum]</p> <p>"we've bought small plates and have been concentrating on smaller portions at dinner times for everyone" [BOB 6 mum]</p> <p>"She gets up more and she's not always in her bedroom and watching Dr Who. I've noticed her walking the dog more. She's also going out with friends and there was no chance she would have done that before" [BOB 11 mum]</p>

	Social Influences	<p>11] <i>"I mean [BOB2] can now go into a shop and get things off shelf. He doesn't have to go to a special shop for things, he can walk into JD sports" [BOB2 mum]</i></p> <p><i>"I won't measure success by weight, I will go on clothes size" [BOB1]</i></p> <p><i>"I play more football at school rather than just standing around. I also go nearly every Saturday and take my dogs out most days hen I used to just let them go in the garden" [BOB9]</i></p>
BOB experience	Intra-gastric Balloon	<p><i>"at first it was rubbish because I had really bad diarrhoea and sickness for 3 weeks" [BOB1]</i></p> <p><i>"I don't really feel it, it's weird, in that sense it is much easier than I had expected" [BOB6]</i></p> <p><i>"for the first week it were killin, you wanted to eat but then you'd be sick, so I didn't eat owt for 2 week. You gradually learnt what to eat and what would cause bellyache, like hash browns and I weren't ok.I had Macdonals and I had chips and chick and be like in pain for 4 days, but after a month of having it done you 'a learn what you can and can't eat" [BOB7]</i></p> <p><i>"if you honestly would have told me the pain before and how excruciating it was I think I would have changed my mind but now that I have been through it, I m proud of myself and would recommend" [BOB10]</i></p>
	Lifestyle programme	<p><i>"its funny , my brother came and we did 1,000m on the rower and we had to try and beat each other. Its better because you've got something to work at – you can have your own goals but then when you've got someone else you can compete, its fun" [BOB1]</i></p> <p><i>"I've lost weight which I didn't think I would" [BOB12]</i></p>

		<p><i>"doing it every week, well attempting to, I am now walking more and I'm not ran out of breath. I can run up the stairs now and I'm not totally out of breath" [BOB12]</i></p>
	<p>Individual experience</p>	<p><i>"I have naturally cut down my portion size" [BOB1]</i></p> <p><i>"I'm making slow changes but it will be a radical one when it's done" [BOB12]</i></p>
	<p>Parental experience</p>	<p><i>"I feel more energetic. I can move around school quicker and more bouncy and happier than before" [BOB12]</i></p> <p><i>"She [her daughter] thinks about what's she's eating more now and is not as nasty tempered. When she eats it like she's having a snack or something, whereas before it would have been a sandwich followed by yogurt, chocolate bar, biscuit and still be looking for something else" [BOB 1 mum]</i></p>

Code (definition) 12 MONTH	Sub codes	Quote [transcript details]
Relationships	Research team	<p>"You've taken him as a human being, not someone like come on get on it , you know like, get it do you've been his friend" [gran BOB2]</p> <p>"just having someone to talk to and just kept saying I could do it" [BOB6]</p> <p>"I learnt how to make a fitness plan and things like that. I think the support from the people involved was a good thing" [BOB 10]</p>
	Friends	<p>"he's got loads of friends now, they're always on the front aren't they at night. I don't mean this to sound funny but instead of having virtual friends or people on the end of the microphone on Xbox he has real friends" [BOB2]</p> <p>"I realised that I prefer to go out and play football or something now, instead of just sitting on the Xbox" [BOB9]</p> <p>"they haven't really been interested to be honest. I don't really see any of them because I am at college. So I try not to have much to do with them" [BOB7]</p> <p>"trying to lose weight. Like some people oh year we'll go out and do something, and then others are like we'll get a KFC or something stupid like that – and you're always battling between them. And like my dad said we'll go cycling and all this but he never does" [BOB 10]</p>
Evidence of Change	Emotional	<p>"I'm independently thinking about what I am eating and what I am doing, and am more positive in" [BOB3]</p>

	<p>“it’s not necessary to eat so much, there is just no need for it. I used to use it as a way of coping emotionally but because now I’m a lot happier that I’m not that weight I don’t snack because of it” [BOE]</p> <p>“before I had the balloon in, to be honest I was just bad. I was putting on weight, like two pounds every month, and it was making me depressed, which caused me to eat more. I wasn’t in an amazing place going though the BOB trial it has made me think, if I hadn’t imagine what size I would be now. My knee used to crack doing the smallest things, no I can do a lot more” [BOB4]</p> <p>“It has given me a lot more confidence, which has made me able to get a job, because I more confident in my ability to do it” [BOB8]</p> <p>“I wish I didn’t regret it because BOB was life changing, because it made me realise I don’t want to be like this” [BOB 10]</p> <p>“I take it day by day now as its easier that way, not looking too far into the future. I open up a bit more and feel more confident” [BOB6]</p>
Family	<p>“I do try and avoid things and if I do eat them , I don’t eat them in front of *** “ [mum BOB3]</p> <p>“We’ve changed everything what we eat. We try to eat the same as what BOB2 does, so that nobody having anything different “ [mum BOB2]</p> <p>“you’ve got to do it all together”</p> <p>“having my mum and dad come made me feel like they actually care. She didn’t have to , most parents</p>

	<p>wouldn't but she is quite confident and always there and my family are always saying, if I put too much my plate they would say do you want to put a bit back and stuff like that" [BOB4]</p> <p>"no one would do anything physical in our house so I would prefer to go out with my mates and stu [BOB9]</p>
Behavioural	<p>"his heads up, instead of walking and looking at the floor all the time, he actually looks at people" [m BOB2]</p> <p>"I don't really like going to gyms because people generally tend to be quite fit there and you just stand c like a sore thumb. So I like just being myself, I use the rowing machine at home now". [BOB4]</p> <p>"I am more active, I am walking more and am now doing PE" [BOB6]</p> <p>"I did start cutting down and eating healthier and going to the gym, then that just stopped" [BOB10]</p> <p>"I'm going out more, I drink lots of water and I eat healthier. We have a lot of fruit in the house and stu [BOB9]</p> <p>"being more active in the day, just lose energy, so then actually needing to go to sleep" [BOB 9]</p> <p>"I've started college now which means I'm going out more, walking more and just more independent which is good" [BOB3]</p> <p>"college is going well and I am enjoying it. I thought maybe I wouldn't fit in but I do perfectly" [BOB4]</p> <p>"we're looking at going away on holiday, like on safari, as we have looked at the alps previously but couldn't walk" [BOB4 mum]</p>
Life events	

BOB experience		Want to go to university hopefully, to study broadcast journalism" [BOB 10]
	Learning	<p>"its helped me mentally realise that its not a quick fix and that I have to do it myself instead of looking for another way out" [BOB3]</p> <p>"well the initial balloon went well because I think , well I hope it demonstrated to her that without so massive surgery or anything then she is capable of losing weight" [Dad BOB6]</p> <p>"not from having it in [balloon] but from the support I got from it, that no matter what happened, friend will stick by me and stuff" [BOB 10]</p>
	Reliance on balloon	<p>"I think I relied on the balloon. Like as soon as it was out,you took it out I thought well, there is no telling me I can't eat as much as I want now. So I'll just go back as I were , type of thing" [BOB1]</p> <p>"When it first came out I just thought I was going to go back to square one I thought it would undo its but my portion sizes are smaller and I don't feel hungry constantly like I used to" [BOB4]</p> <p>"I thought it would be a lot easier, I just thought the balloon would do it all for me. But I've realised that wasn't the answer, it was just the kick start to keep things going but it was partly to help me but I had to do the rest myself" [BOB4]</p>
	Support intervention post	<p>"they need to see someone because I think that just gives – I don't even think a monthly basis, when they've left it six months, probably two months, and then let them be weight, let it just get marked down for kids piece of mind" [mum BOB1]</p> <p>"I had just got settled into a routine, was coming to the gym and everything was going really well a</p>

	<p>then it were time to come out” [BOB1]</p> <p>“I think when the balloon comes out for the first three or four weeks after the balloons come out I think we would have benefitted from a gym membership and some dietetic and advice” [mumBOB1]</p> <p>“To keep the momentum up it needs to be close to home.I mean because of your own influences like work and college and projects everything’s that going on it hard. It’s all sort of outside influences that affect you after balloon out and to me, maybe a bit more intense after the first month.As once its out, it’s don’t know, like a holiday, yay, so you have to be careful” [BOB1]</p> <p>“its not just 6 months, it s two years but you need to find something outside once the balloon is out , whoever is participating in it for the rest of the two years to help with a gym membership or a group outing or something like that” [mum BOB1]</p> <p>“Some of my old habits are creeping back in.Being unhealthy, staying in the house and the food I eat [BOB6]</p> <p>“I’ve been trying but its been quite difficult, not as easy as when the balloon was in. you have to think about things even more” [BOB8]</p> <p>“I think its difficult especially because going back to eating the same as before, you have to try and stick to yourself, tats quite hard. I know how to deal with it better now than before but its actually doing [BOB7]</p> <p>“I still, I live with Jake, I see him everyday, he comes, we cuddle and everything. And he’ll come down in a pair of boxers and I still now double take at him because I can’t believe his shape. I can’t believe it. I can</p>
Parental perceptions of child progress	

	<p>believe my sons gone and he's the shape he is now. It unbelievable" [mum BOB2]</p> <p>"his confidence, from saying I don't want to live anymore to walking round in the house with a pair of boxers shorts on" [mum BOB2]</p> <p>"its gone beyond the physical, if you do this the balloon will help you. Its gone beyond to him realising that I've got to work to work it out, else this is not going to happen " [mum BOB4]</p> <p>"I think its psychological , you know the balloon is in, you know you cant eat more because its going to make you sick or whatever. Once the balloons out, its hard and I mean we're all the same and old habits come back don't they, and its very hard to change" [dad BOB6]</p>
Effectiveness	<p>"it was the best thing for him, he was just ready- we had had a bad time before it when he was crying the time. And then when they said he could do it, it lifted his spirits up a bit didn't it. He just gone forward ever since. I'm so proud of him, because it a big thing for a boy of his age ain't it don't you think for him to do it" [gran BOB2]</p> <p>"be more confident, lose weight and get that clothes that actually fit me. I've achieved that" [BOB2]</p> <p>"Like I said we did stay with the balloon and it didn't work. To be honest for those six months, he did fatter bloated. Now its whether or not he gives it a chance to do it himself" [mum BOB3]</p> <p>"I'm grateful for what they have done. I've spent so many years trying to do something ,looking abroad for surgery, and if it wasn't for this research then I don't think I would be in the position I am now. It might be a bit of a distance but what's 45 mins on the train? Its like they are helping me im going to give it a go" [BOB4]</p>

		<p><i>"It was good at the beginning when it started but then it just went down downhill. I think that was just the balloon wasn't for me. I had a horrible experience with it, the first month was fine and I lost weight then it just went wrong, I didn't like it" [BOB10]</i></p> <p><i>"the actual balloon didn't work as well as I thought it might have done and he didn't lose as much weight as I thought he would. All other aspects and everything put together been fine for me, that what I want for me, to be a bit more social, go out more and be a bit more active and self confident and he has that what he is"</i> <i>[mumBOB10]</i></p>
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