Exploring the evidence base for Tier 3 specialist weight management interventions for children aged 2-18 years in the UK: a rapid systematic review.

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Abstract

Background: The impact of specialist weight management services (Tier 3) for children with severe and complex obesity in the UK is unclear. This review aims to examine the impact of child Tier 3 services in the UK, exploring service characteristics and implications for practice.

Methods: Rapid systematic review of any study examining specialist weight management interventions in any UK setting including children (2-18 years) with a body mass index >99.6th centile or >98th centile with comorbidity.

Results: Twelve studies (5 RCTs and 7 uncontrolled) were included in a variety of settings. Study quality was moderate or low and mean baseline body mass index z-score ranged from 2.7 to 3.6 units. Study samples were small and children were predominantly older (10-14 years), female and white. Multidisciplinary team composition and eligibility criteria varied; dropout ranged from 5% to 43%. Improvements in zBMIover 1-24 months ranged from -0.13 to -0.41 units.

Conclusions: Specialist weight management interventions for children with severe obesity demonstrated a reduction in zBMI, across a variety of UK settings. Studies were heterogeneous in content and thus conclusions on service design cannot be drawn. There is a paucity of evidence for Tier 3 services for children, and further research is required.

Introduction

Overweight and obesity in children aged 2-18 years has increased throughout the world, presenting a global public health crisis[1]. In England there has been a rise in severe pediatric obesity prevalence; an estimated 2.9% of girls and 3.9% of boys aged 10–11 years, have severe obesity (body mass index [BMI] ≥99.6th centile)[2]. The rise in severe pediatric obesity prevalence may result in a greater risk of adverse cardio-metabolic events and severe obesity in adulthood[3]. Generally, socioeconomically disadvantaged children in high-income countries[4-6] such as England are at greater risk of becoming obese. However, this relationship may vary by population demographics such as age, gender, and ethnicity[7,8].

In England, the obesity pathway includes; Tier 1: universal prevention services; Tier 2: lifestyle weight management services (WMS); Tier 3: specialist, multidisciplinary WMS; and Tier 4: bariatric surgery[9]. Recent National Institute for Health and Care Excellence (NICE)[10] quality standards state that 'Children and young people who are overweight or obese and have significant comorbidities or complex needs are referred to a paediatrician with a special interest in obesity for investigations and access to Tier 3 services'[11].

Tier 3 WMS are defined as multicomponent, multidisciplinary and specialist services for children with severe obesity. A Tier 3 service usually comprises of a multidisciplinary team (MDT) of specialists, led by a clinician and typically including: a physician (consultant or GP with a special interest); specialist nurse; specialist dietitian; psychologist or psychiatrist; and physiotherapist/physical activity specialist/physiology[9]. Public Health England (PHE) provides a framework for evaluating WMS enabling standardised evaluation, which is applicable for Tier 3 services[12].

Some clinical commissioning groups and local authorities[i] commission Tier 3 services, although locally what defines a tier 3 service for children and young people varies. There is no universal provision across England, with a number of areas not offering any or little in the way of specialist services[9,13-15]. There is a lack of evidence evaluating the effectiveness and cost-effectiveness of Tier 3 services for children and a lack of information describing the composition of and effectiveness of differing models of the specialist team.

Previous research into the effectiveness of WMS for children has largely focused on lifestyle, multicomponent services, known as Tier 2, though these services are often for overweight children, and don't necessarily meet the needs of children with severe or complex forms of obesity[16]. This review aims to establish the evidence base for Tier 3 WMS for children by exploring service characteristics, impact and implications for practice. This paper is published as a summary of a report commissioned by PHE. Importantly, part of the translational work associated with this review involved the development of toolkits to support commissioners and providers of obesity services, as outlined in The Department of Health's letter detailing PHE's Strategic Remit and Priorities[17].

Methods

A protocol (a priori, unpublished) was developed in collaboration with a project steering group (for membership see Acknowledgements). The methods are underpinned by the Joanna Briggs Institute (JBI) methodology for scoping reviews[18]. The template for intervention description and replication (TIDieR) checklist and guide were used to extract data on delivery and context[19]. The review is reported following the Preferred Reporting Items for Systematic Reviews guidelines (PRISMA)[20]. It was a rapid review that was designed to be responsive to policy need and so a broad and flexible approach was taken. Pragmatic decisions were made

[i] Clinical commissioning groups and local authorities are public bodies with a responsibility for providing clinical and public health services in England

regarding the methodology and inclusion criteria by the project steering group and literature searches were limited to 2005 onwards to ensure studies were most relevant to current clinical practice.

Inclusion criteria

A preliminary scoping search identified very few published randomised controlled trials (RCTs) of Tier 3 WMS for children in the UK. As such, we took an overarching approach used by NICE to identify the best available evidence[21]. Thus studies of any design reporting outcomes pre and post-intervention were included. Studies with and without a comparator group were included without restriction on the type of comparator.

Children aged 2-18 years with a mean baseline BMI >99.6th centile or >98th centile with comorbidities were included. We applied a mean baseline BMI rather than an individual cut-off because we were aware of variability and inconsistency in eligibility. As many of the studies identified would pre-date the concept and definition of a Tier 3 service, a pragmatic decision was taken to include WMS that, although not Tier 3, were specialist multicomponent multidisciplinary services for children that met mean baseline BMI criteria. In addition, if a study reported outcomes for a subgroup that met our mean baseline BMI criteria, although the whole study did not, then the data for the relevant subgroup were extracted.

Multicomponent interventions which included components of diet, physical activity and behaviour change were included. The intervention could also include pharmacotherapy for obesity although pharmacotherapy only interventions were excluded. Interventions delivered by a MDT including specialists or clinicians were included. All study designs which reported weight change data of any duration and in any setting were included. Interventions based in the UK and published from 2005 onwards were included.

Embase, MEDLINE and PsycINFO were searched from January 2005 to March 2016 and articles were retained within a Reference Manager database and further limited to UK-based studies using keywords and text words in the abstracts containing 'England', 'Ireland', 'Scotland', 'United Kingdom' or 'Wales'.

Database searches were supplemented by grey literature searching, including hand searches and resources provided by the steering group and study author contacts. Reference lists of full-text articles were also searched for additional studies. The titles and abstracts were screened by one reviewer (TB) who then screened full-text articles. Articles that were unclear for inclusion were independently screened by a second reviewer (LE) and a steering group member (AA). Articles that remained unclear were referred to PHE for advice (JB, VC, BH).

Data extraction tables were developed to record participant and study characteristics, intervention components and outcomes. Quality appraisals were carried out using the JBI appraisal tools[22]. The studies were subjectively ranked as low (<4/9), moderate (4-6/9) or high quality (≥7/9), the full appraisal results for each study can be found in Table S4. All data were independently extracted by two reviewers (TB, COM); a third reviewer (LE) was consulted if any queries arose. Evidence was appraised taking account of study design, quality and setting.

Results

Due to study heterogeneity, meta-analyses were not possible, therefore a narrative synthesis is provided.

The searches identified 1913 articles of which 120 were obtained and screened as full-text articles. Figure 1 shows the study flow. Grey literature searching, reference list searching and contacting authors resulted in the identification of an additional two studies[23,24]. In total, 12

studies[23-34] met the inclusion criteria and were included; 1 study is ongoing[35] and 109 articles were excluded, of which 15 related to adults and are reported in a separate systematic review (TJ Brown, et al - unpublished data). Table 1 shows study characteristics including participant baseline characteristics. See supporting information for detailed information on the characteristics of included studies (Table S1), descriptions of interventions (Table S2), MDT composition (Table S3) quality assessment (Table S4) and outcomes (Table S5).

Characteristics of the interventions

Study design

Five studies were RCTs and seven were observational studies without a comparison group. The comparator groups in the RCTs were either another active intervention or standard care.

Setting

Six studies (2 RCTs and 4 uncontrolled) evaluated Tier 3 WMS, three of which were based in in an established Bristol service and three were NHS funded service pilots (one hospital and two community-based). Six further studies (3 RCTs and 3 uncontrolled) had similar characteristics to a Tier 3 service and were based in various community settings including four studies at the same residential camp in Leeds.

Content

All interventions were multicomponent and included diet, exercise and behaviour change; no studies included referral to or from bariatric surgery or the use of anti-obesity pharmacotherapy. All of the studies required some form of parental engagement with the intervention. Some studies reported a theoretical underpinning of the intervention and training of programme deliverers. There was no evidence identified regarding user group involvement in the design of the services. The studies were heterogeneous making comparisons of service characteristics difficult.

Delivery

The MDT composition varied across the studies and members included a physician (consultant or GP with a special interest), specialist dietitian, specialist nurse, psychologist or psychiatrist, physiotherapist or physical activity specialist or physiologist. Five studies reported involvement of physician as part of the MDT. Seven studies included a dietitian, of which two were paediatric dietitians. Three studies included a nurse. Two studies included a psychologist or psychiatrist; five studies included a physiotherapist or physical activity specialist or physiologist. It was not always clear if these members were specialists in obesity management. All four studies based in secondary care had physician involvement whereas only one community based study had physician involvement. The four residential camp studies lacked details about programme delivery (Table S3).

Size and duration

Studies included relatively small samples ranging from 7 to 106 participants. Duration of the four camp based interventions ranged from 27 days to 7 weeks. Duration of the other eight studies ranged from 6 to 24 months with only four studies reporting follow up at 12 months or longer. Three studies followed-up participants after a period without active intervention and evaluated the sustainability of weight loss. Only two studies assessed all participants at follow up. Table S2 provides detailed description of interventions.

Quality

None of the studies were rated as high quality, the majority were of moderate quality, and a small number low quality. The quality domains that most studies failed to meet were insufficient duration of follow-up and exclusion of dropouts from the analyses. Most of the RCTs lacked blinding and comparability of groups at baseline. None of the uncontrolled studies were based on random samples and all of them lacked discussion of potential confounding factors.

Participants

All studies reported a mean baseline weight which facilitated their eligibility to be included in this review. BMI was reported in seven studies and ranged from 27 to 35 kg/m^2; mean baseline zBMI [ii]was reported in ten studies and ranged from 2.7 to 3.6. The mean baseline BMI/zBMI was consistently higher than the minimum required to meet the eligibility criteria in each individual study.

Within the individual studies, eligibility criteria for weight varied widely, both in terms of criteria used and cut-off applied. In studies using centile data, cut-offs ranged from the 85th centile to the 98th centile. In four studies, eligibility criteria for weight were not explicit. Two studies reported excluding children with Type 2 Diabetes at baseline[24,27]. One study excluded children with underlying medical problems such as hypothyroidism and medication for insulin resistance[28]. One study included children with complex health and/or social needs but did not further define this[30]. In general the other studies appeared to adopt relatively wide inclusion criteria; two studies[25,33] reported that no exclusion criteria were used in addition to weight.

Baseline age was reported in all studies and ranged from 10 to 14 years. All studies included boys and girls; the majority were girls (54% to 75%). Four studies reported ethnicity, the majority in each sample were 'white' (59% to 92%). Five studies reported socioeconomic status (SES), including employment status[24,27] education level[24] parental marital status[24,25,30] and deprivation scores[33].

Effects of interventions

Table 2 provides zBMI data and Table S5 provides detailed information for all reported outcomes. The camp studies were different from the other studies in that they were all

[ii] BMI adjusted for age and sex.

intensive short-term residential programmes away from parents; for this reason, we analysed effects for the camp studies separately.

Attendance/compliance

Non-residential studies

Seven of eight studies reported dropout of 18%[27] to 43%[23]. Only one study reported comparing the characteristics of dropouts with completers: dropouts had a higher mean baseline BMI[28]. Attendance rates varied between studies, only one study evaluated the effect of attendance on weight loss and reported no significant effect of attendance on weight loss[27].

Residential studies (camps).

Two of four camp studies reported dropout of 5%[26] and 10%[29].

Anthropometric

All studies (apart from one camp study[32] and one non-residential study[30]) reported change in mean zBMI. Seven studies demonstrated significant improvement in anthropometric measurements from baseline to follow-up. One study[24] maintained baseline zBMI and one study showed a non-significant reduction in zBMI at 1.7 years. In studies with a comparison group (all comparison groups involved some form of active care); all comparison groups also reduced zBMI from baseline to follow-up. Change in zBMI from baseline to last follow-up ranged from -0.06 to -0.50 over a duration of six to 12 months. One study[34] used self-reported measures via on online survey and reported reduction of 0.50 zBMI.

Three of the four camp studies[26,29,31] reported change in zBMI over time which ranged from -0.25 to -0.36 over a duration of 27 days to six weeks. Two of these camp studies[26,29] were RCTs comparing high protein diet (22.5% and 25%) with standard diet: there was no significant difference in change in zBMI between the groups (all groups reduced zBMI over time).

There was no discernible pattern between length of the intervention and amount of reduction in zBMI. For example, similar reductions in zBMI were achieved in residential camps of 4-6 weeks duration as in longer-term (six to 24 months) hospital or community-based interventions.

Sustainability of zBMI improvements was only examined in a small number of studies. Sabin et al.[33] reported a zBMI reduction at 1.7 years of -0.24 (95% confidence interval [CI]: −0.48 to 1.43). A crossover study[25] of a 12-month school-based family programme followed by 12 months of body composition monitoring (and vice versa) demonstrated significant reduction in zBMI in the intervention/control group but not the control/intervention group at 12 months and 24 months, with the intervention/control group achieving -0.13 zBMI at 1 year and -0.41 zBMI at two years (but adjusted mean difference between both groups at 12 and 24-month was not significantly different). None of the camp studies reported on sustainability of improvements in outcomes.

Sociodemographic factors as potential effect modifiers

Two non-residential studies evaluated whether change in anthropometric outcomes varied by sociodemographic characteristics. The evidence was inconsistent. Sabin et al[33] reported that age was the most important predictor, with younger children achieving larger reductions in zBMI. More boys than girls were likely to achieve target reductions in zBMI and those without a parental history of obesity were more likely to achieve greater reductions in zBMI. No significant correlation was seen between the Townsend deprivation score and fall in zBMI over one year. Edwards et al[27] reported that loss of overweight during treatment was not related to age, gender or initial %BMI.

Two residential studies reported on potential effect modifiers. Kulendran et al[32] reported that there was a greater reduction in BMI in boys (-3.17, standard deviation [sd] 0.89 kg/m^2) than

in girls (-2.62, sd 0.89 kg/m^2), p=0.03. However, another camp study[31] reported a mean weight change of -8.36 kg with a non-significant difference between boys and girls.

Comorbidities

Two non-residential hospital-based studies reported on clinical outcomes including blood pressure, insulin, leptin and lipids. One hospital-based study[28] significantly improved high-density lipoprotein cholesterol concentration (mean adjusted difference −0.07, 95% CI: −0.14 to −0.00; p=0.043) when a computerised device to slow eating was compared with the standard care group at 12 months. However, there were no significant differences between the groups in low-density lipoprotein cholesterol concentration, high sensitivity C reactive protein, insulin resistance, or blood pressure (BP) at 12 months. However it should be noted that each arm did not receive exactly the same standard care. In another hospital-based study[33] , 'achievers' (i.e. those who have reduced zBMI by at least 0.5 or obtained a BMI centile <99.6) had lower mean levels of insulin, leptin and Homeostasis Model Assessment of Insulin Resistance than the 'non-achievers' and ≤1 year dropouts, but none of the differences were statistically significant.

Three residential camp studies reported on clinical outcomes. Two studies compared varying levels of protein in diets and showed significant improvement over time for diastolic but not systolic BP[26] and for both diastolic and systolic BP[29] for both high and standard protein diets: raising the level of daily dietary protein had no impact on these changes. There was also significant improvement in all blood lipids over time regardless of diet group[29]. Both of these studies were intensive and short-term. Another study reported significant improvement from baseline for diastolic BP[32].

Quality of Life

Three studies (all non-residential) reported on quality of life outcomes, two studies[23,28] based at the children's hospital in Bristol used the same measure (PedsQL version 4.0) and reported similar and positive improvements from baseline to 12-month follow-up for all groups. A community-based study showed improvements to a number of self-report aspects of quality of life[30]. Three studies reported reductions in depression following weight management interventions[24,27,30]. There was also significant improvement in self-concept and in self-perception relating to physical appearance[24,27].

Behaviour change

Five studies (all non-residential) reported behaviour change outcomes related to diet and physical activity. Whilst some improvements were observed, a range of different outcome measures were used making it difficult to compare findings across the studies.

Provider and user views/opinions/satisfaction

Three studies (all non-residential) reported some form of evaluation of the weight management programmes. Banks et al[23] reported primary care clinics scored slightly higher than the hospital-based clinics although all mean scores were equivalent to ratings from 'excellent' to 'good'.

A study of a family-based obesity treatment at Great Ormond St, London reported running the groups was a positive experience for the health professionals and families were extremely enthusiastic about the programme[27,36]. The majority of parents (18/20) and children (16/18) were very pleased that they had attended the programme. Fourteen out of 20 parents considered the written information to be very helpful, as did 9/18 children, the remainder found it quite helpful. Fifteen parents found the individual feedback session very helpful and four quite helpful.

A community based study of the OSCAR programme included a qualitative evaluation which involved both the OSCAR families and the OSCAR team members[30]. Health professionals and participating families had positive attitudes towards the helpfulness of the family meetings though this contrasted with the more negative attitudes of at least one of the families. Both providers and users felt that the 12-week programme was too short.

Costs

None of the studies included a cost-effectiveness analysis.

Discussion

Main finding of this review

We set out to assess the evidence of effectiveness of specialist (Tier 3) WMS interventions for children; however, the majority of evidence was derived from observational studies and none of the RCTs compared a WM intervention to doing nothing (true control). Whilst the results suggest that specialist weight management services can achieve reductions in zBMI across a variety of different settings, we appreciate that much of the evidence derives from uncontrolled studies which should be interpreted with caution. The absence of a comparison group makes it impossible to know what would have happened without the intervention. However, the zBMI reductions observed in the interventions arms of the RCTs fell within the range observed across all study designs.

It was difficult to make further inferences about the impact of intervention characteristics on the specified outcomes, given the heterogeneity of the interventions and the study designs. There was no discernible variation in zBMI by study quality, design or length of intervention. For example, similar reductions in zBMI were achieved in residential camps of 4-6 weeks duration, as those observed in longer-term (six to 24 months) hospital or community-based

interventions. As the camp studies were relatively intense interventions, this evidence might suggest that the intensity of the intervention rather than the duration, influences zBMI reduction. There was very limited evidence to suggest that reduction in zBMI can be maintained up to one year post-intervention. Given the chronic relapsing nature of obesity this requires further investigation.

What is already known on this topic?

A recently updated review[37] examined RCTs of lifestyle treatments for obesity (not restricted to severe obesity and largely similar to Tier 2 services) in children aged 6 to 11 years. When the data from this review was sub-grouped by mean baseline BMI, the severe obesity intervention subgroup (defined as zBMI ≥2.67) had a change in zBMI over time ranging from +0.03 to -0.71. The mean difference between intervention and usual care control groups for this subgroup was not significant (-0.03, 95% CI: -0.10 to -0.02; p=0.46, n=8 trials, n=470 participants). This demonstrates that the reduction in zBMI achieved in children in our review, which includes all types of study design, is within the range observed within RCTs; however, the RCT data did not show a significant difference between intervention and usual care groups. Another recent Cochrane review[38] examining drug interventions for the treatment of childhood obesity, demonstrated an overall reduction in BMI of 1.3 kg/m^2 in favour of drug interventions in children aged 10-14 years. This equates to a reduction of 0.28 zBMI, which again falls within the range reported in this review, although no studies reported in this review included pharmacotherapy.

The results for potential effect modifiers were inconsistent across the studies reported in this review. A recent review[39] found limited evidence for the effectiveness of interventions with the potential to reduce SES inequalities in obesity-related outcomes amongst children. Despite awareness that prevalence of obesity varies by ethnicity in the UK, only four studies in our review reported on ethnicity, and the majority of participants were white. A further systematic

review[40] of lifestyle interventions to prevent or treat obesity in South Asian children, meta-analysed a limited number of controlled trials, and found an unclear picture of the effects of interventions on BMI. Currently, we are unable to assess the equity impacts of WM interventions in the UK, this area consequently urgently requires further work.

Since conducting the review, final outcomes for another Tier 3 service have been published[41]. SHINE (Self-Help, Independence, Nutrition and Exercise) is an established Tier 3 service of psychosocial intervention for children and young people with severe obesity (BMI/waist circumference ≥99.6th centile, with or without comorbidities). The study is a retrospective evaluation of participants who attended the programme between 2011 and 2016 (n = 435; age: 13.1 years, male: 51%, white: 87.4%, zBMI: 3.1 units). At 12-months there was a mean reduction in zBMI of 0.41 units (95% CI: 0.31–0.51, n=107 completers [31%]). This reduction in zBMI is at the upper end of the range of reductions observed in this review.

What this study adds:

This is the first systematic review of Tier 3 WMS for children in the UK, and highlights some important considerations for both practice and research.

The majority of studies centred on children aged 10-14 years old. There appears to be a gap in the evidence for service provision for children under ten and young people over fourteen years. The eligibility criteria for Tier 3 services for children should be standardised and future services designed with user involvement (including family members and carers). The sustainability of zBMI reduction, is another key consideration and there is a need for longer-term follow up data, and further research on the most appropriate forms of post-intervention maintenance support. This longer term research should include both cost and clinical effectiveness analyses.

Future services and research should use the Public Health England standard evaluation framework[iii] and new minimum dataset[iv], to collect comprehensive participant demographic data, to ensure service uptake and impact is equitable. This will also help facilitate necessary improvements in reporting service details, specifically who, when, what and how components are delivered, in order to evaluate these factors as potential effect modifiers. This would be supported by a greater clarity and adherence to, what constitutes a child tier 3 weight management service, particularly regarding the composition of the MDT in terms of the minimum number of specialists, and definition of a specialist, including obesity specialist qualifications, experience and/or membership to specific bodies. In terms of outcome measures, whilst zBMI is a required outcome for any child weight management programme, clarification is required as to what constitutes a clinically meaningful reduction in zBMI in children. It is also important to consider, when delivering multi-component interventions, what it is the impact on wellbeing, and changes in co-morbidities, dietary and activity behaviours. These additional outcomes will help to determine any wider benefits, as well as improve understanding of how the intervention may be working.

Limitations of this study

It is important to note that due to available time and resource constraints only one person (TB) extracted and synthesised the data; thus lacking the rigor of double data extraction and synthesis as determined by Cochrane systematic reviews. It is also important to note that we included interventions that were not established Tier 3 services and would not meet the NICE CG189 guidance for Tier 3 services[10]. Including these studies enabled comparison of services across hospital, community and primary care sites; it also enabled evaluation of such services within select population groups. We took a pragmatic decision to include the residential camp-based studies despite scant details on the intervention, who delivered it and long term

[iii] http://webarchive.nationalarchives.gov.uk/20160805121933/http://www.noo.org.uk/pages.php5?pg=297
[iv] https://www.gov.uk/government/publications/child-weight-management-services-collect-and-record-data

sustainability. These camp studies currently provide unique, intensive WMS; however in some UK areas, these residential interventions are regarded as Tier 4 provision. During screening it was often difficult to ascertain which of the community-based studies were Tier 3 and Tier 2 due to insufficient service delivery information. This highlights the lack of clarity in practice about the distinction between different service tiers.

Despite a broad search for evidence from all study designs, the identified evidence was limited, not just in quality, but also in the fact that three studies were derived from the same hospital-based obesity clinic in Bristol, UK and four studies derived from the same residential camp in Leeds, UK. There is a complete lack of cost effectiveness data, and the clinical relevance of the findings remains unclear, with a lack of universal consensus as to what constitutes a clinically meaningful weight status change in children, despite several studies in the field[42,43,44].

Conclusions

There is a paucity of evidence, however the available literature suggests that Tier 3 WMS and other similar interventions for children with severe obesity (mean baseline BMI >99.6th centile or >98th centile with comorbidities) can demonstrate a reduction in zBMI which was achieved in a variety of settings and timeframes. It was not possible to discern the specific characteristics of an effective specialist weight management service for children with severe obesity. The clinical significance of improvements in zBMI requires clarification and consensus amongst policy-makers, health-care professionals and practitioners. This should be examined in high quality studies, that examine the sustainability of effect, and impact on wellbeing, diet and activity behaviours, co-morbidities and cost effectiveness.

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Author contributions: Tamara J Brown developed the protocol, devised and carried out the searches, screening of references, data extraction and analysis; and wrote the paper. Louisa J Ells developed the protocol, carried out screening of references, data extraction and analysis. Claire O'Malley helped with data collection and carried out data extraction. Jamie Blackshaw and Vicki Coulton developed the protocol and assisted with screening of references. Carolyn Summerbell helped to develop the protocol. All authors were involved in writing the paper and had final approval of the submitted and published versions.

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References

(1) Ng M, Fleming T, Robinson M, et al. Global, regional, and national prevalence of overweight and obesity in children and adults during 1980-2013: a systematic analysis of the Global Burden of Disease Study 2013. *The Lancet* 2014; **384**(9945): 766-781.

(2) Ells LJ, Hancock C, Copley VR, et al. Prevalence of severe childhood obesity in England: 2006-2013. *Archives of Disease in Childhood* 2015; **100**(7): 631-636.

(3) Kelly AS, Barlow SE, Rao G, et al. Severe obesity in children and adolescents: identification, associated health risks, and treatment approaches: a scientific statement from the American Heart Association. *Circulation* 2013; **128**(15): 1689-1712.

(4) Knai C, Lobstein T, Darmon N, Rutter H, McKee M. Socioeconomic patterning of childhood overweight status in Europe. *International Journal of Environmental Research and Public Health* 2012; **9**(4): 1472-1489.

(5) National Children's Bureau. *Poor beginnings. Health inequalities among young children across England. A National Children's Bureau Report*. London; 2015.

(6) Shrewsbury V, Wardle J. Socioeconomic status and adiposity in childhood: a systematic review of cross-sectional studies 1990-2005. *Obesity* 2008; **16**(2): 275-284.

(7) Wang Y, Lim H. The global childhood obesity epidemic and the association between socio-economic status and childhood obesity. *International Review of Psychiatry* 2012; **24**(3): 176-188.

(8) Health and Social Care Information Centre. *National Child Measurement Programme - England, 2015-16*. NHS Digital; 2016.

(9) NHS England and Public Health England Working Group. *Joined up Clinical Pathways for Obesity: Report of the Working Group*. London; 2013.

(10) National Institute for Health and Care Excellence. *Obesity: clinical assessment and management (QS127).* London; 2016.

(11) National Institute for Health and Care Excellence*. Obesity: Identification, Assessment and Management of Overweight and Obesity in Children, Young People and Adults (CG189).* London; 2014.

(12) National Obesity Observatory. *Standard Evaluation Framework for Weight Management Interventions.* London; 2009.

(13) British Obesity and Metabolic Surgery Society, Royal College of Surgeons. *Commissioning Guide: Weight Assessment and Management Clinics (Tier 3).* The Royal College of Surgeons of England: London; 2014.

(14) Public Health England. *National mapping of weight management services. Provision of tier 2 and tier 3 services in England*. London; 2015.

(15) Royal College of Physicians. *Action on obesity: comprehensive care for all. Report of a working party*. London; 2013.

(16) Upton P, Taylor CE, Peters DM, Erol R, Upton D. The effectiveness of local child weight management programmes: an audit study. *Child: Care, Health and Development* 2012; **39**(1): 125-133.

(17) Public Health England. (2015). Public Health England remit and strategic priorities. [WWW Document]. URL https://www.gov.uk/government/publications/phe-remit-letter-2015-to-2016

(18) The Joanna Briggs Institute. *Joanna Briggs Institute Reviewers' Manual: 2015 edition/supplement*. Australia; 2015.

(19) Hoffman T, Glasziou P, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014; **348**: g1687.

(20) Moher D, Liberati A, Tetzlaff J, Altman D, PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med* 2009; **6**(7): e1000097.

(21) National Institute for Health and Clinical Excellence. *Methods for the Development of NICE Public Health Guidance.* 3rd edn. London; 2012.

(22) The Joanna Briggs Institute. *Critical Appraisal Tools*. The Joanna Briggs Institute, Australia; 2015.

(23) Banks J, Sharp DJ, Hunt LP, Shield JP. Evaluating the transferability of a hospital-based childhood obesity clinic to primary care: a randomised controlled trial. *Br J Gen Pract* 2012; **62**: e6-e12.

(24) Murdoch M, Payne N, Samani-Radia D, et al. Family-based behavioural management of childhood obesity: service evaluation of a group programme run in a community setting in the United Kingdom. *European Journal of Clinical Nutrition* 2011; **65**(594): 764-767.

(25) Coppins DF, Margetts BM, Fa JL, Brown M, Garrett F, Huelin S. Effectiveness of a multi-disciplinary family-based programme for treating childhood obesity (the family project). *Eur J Clin Nutr* 2011; **65**(8): 903-909.

(26) Duckworth LC, Gately PJ, Radley D, Cooke CB, King RFGJ, Hill AJ. RCT of a high-protein diet on hunger motivation and weight-loss in obese children: An extension and replication. *Obesity* 2009; **17**(9): 1808-1810.

(27) Edwards C, Nicholls D, Croker H, Van Zyl S, Viner R, Wardle J. Family-based behavioural treatment of obesity: acceptability and effectiveness in the UK. *Eur J Clin Nutr* 2006; **60**(5): 587-592.

(28) Ford AL, Bergh C, Sodersten P, et al. Treatment of childhood obesity by retraining eating behaviour: Randomised controlled trial. *BMJ (Online)* 2010; **340**(7740): b5388.

(29) Gately PJ, King NA, Greatwood HC, et al. Does a high-protein diet improve weight loss in overweight and obese children? *Obesity* 2007; **15**(6): 1527-1534.

(30) Jinks A, English S, Coufopoulos A. Evaluation of a family-centred children's weight management intervention. *Health Education* 2013; **113**(2): 88-101.

(31) King NA, Hester J, Gately PJ. The effect of a medium-term activity- and diet-induced energy deficit on subjective appetite sensations in obese children. *Int J Obes* 2007; **31**(2): 334-339.

(32) Kulendran M, Vlaev I, Sugden C, et al. Neuropsychological assessment as a predictor of weight loss in obese adolescents. *Int J Obes* 2014; **38**(4): 507-512.

(33) Sabin MA, Ford A, Hunt L, Jamal R, Crowne EC, Shield JPH. Which factors are associated with a successful outcome in a weight management programme for obese children? *J Eval Clin Pract* 2007; **13**(3): 364-368.

(34) Stubbs J, Pailster C, Avery A, Allen J, Lavin J. Weight, body mass index and behaviour change in a commercially run lifestyle programme for young people. *Journal of Human Nutrition and Dietetics* 2012; **25**(2): 161-166.

(35) O'Malley G, Clarke M, Burls A, Murphy S, Murphy N, Perry I. A smartphone intervention for adolescent obesity: study protocol for a randomised controlled non-inferiority trial*. Trials* 2014; **15**: 43.

(36) Brown A, Gouldstone A, Fox E, et al. Description and preliminary results from a structured specialist behavioural weight management group intervention: Specialist Lifestyle Management (SLiM) programme. *BMJ Open* 2015; **5**(4): e007217.

(37) Mead E, Brown T, Rees K, et al. Diet, physical activity and behavioural interventions for the treatment of overweight or obese children from the age of 6 to 11 years. Cochrane Database Syst Rev 2017; 6: CD012651. DOI: 10.1002/14651858.CD012651.

(38) Mead E, Atkinson G, Richter B, et al. Drug interventions for the treatment of obesity in children and adolescents. Cochrane Database Syst Rev 2016; 11: CD012436.

(39) Hillier-Brown FC, Bambra CL, Cairns J-M, Kasim A, Moore HJ, Summerbell CD. A systematic review of the effectiveness of individual, community and societal level interventions at reducing socioeconomic inequalities in obesity amongst children. *BMI Public Health* 2014; **14**: 834.

(40) Brown T, Smith S, Bhopal R, Kasim A, Summerbell C. Diet and Physical Activity Interventions to Prevent or Treat Obesity in South Asian Children and Adults: A Systematic Review and Meta-Analysis. Special Issue: Childhood Obesity: Novel Approaches to a Global Problem. *International Journal of Environmental Research and Public Health* 2015; **12**(1): 566-594.

(41) Nobles J, Radley D, Dimitri P et al, Psychosocial Interventions in the Treatment of Severe Adolescent Obesity: The SHINE Program. *Journal of Adolescent Health,* 2016;59(5): 523 - 529

(42) Ford AL, Hunt LP, Cooper A, Shiled JPH. What reduction in BMI SDS is required in obese adolescents to improve body composition and cardiometabolic health? *Archives of Disease in Childhood* 2009; **95**: 256-261.

(43) Reinehr T AW. Changes in the atherogenic risk factor profile according todegree of weight loss. *Archives of Disease in Childhood* 2004; **89**: 414-422.

(44) Kolsgaard ML, Joner G, Brunborg C, et al. Reduction in BMI z-score and improvement in cardiometabolic risk factors in obese children and adolescents The Oslo Adiposity Intervention Study - a hospital/public health nurse combined treatment. *BMC Pediatr.* 2011, 11: 47-10.1186/1471-2431-11-47.

Table 1 Summary of included study characteristics

Author, year	Study design	Setting	Interventions	Mean age, years (sd/95% CI)	Mean baseline BMI z score (sd/95% CI)	Female (%)
*Banks 2012[23]	Pilot RCT	H	Consultant led hospital clinic	11.5 (2.5)	3.17 (0.57)	58
		P	Nurse-led primary care clinic	11.4 (2.8)	2.86 (0.40)	64
Coppins 2011[25]	RCT crossover	S	Multicomponent family focused education followed by control (body composition monitoring)	11.1 (NR)	2.7 (2.6 to 2.9)	63
			Control (body composition monitoring) followed by multicomponent family focused education	9.7 (NR)	2.8 (2.5 to 3.0)	70
Duckworth 2009[26]	RCT	C	High-protein (25%) + physical activity, reduced-energy intake, and behaviour change, residential	14.5 (1.8)	3.03 (0.51)	64
			Standard protein (15%) + physical activity, reduced-energy intake, and behaviour change, residential	14.3 (1.9)	3.00 (0.72)	
**Edwards 2006[27]	BA no control	H	Family based behavioural treatment for simple obesity	10.6 (1.6)	3.23 (0.48)	70
*Ford 2010[28]	RCT	H	Mandometer (portable weighing scale that provides real time feedback during meals to slow down speed of eating and reduce total intake) + standard lifestyle modification	12.7 (2.2)	3.29 (0.52)	56
			Standard lifestyle modification	12.5 (2.3)	3.21 (0.45)	56
Gately 2007[29]	RCT	C	High-protein (22.5%) + multi component residential behaviour change	14.1 (2.0)	2.83 (0.42)	59
			Standard protein (15%) + Multi component residential behaviour change	14.4 (2.0)	3.10 (0.50)	69
**Jinks 2013[30]	Case study	COM	Family based multicomponent with a key worker and based on person-centred planning approach for children with obesity and complex health and/or social needs (not defined)	8, 9, 10, 13 and 14 (sd NR)	NR BMI: Child A: 30.2 Child B: 22.3 Child D: 34.6 Child E: 23.1 Child F: 28.6	40
King 2007[31]	BA no control	C	Residential programme of physical activity, reduced energy intake and behaviour change	13.9 (1.6)	3.19 (0.52)	63

Author, year	Study design	Setting	Interventions	Mean age, years (sd/95% CI)	Mean baseline BMI z score (sd/95% CI)	Female (%)
Kulendran 2014[32]	BA (non-obese control not analysed)	C	Residential programme of lifestyle and physical activity based on behaviour change	14.3 (1.7)	NR BMI**:** 33.75 (7.9)	60
**Murdoch 2011[24]	Pilot BA no control	COM	Family based behavioural treatment (community-based version of hospital-based intervention by Edwards 2006)	10.5 (1.8)	3.16 (0.56)	53
*Sabin 2007[33]	BA no control	H	Paediatric obesity clinic	11.7 (2.2 to 17.8)	3.6 (2.4 to 5.9)	54
Stubbs 2012[34]	Retrospective no control (web-based questionnaire)	COM	Commercial behaviour change weight management programme for young people	13.4 (1.4)	2.7 (0.7)	75

Legend, Table 1: *established Tier 3 service; ** service pilots; BA: observational before-after study; BMI: body mass index; C: camp; CI: confidence interval; C/I: control/intervention; COM: community; F: female; H: hospital; I: intervention group; I/C: intervention/control; M: male; NR: not reported; P: primary care; RCT: randomised controlled trial; S; school; sd: standard deviation

Table 2 Body Mass Index (kg/m^2) standard deviation score (zBMI)

Intervention				Body Mass Index (kg/m^2) standard deviation score (zBMI) and standard deviation (sd)*	
Study ID	**Group**	**No. participants**	**Duration**	**Mean change from baseline (sd/95% CI)**	**Mean difference between groups (sd/95% CI)**
Banks 2012[23]	consultant led hospital clinic	Randomised:31 Assessed: 23	12 months	-0.15 (–0.26 to –0.05)	0.02 (-0.12 to 0.17)
	nurse-led primary care clinic	Randomised:45 Assessed: 29		-0.17 (–0.27 to –0.07)	
Coppins 2011[25]	Family focused education	Randomised: 35 Assessed: 35	24 months	**12 months (adjusted):** -0.13 (95% CI: -0.26 to -0.008) **24 months (adjusted):** -0.41 (95% CI: -0.71 to -0.11)	**12 months (adjusted):** -0.09 (-0.26 to 0.09), p=0.32 **24 months (adjusted):** -0.3 (-0.62 to 0.02), p=0.06
	Control (body composition monitoring)	Randomised: 30 Assessed: 30		**12 months (adjusted):** -0.14 (95% CI: 0.28 to -0.001) **24 months (adjusted):** 0.16 (95% CI: -0.43 to 0.11)	
Edwards 2006[27]	Family based behavioural treatment	Referred: 37 Entered: 33 Assessed:27	8-9 months	-0.15, p<0.001	NA
Ford 2010[28]	Mandometer*** plus standard care	Randomised: 54 Assessed 12 months: 54 Assessed 18 months: 44	18 months	**12 months**: −0.36 (−0.27 to −0.46)	**12 months (adjusted):** 0.24 (0.11 to 0.36), p<0.001 **18-month (adjusted):** 0.27 (0.11 to 0.43), p=0.001
	Standard care	Randomised: 52 Assessed 12 months: 52 Assessed 18 months:43		−0.14 (−0.05 to −0.22)	
Jinks 2013[30]	Family based treatment	Referred: 7 families Assessed: 5 families	6 months	NR, all but one of the referred children had reduced BMI on completion	NA
Murdoch 2011[24]	Family based behavioural treatment	Recruited: NR Assessed: 17 (completers)	6 months	-0.06, p=0.16	NA
Sabin 2007[33]	Paediatric obesity clinic	Attended:137 Assessed:112 (≥2 visits)	19 months	-0.24 (−0.48 to 1.43)	NA
Stubbs 2012[34]	Commercial weight management programme	Recruited: 96 Assessed: 79	6 months	-0.5 (0.4), p<0.001	NA
Camp studies					

Duckworth 2009[26]	High-protein (25%)	Randomised: 100 (both groups) Assessed: 46	31 days	-0.25, p<0.001	NS between groups
	Standard protein (15%)	Randomised: 100 (both groups) Assessed: 49		-0.25, p<0.001	
Gately 2007[29]	High-protein (22.5%)	Randomised: 98 (both groups) Assessed: 41	27 days	-0.29, p<0.05; both groups combined: -0.27 (0.1), p<0.001	NS between groups
	Standard protein (15%)	Randomised: 98 (both groups) Assessed: 39		-0.26, p<0.05; both groups combined: -0.27 (0.1), p<0.001	
King 2007[31]	Physical activity, reduced energy intake, behaviour change	Volunteered: 38 Assessed: 32	6 weeks	-0.36, (p value NR)	NA
Kulendran 2014[32]	Lifestyle and physical activity and behaviour change	Recruited: Unclear Assessed: 53 (completers)	7 weeks	NR, BMI: -2.83 kgm^2 (0.29) reported as significant	NA

Legend, Table 2: *where BMI z score not reported we have reported BMI; ** Coppins 2011: children crossed over after 12 months therefore only first 12 month data analysed; *** Mandometer: (portable weighing scale that provides real time feedback during meals to slow down speed of eating and reduce total intake; C/I: control/intervention; CI: confidence interval; I/C: intervention/control; NA: not applicable; NR: not reported; NS: non-significant; SD: standard deviation

Table and figure Legends

Table 1: *established Tier 3 service; ** service pilots; BA: observational before-after study; BMI: body mass index; C: camp; CI: confidence interval; C/I: control/intervention; COM: community; F: female; H: hospital; I: intervention group; I/C: intervention/control; M: male; NR: not reported; P: primary care; RCT: randomised controlled trial; S; school; sd: standard deviation;

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