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Evaluation of the GOALS family-based childhood obesity treatment intervention during the first three years of implementation

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Manuscripts

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3 **Evaluation of the GOALS family-based childhood obesity treatment**
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6 **intervention during the first three years of implementation**
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ABSTRACT

Objectives: To evaluate the impact of the GOALS family-based childhood obesity treatment intervention during the first three years of implementation, applying the Template for Intervention Description and Replication (TIDieR) checklist to set a standard for improved reporting of childhood obesity interventions.

Design: Repeated measures service evaluation.

Setting: Community venues in a socio-economically deprived, urban location in the North-West of England.

Participants: 70 (/143) overweight or obese children (mean age 10.5 years, 46% boys) and their parents who completed GOALS between September 2006 and March 2009.

Interventions: GOALS was a childhood obesity treatment intervention with a unique focus on whole family lifestyle change. Sessions covered physical activity (PA), diet and behaviour change over 18 x 2-hour weekly group sessions. A TIDieR checklist of intervention components is provided.

Primary and secondary outcome measures: The primary outcome measure was child BMI z-score, collected at baseline, post-intervention (approximately 6 months) and 12 months. Secondary outcome measures were child self-perceptions, parent BMI and qualitative changes in family diet and PA (parent questionnaire).

Results: Child BMI z-score reduced by 0.07 from baseline to post-intervention ($p < 0.001$) and was maintained at 12 months ($p < 0.05$). There was no change in parent BMI or child self-perceptions, other than an increase in perceived social acceptance from baseline to post-intervention ($p < 0.05$). Parents reported positive changes to family PA and dietary behaviours after completing GOALS.

Conclusions: GOALS completion was associated with small improvements in child BMI z-score and improved family PA and dietary behaviours. Use of the TIDieR checklist promoted transparent

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3 reporting of intervention components and showed modifications to delivery mechanisms were
4
5 necessary as GOALS was implemented. Childhood obesity researchers are urged to adopt TIDieR
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7 reporting standards to provide the information needed by policy-makers and practitioners to
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9 implement interventions in practice.
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11 12 13 14 15 16 **ARTICLE SUMMARY**

17 18 19 **Article focus**

- 20
21 • Evidence supports a family-based multidisciplinary approach to childhood obesity treatment,
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23 but a lack of ecological relevance and poor intervention reporting limits the translation of
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25 evidence to practice.
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28 • This study reports post-intervention and 12-month outcomes from the GOALS intervention
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30 during the first three years of implementation, employing the TIDieR checklist to provide a
31
32 transparent intervention description.
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34 35 **Key messages**

- 36
37 • GOALS was a promising childhood obesity treatment intervention that supported changes to
38
39 physical activity and diet for the whole family.
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42 • Delivery challenges are inevitable during complex intervention implementation, therefore it
43
44 is important childhood obesity treatment interventions are given time to embed before
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46 evaluating their worth.
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49 • The TIDieR checklist provides a mechanism for clear reporting of intervention components,
50
51 allowing replicability and comparison between interventions.
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53 54 **Strengths and limitations of this study**

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56 • This study reports ecologically valid data from a childhood obesity treatment intervention as
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58 it was delivered in practice. It is the first paper to use the TIDieR checklist to describe a
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3 childhood obesity treatment intervention, providing valuable information to assist policy-
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5 makers and practitioners wishing to implement interventions in practice.
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- 7 • This service evaluation was limited by a lack of control group and a high attrition rate. It is
8
9 not, therefore, known what change might have occurred without intervention or what
10
11 impact the intervention had for those who did not complete.
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14 15 16 17 INTRODUCTION

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20 Obesity is a known risk factor for cardiovascular disease and diabetes(1) and its increasing
21
22 prevalence in children presents a challenge for public health. Growing evidence supports a family-
23
24 based approach to childhood obesity treatment (e.g. [2-7]), yet there is much heterogeneity in the
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26 level of family involvement between interventions[8]. Parental involvement in “family-based”
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28 interventions varies between parents acting as the exclusive agent of change[9, 10], parents
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30 supporting the child’s behaviour change[3, 11], and parents and children changing their behaviours
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32 together[12, 13]. This study evaluates a community-based childhood obesity treatment
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34 intervention (Getting Our Active Lifestyles Started (GOALS)[5, 14-16]) that was unique in its whole
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36 family approach. To our knowledge GOALS was the first intervention to include a practical weekly
37
38 physical activity (PA) session for children and parents together and to encourage all family members
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40 (regardless of weight status) to make healthy changes to their PA and diet. This emphasis on whole
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42 family change is reflected in previously reported data from GOALS showing a strong positive
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44 association between child and parent BMI reduction[5].
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49 Children who are overweight often suffer low self-esteem[17], and one of the key reasons for
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51 parents seeking treatment is to improve their children’s psychological wellbeing[18]. However
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53 some authors have expressed concern that an increased focus on weight, diet and PA might
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55 heighten weight-related concerns and unhealthy approaches to weight-loss in children who are
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3 overweight[19]. Therefore it is important to measure the effects of obesity treatment on children's
4 self-esteem, not least to ensure against any adverse effects of treatment[20].
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8 Although evidence advocates a multidisciplinary family-based approach to childhood obesity
9 treatment[2], translation of this evidence to practice is hindered by lack of ecological relevance[21]
10 and conflicting pressures of service delivery[16]. During recent years evidence from UK childhood
11 obesity treatment interventions has increased rapidly (e.g.[22-24]), including qualitative insights into
12 reasons for engagement[25, 26], comparisons of parent, child and practitioner views[18, 27] and
13 discussions of evaluation methods[16, 28]. However the poor reporting of intervention
14 components in childhood obesity treatment studies makes it difficult for decision makers to a) assess
15 transferability of interventions for their local context and b) learn how interventions can feasibly be
16 implemented in practice[29]. The recently-developed Template for Intervention Description and
17 Replication (TIDieR) checklist[30] provides a 12-item framework advocating transparent reporting of
18 interventions, supporting comparison between studies and the translation of evidence to practice.
19 The checklist covers aims and rationale, content, providers, modes of delivery, intervention fidelity
20 and modifications made during the study period. Transparent reporting is particularly important
21 during the early stages of a complex intervention, as challenges of delivery and implementation may
22 affect the intervention's effectiveness[31].
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41 The aim of the current paper is to evaluate the impact of the GOALS family-based childhood obesity
42 treatment intervention during the first three years of implementation, applying the TIDieR[30]
43 checklist to set a standard for improved reporting of childhood obesity interventions. Specific
44 objectives are two-fold:
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- 49 a) to report changes (post-intervention and 12 months) in child BMI z-score, child self-
50 perceptions, parent BMI, and parent-reported family diet and PA and to explore the
51 relationship between child BMI z-score change and child self-perception change; and
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- 53 b) to apply the TIDieR checklist[30] to describe the GOALS intervention components.
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GOALS (GETTING OUR ACTIVE LIFESTYLES STARTED!) INTERVENTION

Between 2006 and 2013, Liverpool John Moores University was commissioned annually (through government grants, local authority and NHS public health funds) to deliver a childhood obesity treatment service (GOALS) for socio-economically deprived communities in Liverpool. The aim of GOALS was to support families to increase PA and make healthy dietary changes. GOALS was targeted at families with children aged 4-16 years who were obese (BMI \geq 98th %ile according to the UK 1990 BMI reference charts[32]), although children were occasionally included who were overweight (BMI \geq 91st %ile). Minimal family unit was one child plus one adult carer, although siblings and other adult family members were encouraged to attend.

Twenty-two GOALS interventions were delivered between September 2006 and March 2009. One intervention was excluded from the study because the children received an additional weekly PA session, leaving 21 eligible cohorts. Table 1 outlines key intervention details, drawing on the TIDieR checklist[30]. The intervention framework in table 1 remained constant throughout the study. However the implementation process presented several challenges, and some modifications were necessary to refine the way the intervention was delivered. These included changes to recruitment and assessment processes, delivery venues, staff roles, counselling support, provision of childcare for younger siblings, support with transport to venues and support for children who had finished the intervention. Full details of these delivery issues and resulting modifications are available [here](#) (INSERT HYPERLINK TO SUPPLEMENTARY ONLINE RESOURCE 1) (TIDieR item 10).

Table 1. GOALS intervention details. Numbers in parentheses refer to the item number on the TIDieR checklist[30].

Item	Description
Name (1)	GOALS (Getting Our Active Lifestyles Started!)
Why (2)	<p>The aim of GOALS was to promote a healthy weight trajectory in children who were overweight, with a focus on supporting the whole family to become more physically active and make healthy changes to their diet.</p> <p>Due to the lack of available evidence when GOALS was founded in 2003, a continuous improvement methodology was used to develop and evaluate the intervention (see[16] for a full outline of this process). The whole family, multidisciplinary approach is supported by international evidence (e.g. [2, 33]).</p> <p>Intervention topics were informed by Social Cognitive Theory (SCT,[34, 35]) and the theorised triadic reciprocal causation between environmental, behavioural and cognitive factors. Sessions aimed to enhance the self-efficacy of children and parents for physical activity and healthy eating (see[15]).</p> <p>Dietary objectives:</p> <p>To encourage families to:</p> <ul style="list-style-type: none"> - eat a healthy balanced diet - reduce portion sizes - consume fewer processed foods - cook more meals from fresh - increase fruit and vegetable intake - replace snacks high in fat and sugar with healthier alternatives - reduce the amount of salt and sugar added to food and drink - reduce the frequency of takeaways - increase water consumption - eat regular meals, focussing on breakfast in particular - read food labels and become more aware of what they are eating <p>Physical activity objectives:</p> <p>To encourage families to increase their physical activity through:</p> <ul style="list-style-type: none"> - active transport (e.g. walking to school) - lifestyle activity (e.g. taking stairs instead of lift) - active play (at home, out or with friends) - structured exercise (e.g. Zumba) - sport participation
What – procedure (4)	<p>Children were referred to GOALS through multiple routes, including self-referral in response to promotional activities (e.g. press articles, leaflets, whole school letters) and referral from health professionals in primary or secondary care. In addition from April 2007 children aged 9-10 years were recruited via letters to their parents following participation in a local health and fitness programme in schools (<i>SportsLinx</i>,[36]).</p> <p>Approximately one week before the intervention each family attended a “lifestyle assessment” with an intervention delivery staff member. The purpose of these sessions was to build rapport with families, complete paperwork such as consent and monitoring forms, and to gather information about the family’s physical activity and dietary habits through an informal interview.</p> <p>The intervention sessions focussed on diet (<i>Fun Foods</i>), physical activity (<i>Move It</i>) and behaviour change and wellbeing (<i>Target Time</i>).</p> <p>Fun Foods: Aimed to equip families with the knowledge and practical skills to incorporate a healthy balanced diet into their lifestyle, based on the NHS Choices <i>eatwell plate</i>[37]. A range of classroom-based and practical sessions addressed topics such as portion sizes, reading food labels and healthy snacking. Families were provided with practical opportunities to develop their cooking skills, and to try out new recipes and foods.</p> <p>Move It: Involved a practical physical activity session with the aim of improving self-efficacy to be physically active outside the weekly sessions. Sessions aimed to engage the whole family, with a focus on enjoyment and personal achievement rather than competition.</p> <p>Target Time: Supported families to make their lifestyle changes easier through the use of multiple behaviour change techniques (full description of techniques used available here (INSERT LINK TO SUPPLEMENTARY ONLINE RESOURCE 2) and through promoting and enhancing psychosocial wellbeing. Classroom-based sessions focussed on topics such as hunger and craving, raising self-esteem, dealing with bullying, and parental role-modelling. Each week families were supported to set small, realistic goals focussed on changing their physical activity and dietary behaviours outside of the structured GOALS sessions.</p> <p>Specific content evolved according to ongoing evaluation. An example timetable is available from the first author (p.m.watson@ljamu.ac.uk).</p>

Item	Description
What - materials (3)	Sessions were supported by a number of informative materials, such as parent and child handbooks, personal log books to track progress and a GOALS cookbook containing healthy recipes to cook at home. Delivery staff were supplied with weekly session plans. Copies of all informative materials are available from the first author (p.m.watson@ljmu.ac.uk). Growth charts and BMI charts were used to monitor child height and weight (available from http://www.childgrowthfoundation.org/).
Who provided (5)	<p>GOALS was designed, delivered and evaluated by a team from Liverpool John Moores University (LJMU), operationally led by the project manager/principal researcher (first author). The three sections (<i>Fun Foods, Move It, Target Time</i>) were developed by specifically-employed staff with postgraduate qualifications in public health nutrition, exercise physiology and sport and exercise/health psychology. As well as delivering some interventions themselves, these staff trained and supervised sessional staff to deliver the intervention.</p> <p>Sessional staff were recruited from a range of backgrounds, but the following skills and attributes were essential:</p> <ul style="list-style-type: none"> - minimal vocational qualification for their subject area - an interest in promoting healthy lifestyles - interpersonal skills and the ability to engage groups of different ages and abilities - experience of delivering activities to groups of children and/or families.
How (6)	Interventions were delivered to groups of families, arranged where possible by child age (e.g. 4-7 years, 8-11 years, 12-16 years). Groups ranged from 5-12 families at baseline. Some sessions included parents and children together, but topics involving sensitive discussion (e.g. dealing with bullying) or aimed specifically at parents (e.g. meal planning) were delivered to children and/or parents separately.
Where (7)	Sessions were delivered after-school in primary and secondary schools across Liverpool. Liverpool is a city in the North-West of England with approximately 458,000 residents[38] and high levels of socio-economic deprivation[39]. Despite indications that childhood obesity rates have begun to plateau[40], prevalence of childhood obesity in Liverpool remains higher than the national average with 26.9% of 4-5 year olds and 37.3% of 10-11 year olds overweight or obese[41].
When and how much (8)	<p>Sessions lasted for 2 hours and ran once a week after school (usually 5.30-7.30pm or 6-8pm) during term-time only. During year 1 (Sep 2006-Mar 2007), contact varied between 17,18 and 19 sessions. During years 2 and 3 (April 2007-Mar 2009), the intervention included 18 sessions.</p> <p>Due to the term-time only delivery, interventions varied in duration depending on whether they started during autumn/winter (approximately 5 months) or during spring/summer (approximately 6 months due to the long summer holiday break).</p> <p>Families were invited to individual follow-up sessions 9 months (from April 2007 only) and 12 months after they had started GOALS. These sessions lasted approximately 45 minutes and involved a progress review and height and weight measurements.</p>
Tailoring (9)	<p>Each family was assigned a personal mentor who they met with every few weeks to track their progress. The use of social cognitive theory allowed staff mentors to set weekly goals with families that focussed on either the home environment, parental behaviours/cognitions or child behaviours/cognitions, depending on the underlying cause of the target behaviour. For example, the goal for a family where the child was overeating in response to being bullied might focus on developing coping skills for the child (child cognitions), whereas the goal for a family where the child was overeating because their portions were too large might be for the parent to learn about appropriate child portion sizes (parent cognitions).</p> <p>Provision was made for childcare of younger siblings where required.</p> <p>Taxis were provided for families without transport in 8 of the 21 intervention cohorts.</p>
How well - planned and actual (11, 12)	During the first year, reflective staff meetings were held weekly to ensure the intervention was delivered as intended and to agree actions for the following week. Staff completed a written evaluation after each session to note what worked well, challenges they had faced and ideas for improvement. During the later stages, meetings continued on a six-weekly basis with regular session visits from the project manager. Regular training ensured the GOALS ethos and core framework was understood and practised by all staff.

EVALUATION METHODS

This mixed-method study combined a single-group repeated measures design with qualitative questionnaires to evaluate the impact of GOALS during the first three years of implementation (September 2006 to March 2009). A subsample of parents and children took part in focus groups during the intervention, however due to space limitations this data is not included here (currently in preparation for publication, further details available from the first author).

Participants

Inclusion and exclusion criteria

All families attending GOALS between September 2006 and March 2009 were invited to take part in the study. Children who attended GOALS but were not overweight, had obesity caused or exacerbated through medical conditions or syndromes, had severe learning disabilities, or did not provide baseline data were excluded from the study. Where there was more than one eligible overweight child in the family only the data from the child who was referred to GOALS was included. Families were included in the complete case analysis if the overweight child had complete baseline and 6-month BMI data. If a child was excluded from the analysis, their parent was also excluded.

Participant flow through study (figure 1)

One hundred and forty-three families were included in the study (143 children (63 boys), 168 parents). Mean child age was 10.4 ± 2.2 years (range 4.7-16.0 years) and mean BMI z-score was 3.0 ± 0.57 (range 1.53-4.73). Ethnicity data was only available for 79/143 children, 85% of whom were White-British. Of the 168 adult carers taking part, 71.4% were mothers, 20.4% fathers and 8.2% other relations (e.g. aunts, grandmothers). For the purposes of this article, the term "parents" will be used to encompass all adult carers.

Seventy-four families (74 children, 81 parents) completed the intervention (defined as still attending at the end of the intervention). Of the 74 children who completed, three were excluded (two had

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3 no post-BMI data, the third lost weight due to a medically-prescribed diet), leaving 71 children for
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5 analysis. One further child's data was removed, as his BMI z-score change from baseline to post-
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7 intervention (-0.71) was over three standard deviations greater than the sample mean. Therefore
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9 the complete case analysis included 70 children, 58 of whom had a parent who provided complete
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11 baseline and post-intervention BMI data. One parent was excluded due to following a very low
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13 calorie diet plan independent of GOALS, leaving 57 parents in the analysis (6 healthy weight, 24
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15 overweight, 27 obese). The characteristics of the 70 complete child cases were comparable to those
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17 of the whole cohort at baseline, with a mean age of 10.5 ± 2.1 years and a mean BMI z-score of
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19 3.02 ± 0.60 .

22 23 Measures

24 25 BMI (collected from children and parents at baseline, post-intervention and 12 months)

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27 Weight was recorded to the nearest 0.1kg using a Tanita WB/100MA floor scale. Height was
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29 recorded to the nearest 0.1cm using a portable Leicester Height Measure. BMI was calculated using
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31 the equation $\text{weight (kg)}/\text{height (m)}^2$. To account for change in children's ages from baseline, BMI
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33 was converted to z-scores based on the 1990 UK Growth Reference curves[32].

34 35 36 37 Child self-perceptions (collected from children over 8 years at baseline, post-intervention and 12 38 39 months)

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41 Child self-perceptions were measured using the *Self-Perception Profile for Children (SPPC)*[42]. The
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43 SPPC is a 36-item validated questionnaire consisting of six subscales measuring global self-esteem
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45 plus five specific domains of self-esteem in children. The SPPC is validated for use in children aged
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47 over 8 years and has acceptable internal consistency reliabilities for all six subscales (Cronbach's
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49 Alpha range .71 to .86). To reduce participant burden, four subscales that have been shown to
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51 change through healthy lifestyle intervention[20] were used in the current study (*Social acceptance*;
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53 *Athletic competence*; *Physical appearance*; *Global self-esteem*), yielding a questionnaire with 24
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55 items in total (6 in each subscale).
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Changes in PA and diet (collected from parents who attended after April 2007 at post-intervention and 12 months)

Parents completed a questionnaire containing four qualitative feedback items that explored changes in their own PA levels, their child's PA levels, their child's confidence and their family's diet. At 12 months, parents were also asked questions about their facilitators and barriers to change. Full questionnaire schedules are available [here](#) (LINK TO SUPPLEMENTARY ONLINE RESOURCE 3).

Analysis

Quantitative data was analysed using SPSS version 17 and is presented for complete cases only. Paired samples t-tests (normally distributed data) and Wilcoxon signed rank tests (non-parametric data) were used to assess within-subjects change from baseline to post-intervention, and from baseline to 12-month follow up. Responses to the feedback questionnaires were first coded as "improved", "unchanged" or "declined" (stage 1), then analysed deductively against the GOALS intervention objectives (see table 1) with subsequent inductive analysis to allow new themes to emerge (stage 2). To enhance the credibility of findings, stage 1 analysis was carried out independently by two members of the research team. Inter-rater agreement ranged from 0.80 to 0.91. Stage 2 analysis was carried out by the first author, followed by a process of peer scrutiny and discussion to reach a consensus on the final themes.

RESULTS

Child outcomes

Table 2 shows the BMI z-score and self-perception scores for children at baseline, post-intervention and 12 months. There was a significant decrease in BMI z-score from baseline to post-intervention (-0.07, $p < 0.001$) that was maintained at 12 months for the children who attended follow up (baseline to post -0.09, $p = 0.004$; baseline to 12 months -0.09, $p = 0.041$). Forty-five children provided complete baseline and post-intervention self-perception data (exclusions were due to incomplete

Table 2. Baseline, post-intervention and 12-month child outcomes following completion of GOALS. Means and standard deviations are reported for children with complete baseline and post-intervention data. Outcomes for the subsample who attended 12-month follow up are reported separately.

Measure		n	Baseline	Post-intervention	12 months	Baseline to post-intervention	p	Baseline to 12 months	p
BMI z-score	Complete	70	3.02 (0.60)	2.95 (0.62)	n/a	-0.07*** (0.16)	<0.001	n/a	n/a
	Complete with follow up	40	2.88 (0.60)	2.79 (0.60)	2.79 (0.66)	-0.09** (0.18)	0.004	-0.09* (0.26)	0.041
PSPP Social Acceptance	Complete	45	2.99 (0.74)	3.26 (0.57)	n/a	0.26* (0.78)	0.028	n/a	n/a
	Complete with follow up	22	2.97 (0.70)	3.23 (0.57)	2.99 (0.69)	0.26 (0.75)	0.112	0.02 (0.62)	0.905
PSPP Athletic Competence	Complete	45	2.35 (0.66)	2.46 (0.76)	n/a	0.11 (0.65)	0.244	n/a	n/a
	Complete with follow up	21	2.49 (0.55)	2.65 (0.59)	2.55 (0.66)	0.16 (0.70)	0.315	0.06 (0.63)	0.661
PSPP Physical Appearance	Complete	45	2.04 (0.81)	2.20 (0.77)	n/a	0.16 (0.74)	0.165	n/a	n/a
	Complete with follow up	21	2.05 (0.64)	2.33 (0.70)	2.35 (0.73)	0.28 (0.74)	0.102	0.31 (0.78)	0.087
PSPP Global Self-Esteem	Complete	45	2.72 (0.80)	2.85 (0.69)	n/a	0.13 (0.74)	0.253	n/a	n/a
	Complete with follow up	21	2.70 (0.72)	2.89 (0.71)	2.87 (0.69)	0.18 (0.76) [#]	0.218	0.17 (0.98) [#]	0.727

*p value of within-subject effect (paired samples *t*-test) <0.05

**p value of within-subject effect (paired samples *t*-test) <0.01

***p value of within-subject effect (paired samples *t*-test) <0.001

[#]Data not normally distributed, *Wilcoxon signed rank* test used.

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3 questionnaires (n=10), age under 8 years (n=6) and absence when the questionnaires were
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5 completed (n=9)). There were small improvements in all self-esteem domains from baseline to post-
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7 intervention, though the only change to reach significance was in the social acceptance domain (0.26,
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9 p=0.028).

12 Correlations between BMI z-score and self-perceptions

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15 There were no significant correlations between baseline BMI z-score and either baseline self-
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17 perceptions or baseline to post-intervention self-perceptions. However, the correlation between
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19 baseline BMI z-score and baseline to post-intervention perceived social acceptance did approach
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21 significance (r= .288, p=0.055), suggesting the most obese children experienced the greatest
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23 increase in perceived social acceptance. There were no correlations between BMI z-score change
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25 and change in self-perceptions at either post-intervention or 12-months. However there were
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27 negative correlations between *baseline to post-intervention BMI z-score* and *baseline to 12-month*
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29 *self-perceptions* that were significant in two domains (global self-esteem, r = -.433, p<0.05; physical
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31 appearance, r = -.423, p<0.05) and approached significance in the other two domains (social
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33 acceptance, r = -.380, p=0.061; athletic competence, r = -.390, p=0.060). This indicates the children
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35 who lost the most weight during the intervention had the most improved self-perceptions at 12
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37 months.
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41 Parent BMI

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43 Median BMI did not change between baseline (29.42, interquartile range (IQR) 27.10-35.19, n=57),
44
45 post-intervention (29.89, IQR 27.12-35.24, n=57) and 12 months (30.91, IQR 26.73-34.63, n=33).
46
47

48 Parent-reported changes in family PA and diet

49
50 Of 56 parents who completed GOALS after April 2007, 44 completed questionnaires post-
51
52 intervention and 19 completed questionnaires at 12 months. For items focussed on child or family
53
54 changes, data from same-family pairs (2 pairs post-intervention, 2 pairs at 12 months) was either
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1
2
3 combined (where there was agreement) or excluded (where there was disagreement). A summary
4
5 of the themes that emerged is provided for each section of the post-intervention and 12-month
6
7 questionnaires. Unless specifically stated, quotes in parenthesis provide illustrative examples from
8
9 within the data-set.
10

11 12 Post-intervention changes

13 14 Parent PA levels

15
16 Responses to this question were provided by 41 parents, 34 of whom felt their activity levels had
17
18 improved (six felt there was little or no change, one response was un-coded as it provided
19
20 insufficient information). Many parents cited improvements through structured exercise (*"now*
21
22 *regularly attend the gym"*) and walking (*"I am a lot more active, I always walk instead of getting a*
23
24 *taxi"*).
25
26

27 28 Child PA levels

29
30 After combining responses for the same-family pairs (both in agreement), there were 42 eligible
31
32 responses. Forty-one of these felt their child's PA levels had improved since coming to GOALS, one
33
34 parent felt there had been no change. Compared with the data related to their own PA levels,
35
36 parents described a broader range of PA changes in their children. Many responses referred to
37
38 general improvement in PA levels (*"a lot more activity"*), but there were also specific examples of
39
40 positive improvements related to sport participation (*"he now goes to cricket, football"*), active
41
42 transport (*"walk home from school most nights"*), structured exercise (*"more active, swimming has*
43
44 *improved, little more running"*), lifestyle activity (*"riding bike"*) and active play (*"plays more physical*
45
46 *games"*).
47
48

49
50 Many parents commented on their child's increased willingness to get involved in PA and to try
51
52 harder (*"my son tries much harder now without giving up too soon when tired of struggling"*). Other
53
54 parents suggested there had been some improvement but there were challenges along the way
55
56 (*"has increased [PA] to some degree, but have found it difficult to fit in around school/homework"*).
57
58
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Child confidence

Of 40 eligible responses, 36 reported positive changes in their child's confidence and attitude to PA since starting GOALS (*"he appears to be more positive and has more self-confidence"*). One parent felt there had been no change (*"my son has always been confident so there has been no change"*). The other three responses were not coded as they included both a positive and a negative element (*"my child is positive when he is at GOALS, but still not so in school and around people he doesn't really know"*).

Family diet

After removing one of the same-family pairs (coded differently) there were 40 eligible responses, 38 of whom felt their family's eating habits had improved through attending GOALS. One parent felt there had been little change as they had always eaten healthily, the other response was not coded as it was not clear whether the parent felt there had been an improvement (*"I have been conscious of eating healthily for some time, but found it difficult to control what he ate outside"*).

Parents reported changes related to all GOALS dietary objectives (see table 1) with the exception of reducing the amount of salt or sugar added to food. Many responses focussed on a healthy balanced diet in general (*"a lot more healthier choices at the same cost as before"*) and an increase in fruit and vegetable intake (*"eat far more fruit and veg"*). Examples of healthy choices were provided, such as switching to healthier varieties of foods (e.g. skimmed milk, wholemeal bread), introducing new foods (e.g. fish) or removing high fat foods (e.g. *"sausage rolls or pies are now a definite 'no no' "*). Several parents described their child's increased willingness to try new foods (*"kids more adventurous with trying new foods"*).

12-month changes

Positive changes were reported for all children's PA levels, though in one case this was a delayed change not attributed to GOALS (*"my child's activity levels have gone up since moving into high school"*). Similarly, improvements in child confidence were maintained for all families (*"[my son] is*

1
2
3 *more confident in himself and I feel the change he has made will be forever*). Maintenance levels
4
5 were slightly lower for parent PA (13/19) and family dietary changes (11/17); although there were a
6
7 further three parents who reported keeping up some, but not all, of their dietary changes (*"We have*
8
9 *changed a lot of eating habits, but sometimes will fall back and have to start again"*). The parents
10
11 who had maintained changes provided examples of healthy behaviours that had become a way of
12
13 life for them (*"we now think before we eat "rubbish" and our diet has improved vastly without too*
14
15 *many big changes and it's become a way of life"*), described the acquisition of coping skills to
16
17 prevent relapse (*"I can feel when I'm getting lazy and I up my walking"*) and the formation of healthy
18
19 routines (*"we always do an activity as a family once a week"*).
20
21

22
23 In response to the question about facilitators, parents commented on the importance of education
24
25 (*"GOALS helped me in choosing healthy options and checking labels on food"*), small attainable
26
27 changes (*"the idea that small changes that can be maintained more easily can make a difference to*
28
29 *your weight and shape"*), making exercise fun (*"showing you how to enjoy yourself with your family*
30
31 *during exercise"*) and coping skills for maintaining change (*"the GOALS methods kick in when I start*
32
33 *to feel unhealthy"*). Parents also mentioned the enthusiasm and encouragement from staff, and
34
35 specific sessions that had helped them such as the portion sizes and practical cooking sessions.
36
37

38
39 As most of the families had maintained some changes, very little information was provided on
40
41 barriers. Those who had relapsed said they had done so because of poor health, lack of
42
43 time/planning and other commitments. One parent who had struggled to keep up his PA levels
44
45 noted the GOALS group session finishing had been a big challenge.
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47

48 49 **DISCUSSION**

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51
52 The aim of this paper was to evaluate the impact of the GOALS family-based childhood obesity
53
54 treatment intervention during the first three years of implementation, applying the TIDieR[30]
55
56 checklist to set a standard for improved reporting of childhood obesity interventions. It was found
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1
2
3 that children completing GOALS demonstrated modest improvements in child BMI z-score that were
4
5 maintained at 12-month follow up. There was also a small improvement in perceived social
6
7 acceptance that was most marked in the children with the highest baseline BMI z-score, and a
8
9 moderate correlation between BMI z-score reduction during the intervention and improved self-
10
11 perceptions at 12 months. Whilst there was no change in parental BMI, parents reported positive
12
13 changes to their own and their child's PA and diet.
14

15
16 It is recommended that BMI z-score is used as a primary outcome measure for childhood obesity
17
18 treatment interventions, due to its feasibility and ease of comparison between studies[43]. The
19
20 mean BMI z-score change (-0.07) for children completing GOALS was consistent with other feasibility
21
22 studies[44] and service evaluations[6], yet smaller than that reported in published randomised
23
24 controlled trials (RCTs) of UK community-based childhood obesity treatment interventions [3, 7].
25
26 Whilst discussion surrounds what constitutes a clinically important BMI z-score reduction[45],
27
28 evidence shows that even small reductions in BMI z-score are associated with positive
29
30 improvements to cardiovascular risk factors in obese children[46, 47]. Such observations support
31
32 the international consensus statement that suggests any improvement in BMI z-score should be
33
34 viewed as a positive outcome[48].
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38

39 While reviews have found overall positive effects of childhood obesity treatment on self-esteem [2,
40
41 20], authors have expressed concern that the increased focus on weight-related behaviours could
42
43 have adverse effects on children's self-perceptions[19]. The quantitative data in this study showed
44
45 little change in children's self-perceptions, although parents did report qualitative increases in
46
47 children's confidence. Whilst children's perceived social acceptance scores were comparable with a
48
49 UK-sample of mixed-weight children[49], their scores on the perceived athletic competence and
50
51 physical appearance scales remained low. It is important obesity treatment interventions help
52
53 parents understand how they can promote a healthy body image in children, for example through
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3 focussing on healthy behaviours rather than weight and encouraging children to adopt an identity
4
5 that goes beyond physical appearance[50].
6
7

8 To date, research exploring the relationship between child weight-related change and self-esteem
9
10 change has been equivocal, and where an association has been found the directionality of this
11
12 relationship has been questioned[20]. In the present study BMI z-score change during the
13
14 intervention was not linked to self-perception changes over the same period (as also found by
15
16 Murdoch et al.[6]), but was inversely associated with self-perception change from baseline to 12-
17
18 *month follow up*. The fact this relationship was found in only one direction (i.e. there was no
19
20 correlation between self-perception change during the intervention and baseline to 12-month BMI z-
21
22 score change) suggested that weight-loss in the short-term may lead to improvements in children's
23
24 self-perceptions over the longer-term.
25
26
27

28 A key challenge for childhood obesity treatment is the transition from the safe and supportive group
29
30 environment to long-term behaviour change at home[27]. Although most parents reported positive
31
32 changes to PA and diet that were maintained after finishing GOALS, many parents spoke of the
33
34 tendency to fall back into old habits from time to time. Such cycles of change are well-established
35
36 in the health behaviour literature[51], and data from the current study suggests the skills learned at
37
38 GOALS were used as an effective coping mechanism to prevent full relapse. As theorised by the
39
40 social cognitive framework on which GOALS is based[34, 35], family support may also be important
41
42 in maintaining healthy behaviours. Previous research from childhood obesity treatment shows the
43
44 most successful families are those who work together to achieve healthy lifestyle changes[5, 18].
45
46 GOALS placed a strong emphasis on family involvement, with parents and siblings encouraged to join
47
48 in all aspects of the intervention including participation in the PA sessions. Whilst this whole family
49
50 focus did not result in a change in parental BMI (which could have been due to the lack of specific
51
52 emphasis on parental weight loss), the qualitative data did suggest parents made changes to their
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3 own PA levels and to the whole family's dietary habits. Further research is required to understand
4
5 how interventions can best promote long-term behavioural change in families.
6
7

8 In an attempt to improve the current state of reporting in childhood obesity studies, this paper
9
10 followed the TREND[52] guidelines (for reporting nonrandomized evaluations of behavioural and
11
12 public health interventions) and was the first childhood obesity treatment intervention to be
13
14 mapped onto the TIDieR checklist[30]. This comprehensive account sets a standard for reporting
15
16 future childhood obesity treatment intervention evaluations, aiding comparison between studies
17
18 and providing important information for policy-makers and practitioners wishing to implement
19
20 interventions in practice. During the study period several modifications were necessary to overcome
21
22 delivery challenges. Such "teething problems" are a natural process of complex intervention
23
24 implementation[31], and flexibility is important to tailor interventions to local needs[53]. Yet
25
26 delivery challenges are rarely acknowledged in the research literature, nor consideration given to
27
28 the potential impact of modifications on intervention outcomes. In the current study, the
29
30 proportion of children who reduced BMI z-score during GOALS increased each year (43%, 63% and
31
32 80% respectively) and service audit data suggests these figures continued to rise after the study
33
34 period. Whilst there is insufficient data to link these improvements to intervention refinements, it
35
36 is plausible that results from the first year did not reflect the true potential of the intervention.
37
38 GOALS staff turnover during the study period was low (by the final year 12/14 staff had been
39
40 delivering GOALS for at least two years), therefore knowledge and experience increased
41
42 substantially during the three years and it is likely the intervention improved as a result.
43
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48 Whilst this study provides an important insight into childhood obesity treatment in practice, some
49
50 limitations must be acknowledged. Due to a service requirement for universal provision (see[16]) it
51
52 was not possible to include a control group. Furthermore, there was a high attrition rate from the
53
54 intervention and it is not known whether those who dropped out achieved any benefits. It was not
55
56 always possible to attain reasons for drop out, but reasons cited included difficulty with transport,
57
58
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1
2
3 clashes with other commitments (e.g. sports clubs), and adverse life events (e.g. relationship
4
5 breakdown, family illness). The observed attrition rate (48%) is comparable to that observed in
6
7 other childhood obesity treatment interventions[54] and as the children who completed did not
8
9 differ from the baseline population, a complete case analysis was conducted to explore the impact
10
11 of the intervention for children who completed GOALS. However it is acknowledged these children
12
13 represented less than 50% of the baseline cohort therefore the current results must be interpreted
14
15 with caution. Finally, the sample was predominantly White-British. Results cannot therefore be
16
17 generalised to other ethnic populations living in the UK, for whom engagement with childhood
18
19 obesity treatment interventions may be differentially influenced by cultural perceptions of
20
21 obesity[55].
22
23
24

25 **Conclusions**

26
27 A key strength of service evaluation is its high ecological validity and capacity to investigate
28
29 intervention impact as it is delivered in practice. This study suggests GOALS was a promising
30
31 childhood obesity treatment intervention that supported families to change their PA and dietary
32
33 behaviours, resulting in small improvements to children's BMI z-scores. Delivery challenges are
34
35 inevitable when implementing a complex intervention, and it is possible the current results were
36
37 diluted by early implementation difficulties. Therefore commissioners are encouraged to dedicate
38
39 long-term funding to allow childhood obesity treatment interventions time to embed before
40
41 evaluating their worth[33]. To support the translation of evidence to practice, researchers are
42
43 urged to draw on relevant reporting guidelines (e.g.[30, 52, 56]) to ensure transparency of
44
45 intervention components, necessary modifications and evaluation methods. Doing so will enable
46
47 comparison between studies and provide vital information for policy-makers and practitioners
48
49 wishing to implement a childhood obesity treatment intervention in their locality.
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FIGURE LEGENDS

Figure 1: Participant flow through study

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CONTRIBUTORS

PW conducted the study as part of her doctoral degree and drafted the article. TC and LD conceived the study, secured funding and contributed to the analysis and interpretation of data. TC managed the overall project and supervised PW's doctoral programme, along with RM and ZK who both contributed to the analysis and interpretation of data. KP, SO, JH and LS designed the intervention and worked alongside PW to develop it according to ongoing feedback. All authors critically reviewed and contributed to the writing of the paper.

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COMPETING INTERESTS

PW, KP, SO, JH and LS were employed by Liverpool John Moores University to design, deliver and evaluate the GOALS intervention.

ETHICS APPROVAL

Ethical approval was received from the Liverpool NHS Paediatric Research Ethics Committee [05/Q1502/28]. Written informed consent was obtained from parents, and written assent from children over 8 years and deemed capable of understanding.

DATA SHARING STATEMENT

No additional data available.

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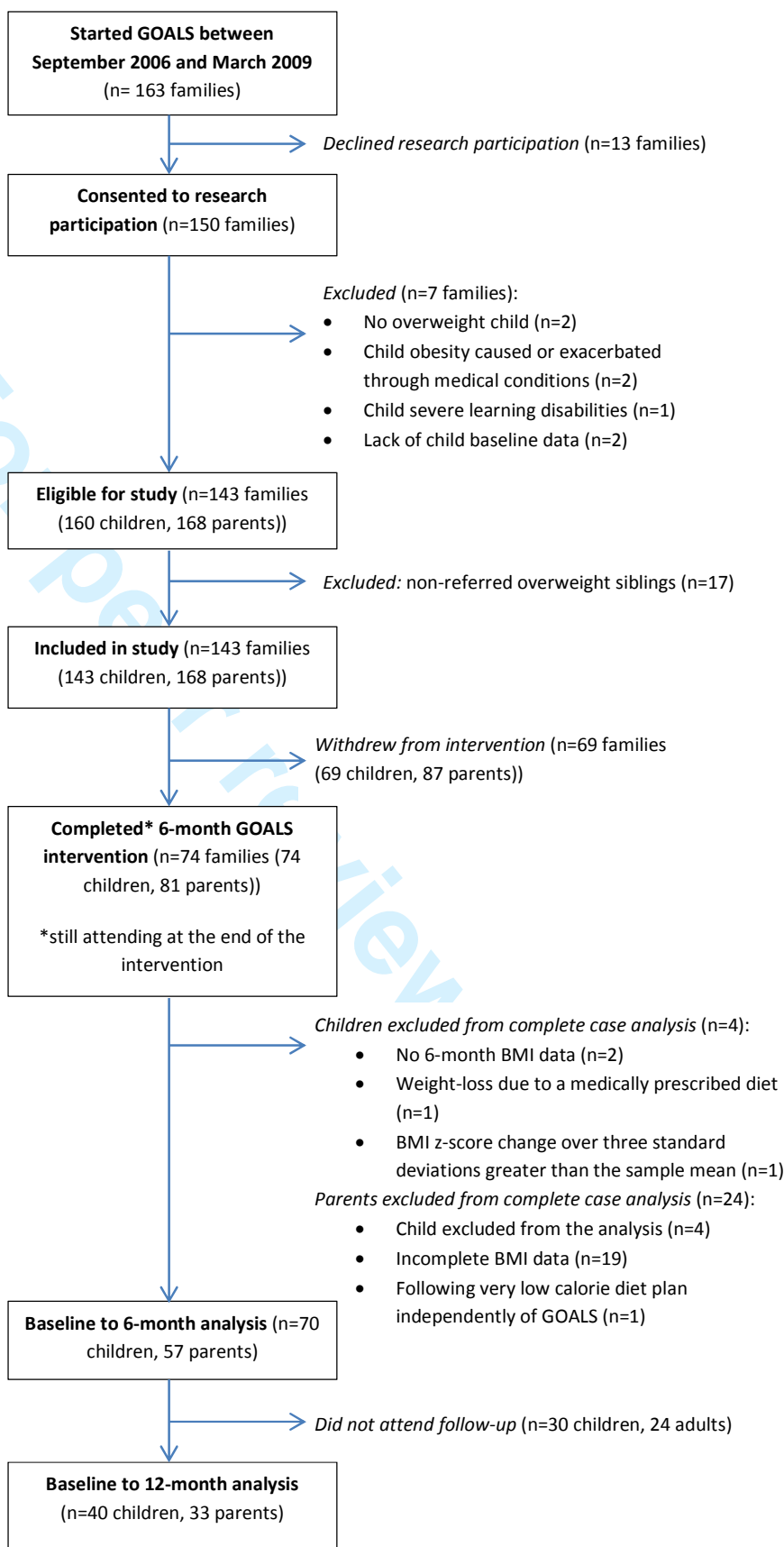


Figure 1: Participant flow through study

Supplementary Online Resource 1

Modifications to the GOALS delivery mechanisms during the study period and lessons learned. Numbers in parentheses in the first column refer to the item number on the TIDieR checklist[1].

TIDieR item	Modification	Rationale and lessons learned
What – procedure (4)	During year 1 every child was assessed for underlying causes of obesity and comorbidities by a community paediatrician. In year 2, this was replaced with an assessment with a school nurse and later a self-completion form by the parent with recommendations to visit the family GP before starting the intervention.	The available guidelines for treating childhood obesity recommended all children with a BMI \geq 99.6 th %ile be referred to hospital or community paediatric consultants before treatment was considered[2] and a medical assessment be undertaken of presenting symptoms and underlying causes of overweight and obesity, comorbidities and risk factors, and growth and pubertal status[3]. As the majority of children registering for GOALS had a BMI \geq 99.6 th %ile, assessment by community paediatricians proved a time-consuming and costly arrangement, and research suggested these assessments may not be necessary for all obese children[4]. The protocol was therefore replaced by an assessment with a school health practitioner and later a self-completion form by the parent, in which they were signposted to the GP.
Where (7)	Year 1 interventions delivered in both primary (n=4) and secondary schools (n=3). Year 2 & 3 interventions delivered in secondary schools only.	Due to the multidisciplinary nature of the intervention, each site required space for physical activity, facilities for cooking and classrooms for general activities. It was difficult to gain access to cooking facilities in primary schools, and they were rarely open during evening hours and thus incurred costs for site management. By contrast, secondary schools provided ideal space for group cooking sessions in food technology rooms and were often open during the evening for adult education classes (thus allowing free access).
Who provided (5)	During year 1, Fun Foods was led by community dietitians (theory-based sessions) and community food workers (practical sessions) employed by the NHS in Liverpool. From year 2, the employment of all Fun Foods staff was transferred to Liverpool John Moores University. A public health nutritionist delivered the theory-based sessions and food workers continued to deliver practical elements. In September 2008 (mid-year 3) all food workers were trained to be “nutrition mentors”, responsible for the delivery of both theory-based and practical sessions with ongoing training and supervision from the public health nutritionist.	Little guidance was available outlining the skills required for delivery of healthy eating sessions in the community. Since the intervention focussed on general healthy eating advice rather than individually-prescribed diets, it was established that a public health nutritionist possessed the relevant skills for supervision and quality assurance of the Fun Foods element of the intervention.

TIDieR item	Modification	Rationale and lessons learned
Who provided (5)	A qualified counsellor began working with GOALS in February 2007 (end of year 1) to provide additional support for children and families where appropriate.	The group session provided little opportunity for children or families to discuss personal issues that may have been affecting their lifestyle change (e.g. if children were being bullied). The GOALS lifestyles counsellor provided an impartial source of support for children or families who needed to talk something through that went beyond the remit of the GOALS staff. Several different ways of working were explored, ranging from informal drop-ins during the weekly session, group sessions about feelings, and fixed appointment times for families either during or outside of the weekly session. Whilst the support was deemed beneficial for families, it proved difficult to sustain financially and the counsellor's involvement ceased a short time after the study period.
Tailoring (9)	During years 1 & 2, a mobile crèche was provided on site for younger siblings (if required). During year 3, younger siblings were included in the main programme.	To allow whole families to attend, it was important provision was made for the childcare of younger siblings. Therefore a free crèche was provided for families at the intervention site. However the mobile crèche proved costly given the small number of children who used it, and children often expressed a wish to join in the main group's activities. The option of arranging local child-minders was explored but the families concerned were reluctant to leave their children with an unknown adult. Therefore the most appropriate solution was to accommodate young children within the main session, with an allocated staff member to take them aside for age-appropriate activities where necessary.
Tailoring (9)	The number of interventions in which taxis were provided for families increased with each year (1/7 in year 1; 3/7 in year 2; 4/7 in year 3).	As it was not possible to provide intervention sites in every district of the city, consideration was given to the provision of transport for families who lived further afield. Several options were explored, including reimbursement of public transport expenses for families without a car and arrangement of taxis to and from sessions. It was however a challenge to develop objective criteria for offering these services and there was some concern the arrangement of taxis hindered the lifestyle change process for families. Financial support for transport was ceased after the study period, and staff instead supported families to identify appropriate public transport solutions.
When and how much (8)	A family-based weekly physical activity session for "GOALS graduates" was piloted between May 2007 (start of year 2) and July 2008 (mid-year 3).	Families expressed a wish for continued support beyond the 18-week intervention. However sessions later ceased due to poor attendance and pressure to allocate financial resources to the main intervention.

Key: Year 1 = September 2006-March 2007; Year 2 = April 2007-March 2008; Year 3 = April 2008-March 2009

References

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Supplementary Online Resource 2

Most frequently used behaviour change techniques (BCTs) at GOALS and examples of their application. Figures refer to the corresponding number on Michie et al.'s (2011) CALO-RE taxonomy[1].

BCT	Examples of application
Provide information about consequences of behaviour in general (1)	Written information about benefits of physical activity/healthy eating and dangers of being overweight in handbooks; Giving verbal information about physical activity/diet and health during group and one to one sessions.
Provide information on consequences of behaviour to the individual (2)	Going through the BMI and growth charts, showing parents the extent of their child's obesity and explaining the risks their child faces unless something changes; Decisional balance during Target Time session; Talking about positive outcomes of change during mentor/goal setting sessions (e.g. "eating breakfast will give you more energy in the morning").
Provide normative information about others' behaviour (4)	Giving messages during group and one to one sessions to help families understand they are not alone (e.g. "most children in the UK do not get enough physical activity") and support the health messages given (e.g. "we have seen most success with families who really put in the effort at home").
Goal setting (5, 6)	Setting long and medium-term goals with families. These may focus both on outcomes and behaviours.
Action planning (7)	Setting specific weekly goals with each family (i.e. what will be done, where and when).
Barrier identification/problem solving (8)	Target Time session on addressing barriers to healthy lifestyles; Problem solving when setting goals with families, e.g. If someone is struggling asking "what is stopping you doing this and how can it be overcome?"
Set graded tasks (9)	Breaking medium and long-term goals down into small manageable steps (e.g. if target is to reduce from 2 bags of crisps a day to 1 bag a week, the first step might be to reduce to 1 bag a day).
Prompt review of goals (10, 11)	Following up families to review their goals on a weekly basis; Six-weekly mentor sessions to review weight outcomes and overall progress.
Provide rewards contingent on successful behaviour (13)	Allocating points when a weekly goal is achieved (points add up to earn tangible rewards).

BCT	Examples of application
Prompting generalisation of a target behaviour (15)	Mastering new cooking skills at GOALS, then setting a goal to try cooking the same meal at home; Signposting families to local physical activity sessions.
Prompt self-monitoring of behaviour (16)	Food diaries as part of initial assessment; Asking families to write down their progress towards their weekly goals.
Prompting focus on past success (18)	Increasing confidence by asking families to think of a time they have successfully carried out a behaviour or made a change. Used particularly during Target Time sessions towards start of programme.
Provide feedback on performance (19)	Feedback from food diaries; Providing specific verbal feedback when reviewing weekly goals; Providing feedback during Move It or Fun Foods sessions to correct technique, or confirm that an action is being performed correctly.
Provide instruction on how to perform the behaviour (21)	Teaching people how to read food labels or plan meals; Providing written advice and tips in handbooks; Teaching skills related to physical activity.
Model/demonstrate the behaviour (22)	Demonstrating technique and showing how to play games during Move It; Staff as role-models.e.g. Showing a willingness to try new foods, joining in Move It.
Environmental restructuring (24)	Discuss ways of restructuring the home environment to support change – e.g. put gym clothes out ready for the morning, have bowl of fruit on the table, remove tempting foods from house etc.
Agree behavioural contract (25)	Asking families to sign a “promise sheet” during their final mentor session, outlining specific behaviours they will continue.
Prompt practice (26)	Weekly goal setting is aimed at habit formation. Each goal is continued to prompt practice until it comes more easily.
Use of follow up prompts (27)	Post-intervention family follow ups; Newsletters and invites to events or to take part in GOALS activities; Ad hoc phone calls to families.
Facilitate social comparison (28)	Weekly group sessions provide opportunity to mix with others “in the same boat”; Move It sessions – comparison of own sporting/PA ability with that of others. Also provides opportunity for parents to compare their own children to other overweight children (visually and behaviourally).
Plan social support/social	Whole family approach; Weekly goals aimed at involving non-attending family members (particularly if their actions are acting

BCT	Examples of application
change (29)	as a barrier to progress); Encouraging group to attend local activities together and help each other out (e.g. Provision of lifts).
Prompt identification as a role model (30)	Parents encouraged to look at their own physical activity, diet and weight-related behaviours; Target Time session on positive role-modelling and supporting information in handbook; Parent discussion groups to allow sharing of ideas (i.e. “what worked for them”).
Prompt anticipated regret (31)	Managing expectations during group and one to one sessions – e.g. 18 weeks sounds a long time now but it will pass quickly so it is important to make the most of this opportunity, it is only going to become more difficult to address the obesity as children get older etc.
Fear arousal (32)	Visual demonstration of amount of fat and sugar in popular foods; Use of replica fat and models of clogging arteries to explain risks of obesity and physical inactivity.
Prompt self-talk (33)	Encouraging families to replace negative thoughts with more helpful thoughts (e.g. “I may not feel like exercising now, but I know it’ll make me feel better”). Used particularly during Target Time session about addressing barriers.
Relapse prevention/coping planning (35)	Discussions during mentor chats to identify potential challenges in maintaining changed behaviours, identifying coping strategies throughout programme.
Motivational interviewing (37)*	<i>Trained staff used core skills of motivational interviewing throughout (e.g. empathy, rolling with resistance), particularly during one to one sessions.</i>
Time management (38)	Discussing how families can free up time for physical activity; Group session with parents on planning meals in advance.

*Target Time staff were trained in motivational interviewing, but no formal training was provided for other staff.

Reference

1. Michie S, Ashford S, Sniehotta FF, Dombrowski SU, Bishop A, French DP. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy. *Psychol Health* 2011;26(11):1479-98.

Supplementary Online Resource 3

Parent feedback questions asked post-intervention and at 12-month follow up (via written questionnaire)

Theme	Post-intervention	12-month follow up
Parent physical activity	How do your activity levels <u>now</u> compare to your activity levels <u>before you came to GOALS</u> ? Please describe anything that is different.	How do your activity levels <u>now</u> compare to your activity levels <u>before you came to GOALS</u> ? Please describe anything that is different. How do your activity levels <u>now</u> compare to your activity levels <u>immediately after GOALS finished</u> ? If there are differences, what are the reasons for these?
Child physical activity	How do you feel <u>your child's</u> activity levels compare to their activity levels before GOALS?	How do you feel <u>your child's</u> activity levels compare to their activity levels before, and immediately after, GOALS?
Child confidence	Have you noticed any changes in your child's confidence and attitude to physical activity since coming to GOALS (either positive or negative)?	Have you noticed any changes in your child's confidence and attitude to physical activity since finishing GOALS (either positive or negative)?
Family diet	How do your family's eating habits <u>now</u> compare to your eating habits <u>before you came to GOALS</u> ? Please describe anything that is different.	How do your family's eating habits <u>now</u> compare to your eating habits <u>before you came to GOALS</u> ? Please describe anything that is different. How do your family's eating habits <u>now</u> compare to your eating habits <u>immediately after GOALS finished</u> ? If there are differences, what are the reasons for these?
Facilitators/barriers		If you have continued with your healthy lifestyle, what was it about GOALS that prepared you to do this? If you have not managed to keep up as healthy a lifestyle as you'd have liked, what do you feel has prevented you? If there are differences, how could

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TREND Statement Checklist

Paper Section/Topic	Item No.	Descriptor	Reported?	
			✓	Pg #
TITLE and ABSTRACT				
Title and Abstract	1	• Information on how units were allocated to interventions	n/a	
		• Structured abstract recommended	✓	p. 3
		• Information on target population or study sample	✓	p. 3
INTRODUCTION				
Background	2	• Scientific background and explanation of rationale	✓	p. 5-6
		• Theories used in designing behavioral interventions		Not in intro due to space limitations, but is in table on p.8 (table 1)
METHODS				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	✓	For intervention: p.7 For research: p.10
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	✓	p.10
		• Recruitment setting	✓	p. 8 (table 1)
		• Settings and locations where the data were collected		Not specified due to space limitations. Data was collected at intervention sites.
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	✓	p.8-9 (table 1) See TIDieR checklist also.
		○ Content: what was given?	✓	
		○ Delivery method: how was the content given?	✓	
		○ Unit of delivery: how were subjects grouped during delivery?	✓	
		○ Deliverer: who delivered the intervention?	✓	
		○ Setting: where was the intervention delivered?	✓	
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	✓	
		○ Time span: how long was it intended to take to deliver the intervention to each unit?	✓	
○ Activities to increase compliance or adherence (e.g., incentives)	✓			
Objectives	5	• Specific objectives and hypotheses	✓	p.6
Outcomes	6	• Clearly defined primary and secondary outcome measures	✓	p.6 & p.11
		• Methods used to collect data and any methods used to enhance the quality of measurements	✓	p.11
		• Information on validated instruments such as psychometric and biometric properties	✓	p.11
Sample size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	n/a	
Assignment method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	n/a	
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	n/a	
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	n/a	
Blinding (masking)	9	• Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed	n/a	
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	✓	p.10
		• If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)	n/a	

TREND Statement Checklist

Statistical methods	11	<ul style="list-style-type: none"> Statistical methods used to compare study groups for primary methods outcome(s), including complex methods for correlated data 	✓	p.12
		<ul style="list-style-type: none"> Statistical methods used for additional analyses, such as subgroup analyses and adjusted analysis 	n/a	
		<ul style="list-style-type: none"> Methods for imputing missing data, if used 	n/a	
		<ul style="list-style-type: none"> Statistical software or programs used 	✓	
RESULTS				
Participant flow	12	<ul style="list-style-type: none"> Flow of participants through each stage of the study: enrollment, assignment, allocation and intervention exposure, follow-up, analysis (a diagram is strongly recommended) <ul style="list-style-type: none"> Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study Assignment: the numbers of participants assigned to a study condition Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition Analysis: the number of participants included in or excluded from the main analysis, by study condition Description of protocol deviations from study as planned, along with reasons 	✓	p.10 & figure 1
Recruitment	13	<ul style="list-style-type: none"> Dates defining the periods of recruitment and follow-up 	✓	Figure 1
Baseline data	14	<ul style="list-style-type: none"> Baseline demographic and clinical characteristics of participants in each study condition Baseline characteristics for each study condition relevant to specific disease prevention research Baseline comparisons of those lost to follow-up and those retained, overall and by study condition Comparison between study population at baseline and target population of interest 	✓	p.10
			n/a	
			✓	p.10-11
			n/a	
Baseline equivalence	15	<ul style="list-style-type: none"> Data on study group equivalence at baseline and statistical methods used to control for baseline differences 	n/a	
Numbers analyzed	16	<ul style="list-style-type: none"> Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses 	✓	p.13 (table 2)
			✓	p.10
Outcomes and estimation	17	<ul style="list-style-type: none"> For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision Inclusion of null and negative findings Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any 	✓	p.13 (table 2) – p values rather than confidence intervals
			✓	p.13 (table 2)
			✓	p.14-17
Ancillary analyses	18	<ul style="list-style-type: none"> Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory 	n/a	
Adverse events	19	<ul style="list-style-type: none"> Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals) 	n/a	
DISCUSSION				
Interpretation	20	<ul style="list-style-type: none"> Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations Discussion of the success of and barriers to implementing the intervention, fidelity of implementation Discussion of research, programmatic, or policy implications 	✓	p.17-21
			✓	p.19-20
			✓	p.20
			✓	p.21
Generalizability	21	<ul style="list-style-type: none"> Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other 	✓	p.20-21 (limitations acknowledged)

TREND Statement Checklist

		contextual issues		
Overall evidence	22	• General interpretation of the results in the context of current evidence and current theory	✓	p.17-21

From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: <http://www.cdc.gov/trendstatement/>

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The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	p.8 (table 1)	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	p.8 (table 1)	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	p.9 (table 1)	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	p.8 (table 1)	Supplementary online resource 2
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	p.9 (table 1)	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	p.9 (table 1)	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	p.9 (table 1)	_____
	WHEN and HOW MUCH		

TIDieR checklist

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8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	p.9 (table 1)	
TAILORING			
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	p.9 (table 1)	
MODIFICATIONS			
10.*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	/	Supplementary online resource 1
HOW WELL			
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	p.9 (table 1)	
12.*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	p.9 (table 1)	

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**. When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

TIDieR checklist

BMJ Open

Service evaluation of the GOALS family-based childhood obesity treatment intervention during the first three years of implementation

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-006519.R1
Article Type:	Research
Date Submitted by the Author:	24-Nov-2014
Complete List of Authors:	Watson, Paula; Liverpool John Moores University, Physical Activity Exchange, Research Institute for Sport and Exercise Sciences Dugdill, Lindsey; University of Salford, School of Health Sciences Pickering, Katie; Leeds Beckett University, Carnegie Faculty Owen, Stephanie; Betsi Cadwaladr University Health Board, Hargeaves, Jackie; Leeds Beckett University, Carnegie Faculty Staniford, Leanne; Leeds Beckett University, Carnegie Faculty Murphy, Rebecca; Liverpool John Moores University, Physical Activity Exchange, Research Institute for Sport and Exercise Sciences Knowles, Zoe; Liverpool John Moores University, Physical Activity Exchange, Research Institute for Sport and Exercise Sciences Cable, Tim; Liverpool John Moores University, Research Institute for Sport and Exercise Sciences
Primary Subject Heading:	Paediatrics
Secondary Subject Heading:	Public health, Evidence based practice
Keywords:	childhood obesity, behaviour change, evaluation, diet, physical activity, family

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Manuscripts

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ABSTRACT

Objectives: To evaluate the impact of the GOALS family-based childhood obesity treatment intervention during the first three years of implementation.

Design: Single-group repeated measures with qualitative questionnaires.

Setting: Community venues in a socio-economically deprived, urban location in the North-West of England.

Participants: 70 overweight or obese children (mean age 10.5 years, 46% boys) and their parents/carers who completed GOALS between September 2006 and March 2009.

Interventions: GOALS was a childhood obesity treatment intervention that drew on social cognitive theory to promote whole family lifestyle change. Sessions covered physical activity (PA), diet and behaviour change over 18 two-hour weekly group sessions (lasting approximately 6 months). A TIDieR checklist of intervention components is provided.

Primary and secondary outcome measures: The primary outcome measure was child BMI z-score, collected at baseline, post-intervention and 12 months. Secondary outcome measures were child self-perceptions, parent BMI and qualitative changes in family diet and PA (parent questionnaire).

Results: Child BMI z-score reduced by 0.07 from baseline to post-intervention ($p < 0.001$) and was maintained at 12 months ($p < 0.05$). There was no change in parent BMI or child self-perceptions, other than an increase in perceived social acceptance from baseline to post-intervention ($p < 0.05$). Parents/carers reported positive changes to family PA and dietary behaviours after completing GOALS.

Conclusions: GOALS completion was associated with small improvements in child BMI z-score and improved family PA and dietary behaviours. Use of the TIDieR checklist promoted transparent reporting of intervention components and showed modifications to delivery mechanisms were

necessary as GOALS was implemented. Childhood obesity researchers are urged to adopt TIDieR reporting standards to provide the information needed by policy-makers and practitioners to implement interventions in practice.

ARTICLE SUMMARY

Article focus

- Evidence supports a family-based multidisciplinary approach to childhood obesity treatment, but a lack of ecological relevance and poor intervention reporting limits the translation of evidence to practice.
- This study reports post-intervention (6-month) and 12-month outcomes from the GOALS intervention during the first three years of implementation, employing the TIDieR checklist to provide a transparent intervention description.

Key messages

- Children and families who completed GOALS made positive changes to their PA and diet, which resulted in improvements to children's BMI z-score.
- Delivery challenges are inevitable during complex intervention implementation, therefore it is important childhood obesity treatment interventions are given time to embed before evaluating their worth.
- Accurate description of intervention components is essential for interventions to be implemented in practice. Researchers are urged to use frameworks such as the TIDieR checklist to improve the standard of reporting in childhood obesity treatment research.

Strengths and limitations of this study

- This study reports ecologically valid data from a childhood obesity treatment intervention as it was delivered in practice. It is the first paper to use the TIDieR checklist to describe a

childhood obesity treatment intervention, providing valuable information to assist policy-makers and practitioners wishing to implement interventions in practice.

- This service evaluation was limited by a lack of control group and a high attrition rate. It is not, therefore, known what change might have occurred without intervention or what impact the intervention had for those who did not complete.

INTRODUCTION

Currently 28% of children aged 2-15 years in England are overweight or obese[1]. Children who are obese face psychological[2] and physical[3] health complications in the short-term and are more likely to become obese adults[4]. Since adult obesity is a key risk factor for lifestyle-related morbidity and mortality[5], it is important to develop effective interventions for treating obesity in childhood. Growing evidence supports a family-based approach to childhood obesity treatment that focusses on physical activity, diet and behaviour change (e.g. [6-11]). Bandura's social cognitive theory[12] provides a framework within which to understand the importance of family involvement in children's physical activity and eating behaviours. The theory posits that behaviour interacts in an ongoing reciprocal manner with personal cognitions and the surrounding environment (triadic reciprocal causation). In children, the cognitions and behaviours of parents/carers also form part of this reciprocal interaction[13], as parents/carers play a key role in both child physical activity[14] and child eating behaviours[15]. Therefore for children who are overweight to make healthy changes to their physical activity and diet, changes may also be required in their parents/carers weight-related cognitions and behaviours.

Despite many childhood obesity treatment interventions using the term "family-based", the term is invariably limited to parents/carers and there is much heterogeneity in the level of parent/carer involvement between interventions[16]. Some interventions focus on parents/carers as the exclusive agents of change[17, 18], others promote parent/carer support of the child's behaviour

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3 change[7, 19] and others focus on changing both parent/carer and child behaviours together[20, 21].

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5 In social cognitive theory parental role-modelling plays a pivotal role in child behaviour, yet to our
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7 knowledge no childhood obesity treatment intervention has provided practical PA sessions that
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9 involve both children and parents/carers. The inclusion of parents/carers in practical PA sessions
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1 has received support in preschool settings[22,23] and the recent Healthy Dads, Healthy Kids trial
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3 showed that a healthy lifestyle intervention including father-child PA sessions led to changes in
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5 children's PA and eating behaviours[24].
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9 Children who are overweight often suffer low self-esteem[2], and one of the key reasons for
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1 parents/carers seeking treatment is to improve children's psychological wellbeing[25]. Despite
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3 early concerns that an increased focus on weight, diet and PA might heighten weight-related
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5 concerns in children[26], recent reviews have found overall positive effects of childhood obesity
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7 treatment on self-esteem[6,27]. However the evidence exploring the relationship between child
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9 weight change and self-esteem change remains inconclusive, with some studies (e.g.[28]) showing
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1 an association between child BMI reduction and increases in self-esteem and others (e.g.[10])
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3 finding no association.
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7 Although systematic review evidence supports a multidisciplinary family-based approach to
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9 childhood obesity treatment[6], the controlled studies on which systematic reviews are based often
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1 lack the external validity and process information required for implementing interventions in
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3 practice[29]. During recent years evidence from UK childhood obesity treatment interventions has
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5 increased rapidly (e.g.[30-32]), including qualitative insights into reasons for engagement[33,34],
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7 comparisons of parent, child and practitioner views[25, 35] and discussions of evaluation
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9 methods[36,37]. The poor reporting of intervention components in childhood obesity treatment
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1 studies however makes it difficult for decision makers to a) assess transferability of interventions for
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3 their local context and b) learn how interventions can feasibly be implemented in practice[38].
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7 Transparent reporting is particularly important during the early stages of a complex intervention, as
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3 challenges of delivery and implementation may affect the intervention's effectiveness[39]. Use of
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5 tools such as the Template for Intervention Description and Replication (TIDieR) checklist[40] have
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7 been advocated to support comparison between studies and facilitate the translation of evidence to
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9 practice.
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3 The aim of the current paper is to evaluate a community-based childhood obesity treatment
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5 intervention (Getting Our Active Lifestyles Started (GOALS)[9,36,41,42]) that draws on social
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7 cognitive theory[12] to encourage healthy lifestyle changes for the whole family. The intervention
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9 included weekly practical PA sessions that involved children, parents/carers, siblings, and other
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1 family members. Previous findings from GOALS showed a positive association between child and
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3 parent/carer Body Mass Index (BMI) reduction, whereby children attending GOALS were more likely
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5 to lose weight if their attending parent/carer also lost weight[9]. This study will evaluate the
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7 impact of GOALS during the first three years of implementation, applying the TIDieR checklist[40] to
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9 describe intervention components. We will report post-intervention (6-month) and 12-month
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1 outcomes, explore qualitative reports of lifestyle changes from parents/carers and assess the
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3 relationship between child BMI z-score change and child self-perception change.
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METHODS

Participants

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2 All families attending GOALS between September 2006 and March 2009 were invited to take part in
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4 the study. Children who attended GOALS but were not overweight, had obesity caused or
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6 exacerbated through medical conditions or syndromes, had severe learning disabilities, or did not
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8 provide baseline data were excluded from the study. Where there was more than one eligible
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0 overweight child in the family only the data from the child who was referred to GOALS was included.
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Demographic information (age, gender, ethnicity, socio-economic status by postcode, parent/carer relationship to child) was collected from participants at baseline.

Intervention (GOALS)

Between 2006 and 2013, Liverpool John Moores University, UK, was commissioned annually (through government grants, local authority and National Health Service (NHS) public health funds) to deliver a childhood obesity treatment service (GOALS) for socio-economically deprived communities in Liverpool. The aim of GOALS was to support families to increase PA and make healthy dietary changes. GOALS was targeted at families with children aged 4-16 years who were obese (BMI \geq 98th percentile according to the UK 1990 BMI reference charts[43]), although children were occasionally included who were overweight (BMI \geq 91st percentile). Minimal family unit was one child plus one adult carer, although siblings and other adult family members were encouraged to attend.

Twenty-two GOALS interventions were delivered between September 2006 and March 2009. One intervention was excluded from the study because the children received an additional weekly PA session, leaving 21 eligible cohorts. Table 1 outlines key intervention details, drawing on the TIDieR checklist[40]. The intervention framework in table 1 remained constant throughout the study.

However the implementation process presented several delivery challenges, and some modifications were necessary. These included changes to recruitment and assessment processes, delivery venues, staff roles, counselling support, provision of childcare for younger siblings, support with transport to venues and support for children who had finished the intervention. Full details of these delivery issues and resulting modifications are provided in table 2 (TIDieR item 10).

Table 1. GOALS intervention details. Numbers in parentheses refer to the item number on the TIDieR checklist[40].

Item	Description
Name (1)	GOALS (Getting Our Active Lifestyles Started!)
Why (2)	<p>The aim of GOALS was to promote a healthy weight trajectory in children who were obese, with a focus on supporting the whole family to become more physically active and make healthy changes to their diet.</p> <p>Due to the lack of available evidence when GOALS was founded in 2003, a continuous improvement methodology was used to develop and evaluate the intervention (see[36] for a full outline of this process). The whole family, multidisciplinary approach is supported by international evidence (e.g. [6, 44]).</p> <p>Intervention topics were informed by social cognitive theory ([12, 13]) and the theorised triadic reciprocal causation between environmental, behavioural and cognitive factors. Sessions aimed to enhance the self-efficacy of children and parents/carers for physical activity and healthy eating by providing positive mastery experiences, reciprocal modelling opportunities, and positive encouragement (see[42] for further details).</p> <p>Dietary objectives:</p> <p>To encourage families to:</p> <ul style="list-style-type: none"> - eat a healthy balanced diet - reduce portion sizes - consume fewer processed foods - cook more meals from fresh - increase fruit and vegetable intake - replace snacks high in fat and sugar with healthier alternatives - reduce the amount of salt and sugar added to food and drink - reduce the frequency of takeaways - increase water consumption - eat regular meals, focussing on breakfast in particular - read food labels and become more aware of what they are eating <p>Physical activity objectives:</p> <p>To encourage families to increase their physical activity through:</p> <ul style="list-style-type: none"> - active transport (e.g. walking to school) - lifestyle activity (e.g. taking stairs instead of lift) - active play (at home, out or with friends) - structured exercise (e.g. Zumba) - sport participation
What – procedure (4)	<p>Children were referred to GOALS through multiple routes, including self-referral in response to promotional activities (e.g. press articles, leaflets, whole school letters) and referral from health professionals in primary or secondary care. In addition from April 2007 children aged 9-10 years were recruited via letters to their parents/carers following participation in a local health and fitness programme in schools (<i>SportsLinx</i>,[45]).</p> <p>Approximately one week before the intervention each family attended a “lifestyle assessment” with an intervention delivery staff member. The purpose of these sessions was to build rapport with families, complete paperwork such as consent and monitoring forms, and to gather information about the family’s physical activity and dietary habits through an informal interview.</p> <p>The intervention sessions focussed on diet (<i>Fun Foods</i>), physical activity (<i>Move It</i>) and behaviour change and wellbeing (<i>Target Time</i>).</p> <p>Fun Foods: Aimed to equip families with the knowledge and practical skills to incorporate a healthy balanced diet into their lifestyle, based on the NHS Choices <i>eatwell plate</i>[46]. A range of classroom-based and practical sessions addressed topics such as portion sizes, reading food labels and healthy snacking. Families were provided with practical opportunities to develop their cooking skills, and to try out new recipes and foods.</p> <p>Move It: Involved a practical physical activity session with the aim of improving self-efficacy to be physically active outside the weekly sessions. Sessions aimed to engage the whole family, with a focus on enjoyment and personal achievement rather than competition.</p> <p>Target Time: Supported families to make their lifestyle changes easier through the use of multiple behaviour change techniques (full description of techniques used is available here (INSERT LINK TO SUPPLEMENTARY ONLINE RESOURCE 1) and through promoting and enhancing psychosocial wellbeing. Classroom-based sessions focussed on topics such as hunger and craving, raising self-esteem, dealing with bullying, and parental role-modelling. Each week families were supported to set small, realistic goals focussed on changing their physical activity and dietary behaviours outside of the structured GOALS sessions.</p> <p>Specific content evolved according to ongoing evaluation. An example timetable is available from the first author (p.m.watson@ljmu.ac.uk).</p>

Item	Description
What - materials (3)	Sessions were supported by a number of informative materials, such as parent and child handbooks, personal log books to track progress and a GOALS cookbook containing healthy recipes to cook at home. Delivery staff were supplied with weekly session plans. Copies of all informative materials are available from the first author (p.m.watson@ljmu.ac.uk). Growth charts and BMI charts were used to monitor child height and weight (available from http://www.childgrowthfoundation.org/).
Who provided (5)	GOALS was designed, delivered and evaluated by a team from Liverpool John Moores University (LJMU), operationally led by the project manager/principal researcher (PW). The team consisted of one senior staff member and several sessional staff for each section (<i>Fun Foods, Move It, Target Time</i>). Both senior and sessional staff were involved in delivering the intervention. Senior staff held postgraduate qualifications in public health nutrition (SB – Fun Foods lead), exercise physiology (KP – Move It lead), health psychology (JH – Target Time lead to April 2008) and sport and exercise psychology (LS – Target Time lead from September 2008) and were responsible for developing the intervention content, delivering sessions and supervising sessional staff in the delivery of sessions. Sessional staff were recruited from a range of backgrounds and were employed part-time to deliver the intervention. For the sessional staff, the following skills and attributes were pre-requisites: <ul style="list-style-type: none"> - minimal vocational qualification for their subject area - an interest in promoting healthy lifestyles - interpersonal skills and the ability to engage groups of different ages and abilities - experience of delivering activities to groups of children and/or families.
How (6)	Interventions were delivered to groups of families, arranged where possible by child age (e.g. 4-7 years, 8-11 years, 12-16 years). Groups ranged from 5-12 families at baseline. Some sessions included parents/carers and children together, but topics involving sensitive discussion (e.g. dealing with bullying) or aimed specifically at parents/carers (e.g. meal planning) were delivered to children and/or parents/carers separately.
Where (7)	Sessions were delivered after school in primary and secondary schools across Liverpool. Liverpool is a city in the North-West of England with approximately 470,780 residents[47] and high levels of socio-economic deprivation[48]. Despite indications that childhood obesity rates have begun to plateau[49], prevalence of childhood obesity in Liverpool remains higher than the national average with 28.6% of 4-5 year olds and 39% of 10-11 year olds overweight or obese[50].
When and how much (8)	<p>Sessions lasted for 2 hours and ran once a week after school (usually 5.30-7.30pm or 6-8pm) during term-time only. During year 1 (Sep 2006-Mar 2007), contact varied between 17,18 and 19 sessions. During years 2 and 3 (April 2007-Mar 2009), the intervention included 18 sessions.</p> <p>Due to the term-time only delivery, interventions varied in duration depending on whether they started during autumn/winter (approximately 5 months) or during spring/summer (approximately 6 months due to the long summer holiday break).</p> <p>Families were invited to individual follow-up sessions 9 months (from April 2007 only) and 12 months after they had started GOALS. These sessions lasted approximately 45 minutes and involved a progress review and height and weight measurements.</p>
Tailoring (9)	<p>Each family was assigned a personal mentor who they met with every few weeks to track their progress. The use of social cognitive theory allowed staff mentors to set weekly goals with families that focussed on either the home environment, parental behaviours/cognitions or child behaviours/cognitions, depending on the underlying cause of the target behaviour. For example, the goal for a family where the child was overeating in response to being bullied might focus on developing coping skills for the child (child cognitions), whereas the goal for a family where the child was overeating because their portions were too large might be for the parent to learn about appropriate child portion sizes (parent cognitions).</p> <p>Provision was made for childcare of younger siblings where required.</p> <p>Taxis were provided for families without transport in 8 of the 21 intervention cohorts.</p>
How well - planned and actual (11, 12)	During the first year, reflective staff meetings were held weekly to ensure the intervention was delivered as intended and to agree actions for the following week. Staff completed a written evaluation after each session to note what worked well, challenges they had faced and ideas for improvement. During the later stages, meetings continued on a six-weekly basis with regular session visits from the project manager. Regular training ensured the GOALS ethos and core framework was understood and practised by all staff.

Table 2. Modifications to the GOALS delivery mechanisms during the study period and lessons learned.
Numbers in parentheses in the first column refer to the item number on the TiDieR checklist[40].

TiDieR item	Modification	Rationale and lessons learned
What – procedure (4)	During Year 1 every child was assessed for underlying causes of obesity and co-morbidities by a community paediatrician. In Year 2, this was replaced with an assessment with a school nurse and later a self-completion form by the parent with recommendations to visit the family GP before starting the intervention.	The available guidelines for treating childhood obesity recommended all children with a BMI \geq 99.6 th percentile be referred to hospital or community paediatric consultants before treatment was considered[51] and a medical assessment be undertaken of presenting symptoms and underlying causes of overweight and obesity, comorbidities and risk factors, and growth and pubertal status[52]. As the majority of children registering for GOALS had a BMI \geq 99.6 th percentile, assessment by community paediatricians proved a time-consuming and costly arrangement, and research suggested these assessments may not be necessary for all obese children[53]. The protocol was therefore replaced by an assessment with a school health practitioner and later a self-completion form by the parent, in which they were signposted to the GP.
Where (7)	Year 1 interventions were delivered in both primary (n=4) and secondary schools (n=3). Year 2 & 3 interventions were delivered in secondary schools only.	Due to the multidisciplinary nature of the intervention, each site required space for physical activity, facilities for cooking and classrooms for general activities. Primary schools were rarely open during evening hours (and thus incurred costs for site management) and cooking facilities were often limited to the school kitchens. By contrast, secondary schools provided ideal space for group cooking sessions in food technology rooms and were often open during the evening for adult education classes (thus allowing free access).
Who provided (5)	During Year 1, Fun Foods was led by community dietitians (theory-based sessions) and community food workers (practical sessions) employed by the NHS in Liverpool. From Year 2, the employment of all Fun Foods staff was transferred to Liverpool John Moores University. A public health nutritionist delivered the theory-based sessions and food workers continued to deliver practical elements. In September 2008 (mid-Year 3) all food workers were trained to be “nutrition mentors”, responsible for the delivery of both theory-based and practical sessions with ongoing training and supervision from the public health nutritionist.	Little guidance was available outlining the skills required for delivery of healthy eating sessions in the community. Since the intervention focussed on general healthy eating advice rather than individually-prescribed diets, it was established that a public health nutritionist possessed the relevant skills for supervision and quality assurance of the Fun Foods element of the intervention.

TIDieR item	Modification	Rationale and lessons learned
Who provided (5)	A qualified counsellor began working with GOALS in February 2007 (end of Year 1) to provide additional support for children and families where appropriate.	The group session provided little opportunity for children or families to discuss personal issues that may have been affecting their lifestyle change (e.g. if children were being bullied). The GOALS lifestyles counsellor provided an impartial source of support for children or families who needed to talk something through that went beyond the remit of the GOALS staff. Several different ways of working were explored, ranging from informal drop-ins during the weekly session, group sessions about feelings, and fixed appointment times for families either during or outside of the weekly session. Whilst the support was deemed beneficial for families, it proved difficult to sustain financially and the counsellor's involvement ceased a short time after the study period.
Tailoring (9)	During Years 1 & 2, a mobile crèche was provided on site for younger siblings (if required). During Year 3, younger siblings were included in the main programme.	To allow whole families to attend, it was important provision was made for the childcare of younger siblings. Therefore a free crèche was provided for families at the intervention site. However the mobile crèche proved costly given the small number of children who used it, and children often expressed a wish to join in the main group's activities. The option of arranging local child-minders was explored but the families concerned were reluctant to leave their children with an unknown adult. Therefore the most appropriate solution was to accommodate young children within the main session, with an allocated staff member to take them aside for age-appropriate activities where necessary.
Tailoring (9)	The number of interventions in which taxis were provided for families increased with each year (1/7 in Year 1; 3/7 in Year 2; 4/7 in Year 3).	As it was not possible to provide intervention sites in every district of the city, consideration was given to the provision of transport for families who lived further afield. Several options were explored, including reimbursement of public transport expenses for families without a car and arrangement of taxis to and from sessions. It was however a challenge to develop objective criteria for offering these services and there was some concern the arrangement of taxis hindered the lifestyle change process for families. Financial support for transport was ceased after the study period, and staff instead supported families to identify appropriate public transport solutions.
When and how much (8)	A family-based weekly physical activity session for "GOALS graduates" was piloted between May 2007 (start of Year 2) and July 2008 (mid-Year 3).	Families expressed a wish for continued support beyond the 18-week intervention. However sessions later ceased due to poor attendance and pressure to allocate financial resources to the main intervention.

Key: Year 1 = September 2006-March 2007; Year 2 = April 2007-March 2008; Year 3 = April 2008-March 2009

Outcome measures

BMI (collected from children and parents/carers at baseline, post-intervention and 12 months)

Height and weight measures were taken by PW and senior staff (KP, SO, JH, LS). Weight was recorded to the nearest 0.1kg using a Tanita WB/100MA floor scale. Height was recorded to the nearest 0.1cm using a portable Leicester Height Measure. To control for measurement error staff took two height measures and calculated the mean. If these two measures differed by 1% or more a third measure was taken and the median used. BMI was calculated using the equation $\text{weight (kg)}/\text{height (m)}^2$. To account for change in children's ages from baseline, BMI was converted to z-scores based on the 1990 UK Growth Reference curves[43] using LMS Growth Software[54].

Child self-perceptions (collected from children over 8 years at baseline, post-intervention and 12 months)

Child self-perceptions were measured using the Self-Perception Profile for Children (SPPC)[55]. The SPPC is a 36-item validated questionnaire consisting of six subscales measuring global self-esteem plus five specific domains of self-esteem in children. The SPPC is validated for use in children aged over 8 years and has acceptable internal consistency reliabilities for all six subscales (Cronbach's Alpha range .71 to .86). To reduce participant burden, four subscales that have been shown to change through healthy lifestyle intervention[27] were used in the current study (*Social acceptance; Athletic competence; Physical appearance; Global self-esteem*), yielding a questionnaire with 24 items in total (6 in each subscale).

Changes in PA and diet (collected from parents/carers who attended after April 2007 at post-intervention and 12 months)

Parents/carers completed a questionnaire containing four qualitative feedback items that explored changes in their own PA levels, their child's PA levels, their child's confidence and their family's diet. At 12 months, parents/carers were also asked questions about their facilitators and barriers to change. Full questionnaire schedules are available [here](http://bmjopen.bmj.com/site/about/guidelines.xhtml) (LINK TO SUPPLEMENTARY ONLINE

RESOURCE 2).

Analysis

To account for clustering of children within intervention cohorts, data were first entered into MLwiN version 2.24 (Centre for Multilevel Modelling, Bristol, 2011) to explore the variance contributed by between-cohort differences (comparison of a two-level model (time; child) with a three-level model (time; child; cohort), BMI z-score change as the outcome variable). As inclusion of cohort as a random variable did not improve the fit of the model, data were treated as independent and pooled for analysis in SPSS version 17 (SPSS Inc., 2008). Outcome data is presented for complete cases only. Paired samples t-tests (normally distributed data) and Wilcoxon signed rank tests (non-parametric data) were used to assess within-subjects change from baseline to post-intervention, and from baseline to 12-month follow up. Pearson correlations were used to measure relationships between child BMI z-score change and child self-perception change, and child BMI z-score change and age. Independent t-tests were used to compare results by gender. Responses to the feedback questionnaires were first coded as “improved”, “unchanged” or “declined” (stage 1), then analysed against the GOALS intervention objectives (see table 1) with subsequent inductive analysis to allow new themes to emerge (stage 2). To enhance the credibility of findings, stage 1 analysis was carried out independently by two members of the research team (PW and RM). Inter-rater agreement ranged from 0.80 to 0.91. Stage 2 analysis was carried out by PW, followed by a process of peer scrutiny and discussion to reach a consensus on the final themes.

RESULTS

Baseline characteristics

One hundred and forty-three families were included in the study (143 children (63 boys), 168 parents/carers). According to the 2007 indices of deprivation[56], 92 families lived within the most 10% deprived neighbourhoods in England, 34 in the 11-50% most deprived and 17 in the least 50%

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3 deprived. Mean child age was 10.4 ± 2.2 years (range 4.7-16.0 years) and mean BMI z-score was
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5 3.0 ± 0.57 (range 1.53-4.73). One hundred and eight children were superobese (BMI $\geq 99.6^{\text{th}}$
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7 percentile), 29 children were obese (BMI $\geq 98^{\text{th}}$ percentile) and 6 children were overweight (BMI \geq
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9 91^{st} percentile) according to the 1990 UK Growth Reference data[43]. Ethnicity data was provided
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1 for 79 children, 67 of whom were white-British, 2 white-other background, 3 mixed race, 3 black-
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3 British, 1 Asian and 3 from other backgrounds. Whilst this ethnic profile is representative of the
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5 Liverpool population, it is less diverse than the national population in England and Wales, where
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7 there is a higher proportion of ethnic minority groups[47]. Of the 168 parents/carers taking part, 120
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9 were mothers, 34 fathers, 13 other relations (7 grandmothers, 3 adult siblings, 1 aunt, 2 other carers)
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Participant flow through study (see figure 1)

Seventy-four families (74 children, 81 parents/carers) completed the intervention (at least 50% attendance and still attending at the end of the intervention). Median attendance for these families was 83.3%. Families were included in the complete case analysis if the overweight child in the family had complete baseline and post-intervention (6-month) BMI data. If a child was excluded from the analysis, their parents/carers were also excluded. Of the 74 children who completed, three were excluded (two had no post-BMI data, the third lost weight due to a medically-prescribed diet), leaving 71 children for analysis. One further child's data was removed, as his BMI z-score change from baseline to post-intervention (-0.71) was over three standard deviations greater than the sample mean. Therefore the complete case analysis included 70 children, with 58 parents/carers providing complete baseline and post-intervention BMI data. One parent was excluded due to following a very low calorie diet plan independent of GOALS, leaving 57 parents/carers in the BMI analysis (6 healthy weight, 24 overweight, 27 obese). The characteristics of the 70 complete child cases were comparable to those of the whole cohort at baseline, with a mean age of 10.5 ± 2.1 years and a mean BMI z-score of 3.02 ± 0.60 .

Child outcomes

Table 3 shows the BMI z-score and self-perception scores for children at baseline, post-intervention and 12 months. There was a significant decrease in BMI z-score from baseline to post-intervention (-0.07, $p < 0.001$) that was maintained at 12 months for the children who attended follow up (baseline to post -0.09, $p = 0.004$; baseline to 12 months -0.09, $p = 0.041$). Forty-five children provided complete baseline and post-intervention self-perception data (exclusions were due to incomplete questionnaires ($n = 10$), age under 8 years ($n = 6$) and absence when the questionnaires were completed ($n = 9$)). There were small improvements in all self-esteem domains from baseline to post-intervention, though the only change to reach significance was in the social acceptance domain (0.26, $p = 0.028$). There were no significant differences in child outcomes by gender or age.

Correlations between BMI z-score and self-perceptions

There were no correlations between baseline BMI z-score and baseline self-perceptions, or between BMI z-score change and self-perception change at either post-intervention or 12 months. However, the correlation between baseline BMI z-score and perceived social acceptance change from baseline to post-intervention approached significance ($r = .288$, $p = 0.055$), suggesting the most obese children experienced the greatest increase in perceived social acceptance. There were also significant correlations between baseline to *post-intervention* BMI z-score change and baseline to *12-month* self-perception change in two domains (global self-esteem, $r = -.433$, $p < 0.05$; physical appearance, $r = -.423$, $p < 0.05$) and correlations that approached significance in the other two domains (social acceptance, $r = -.380$, $p = 0.061$; athletic competence, $r = -.390$, $p = 0.060$). This indicates the children who lost the most weight during the intervention had the most improved self-perceptions at 12 months.

Change in parent BMI

Median BMI did not change between baseline (29.42, interquartile range (IQR) 27.10-35.19, $n = 57$), post-intervention (29.89, IQR 27.12-35.24, $n = 57$) and 12 months (30.91, IQR 26.73-34.63, $n = 33$).

Table 3. Baseline, post-intervention and 12-month child outcomes following completion of GOALS. Means and standard deviations are reported for children with complete baseline and post-intervention data. Outcomes for the subsample who attended 12-month follow up are reported separately.

Measure		n	Baseline	Post-intervention	12 months	Baseline to post-intervention	p	Baseline to 12 months	p
BMI z-score	Complete	70	3.02 (0.60)	2.95 (0.62)	n/a	-0.07*** (0.16)	<0.001	n/a	n/a
	Complete with 12-month follow up	40	2.88 (0.60)	2.79 (0.60)	2.79 (0.66)	-0.09** (0.18)	0.004	-0.09* (0.26)	0.041
PSPP Social Acceptance	Complete	45	2.99 (0.74)	3.26 (0.57)	n/a	0.26* (0.78)	0.028	n/a	n/a
	Complete with 12-month follow up	22	2.97 (0.70)	3.23 (0.57)	2.99 (0.69)	0.26 (0.75)	0.112	0.02 (0.62)	0.905
PSPP Athletic Competence	Complete	45	2.35 (0.66)	2.46 (0.76)	n/a	0.11 (0.65)	0.244	n/a	n/a
	Complete with 12-month follow up	21	2.49 (0.55)	2.65 (0.59)	2.55 (0.66)	0.16 (0.70)	0.315	0.06 (0.63)	0.661
PSPP Physical Appearance	Complete	45	2.04 (0.81)	2.20 (0.77)	n/a	0.16 (0.74)	0.165	n/a	n/a
	Complete with 12-month follow up	21	2.05 (0.64)	2.33 (0.70)	2.35 (0.73)	0.28 (0.74)	0.102	0.31 (0.78)	0.087
PSPP Global Self-Esteem	Complete	45	2.72 (0.80)	2.85 (0.69)	n/a	0.13 (0.74)	0.253	n/a	n/a
	Complete with 12-month follow up	21	2.70 (0.72)	2.89 (0.71)	2.87 (0.69)	0.18 (0.76) [#]	0.218	0.17 (0.98) [#]	0.727

*p value of within-subject effect (paired samples *t*-test) <0.05

**p value of within-subject effect (paired samples *t*-test) <0.01

***p value of within-subject effect (paired samples *t*-test) <0.001

[#]Data not normally distributed, *Wilcoxon signed rank* test used.

Parent/carer-reported changes in family PA and diet

Of 56 parents/carers who completed GOALS after April 2007, 44 completed questionnaires post-intervention and 19 completed questionnaires at 12 months. In some families (two at post-intervention, two at 12 months) two parents/carers completed a questionnaire. Therefore for items related to child or family changes the data from both parents/carers was either combined (where there was agreement) or excluded (where there was disagreement).

Post-intervention changes

A summary of the post-intervention questionnaire responses with example quotes is provided in table 4. None of the parents/carers reported declines in their family's PA and diet behaviours, although there were a few cases where no change was reported (six for parent/carer PA levels, one each for child PA levels, child confidence and family diet). Improvements to parents/carers' own PA levels focussed mostly on structured exercise and walking, whereas in their children they reported examples related to sport participation, active transport, exercise and active play. The majority of parents/carers commented on their child's improved confidence and increased willingness to get involved in PA, although some noted their child still lacked confidence outside of the GOALS setting. In terms of diet, many responses focussed on a healthy balanced diet in general and an increase in fruit and vegetable intake. Examples of healthy choices were provided, such as switching to healthier varieties of foods, introducing new foods or removing high fat foods. Several parents/carers described their child's increased willingness to try new foods.

12-month changes

Positive changes were reported for all children's PA levels, though in one case this was a delayed change not attributed to GOALS (*"my child's activity levels have gone up since moving into high school"*). Similarly, improvements in child confidence were maintained for all families (e.g. *"[my son] is more confident in himself and I feel the change he has made will be forever"*). Maintenance levels were slightly lower for parent PA (13/19) and family dietary changes (11/17); although there were a

Table 4. Post-intervention parent/carer-reported changes in family PA and diet. Eligible responses represent the number of responses for each item after accounting for agreement/disagreement between parents/carers from within the same family. For the parent/carer PA levels item, only 41 responses were provided (3 were left blank). Example quotes are provided to illustrate the range of responses for each item in the improved (I) category, plus single examples for the unchanged (U) and un-coded (n/a) categories where applicable.

Questionnaire item	Eligible responses	I	U	D	n/a	Example quotes (category in parentheses)
Parent/carer PA levels	41	34	6	-	1	<p>"[I] regularly attend the gym" (I)</p> <p>"I am a lot more active, I always walk instead of getting a taxi" (I)</p> <p>"[My PA levels have] stayed the same" (U)</p> <p>"Doing Move It has made me realise just how unfit I really am" (n/a)</p>
Child PA levels	42	41	1	-	-	<p>"[My child is] more active, swimming has improved, little more running" (I)</p> <p>"[My son] now goes to cricket, football" (I)</p> <p>"Walk home from school most nights" (I)</p> <p>"[My daughter] plays more physical games" (I)</p> <p>"My son tries much harder now without giving up too soon" (I)</p> <p>"[My child] has increased [PA] to some degree, but have found it difficult to fit in around school/homework" (I)</p> <p>"[My child's PA levels are] the same" (U)</p>
Child confidence	40	36	1	-	3	<p>"[My grandson] doesn't seem to worry so much now about his weight and looks more confident" (I)</p> <p>"[My daughter] is more positive and confident towards exercise" (I)</p> <p>"[My son] has become more involved and will try most things" (I)</p> <p>"My son has always been confident so there has been no change" (U)</p> <p>"My child is positive when he is at GOALS, but still not so in school and around people he doesn't really know" (n/a)</p>
Family diet	40	38	1	-	1	<p>"[We make] a lot more healthier choices at the same cost as before" (I)</p> <p>"[We] eat far more fruit and veg" (I)</p> <p>"Sausage rolls or pies are now a definite 'no no'" (I)</p> <p>"Kids more adventurous with trying new foods" (I)</p> <p>"Not much change as we have always ate fairly healthy" (U)</p> <p>"I have been conscious of eating healthily for some time, but found it difficult to control what [my son] ate outside" (n/a)</p>

Key: I: improved; U: unchanged; D: declined; n/a: un-coded (was not possible to deduce from the response whether there was any change)

further three parents/carers who reported keeping up some, but not all, of their dietary changes (e.g. “We have changed a lot of eating habits, but sometimes will fall back and have to start again”). The parents/carers who had maintained changes provided examples of healthy behaviours that had become a way of life for them (e.g. “we now think before we eat “rubbish” and our diet has improved vastly without too many big changes and it’s become a way of life”), described the acquisition of coping skills to prevent relapse (e.g. “I can feel when I’m getting lazy and I up my walking”) and the formation of healthy routines (e.g. “we always do an activity as a family once a week”).

In response to the question about facilitators, parents/carers commented on the importance of education (e.g. “GOALS helped me in choosing healthy options and checking labels on food”), small attainable changes (e.g. “the idea that small changes that can be maintained more easily can make a difference to your weight and shape”), making exercise fun (e.g. “showing you how to enjoy yourself with your family during exercise”) and coping skills for maintaining change (e.g. “the GOALS methods kick in when I start to feel unhealthy”). Parents/carers also mentioned the enthusiasm and encouragement from staff, and specific sessions that had helped them such as the portion sizes and practical cooking sessions.

As most of the families had maintained some changes, very little information was provided on barriers. Those who had relapsed said they had done so because of poor health, lack of time/planning and other commitments. One parent who had struggled to keep up his PA levels noted the GOALS group session finishing had been a big challenge.

DISCUSSION

The aim of this paper was to evaluate the impact of the GOALS family-based childhood obesity treatment intervention during the first three years of implementation, applying the TIDieR[40] checklist to describe intervention components. It was found that children completing GOALS demonstrated modest improvements in child BMI z-score that were maintained at 12-month follow

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3 up. There was also a small improvement in perceived social acceptance that was most marked in
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5 the children with the highest baseline BMI z-score, and a moderate correlation between BMI z-score
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7 reduction during the intervention and improved self-perceptions at 12 months. Whilst there was no
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9 change in parental BMI, parents/carers reported positive changes to their own and their child's PA
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1 and diet.
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4 The mean BMI z-score change (-0.07) for children completing GOALS was consistent with the
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6 outcomes of other evaluations carried out in a service-delivery setting (e.g. [10,57]), yet smaller than
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8 that reported in published randomised controlled trials (RCTs) of UK community-based childhood
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0 obesity treatment interventions (e.g. [7, 11]). Whilst discussion surrounds what constitutes a
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2 clinically important BMI z-score reduction[58], evidence shows that even small reductions in BMI z-
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4 score are associated with positive improvements to cardiovascular risk factors in obese children[59,
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6 60]. Such observations support the international consensus statement that suggests any
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8 improvement in BMI z-score should be viewed as a positive outcome[61].
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1 While reviews have found overall positive effects of childhood obesity treatment on self-esteem [6,
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3 27], authors have expressed concern that the increased focus on weight-related behaviours could
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5 have adverse effects on children's self-perceptions[26]. The quantitative data in this study showed
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7 little change in children's self-perceptions, although parents/carers did report qualitative increases
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9 in children's confidence. Whilst children's perceived social acceptance scores were comparable
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1 with a UK-sample of mixed-weight children[62], their scores on the perceived athletic competence
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3 and physical appearance scales remained low. It is important obesity treatment interventions help
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5 parents/carers understand how they can promote a healthy body image in children, for example
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7 through focussing on healthy behaviours rather than weight and encouraging children to adopt an
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9 identity that goes beyond physical appearance[63].
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2 Whilst child weight loss has previously been linked to increases in self-esteem[28], it is not clear
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4 whether child weight loss increases self-esteem or increased self-esteem facilitates child weight loss,
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3 or both[27]. In the present study BMI z-score change during the intervention was not linked to self-
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5 perception changes over the same period (as also found in[10]), but was inversely associated with
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7 self-perception change from baseline to *12-month follow up*. The fact this relationship was found in
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9 only one direction (i.e. there was no correlation between self-perception change during the
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1 intervention and baseline to 12-month BMI z-score change) suggested that weight-loss in the short-
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3 term may lead to improvements in children's self-perceptions over the longer-term.
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7 A key challenge for childhood obesity treatment is the transition from the safe and supportive group
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9 environment to long-term behaviour change at home[35]. Although most parents/carers reported
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1 positive changes to PA and diet that were maintained after finishing GOALS, many parents/carers
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3 spoke of the tendency to fall back into old habits from time to time. Such cycles of change are
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5 well-established in the health behaviour literature[64], and data from the current study suggests the
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7 skills learned at GOALS were used as an effective coping mechanism to prevent full relapse. As
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9 theorised by the social cognitive framework on which GOALS was based[12,13], family support may
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1 also be important in maintaining healthy behaviours. Previous research from childhood obesity
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3 treatment shows the most successful families are those who work together to achieve healthy
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5 lifestyle changes[9,25]. GOALS placed a strong emphasis on family involvement through an inclusive
6
7 PA session for children, parents/carers and siblings and a focus on changing the whole family's
8
9 lifestyle. The success of these attempts to engage the wider family were evidenced in the
0
1 proportion of children who attended with at least two other family members (approximately 60%).
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3 Whilst this whole family focus did not result in a change in parental BMI (which could have been due
4
5 to the lack of specific emphasis on parental weight loss), the qualitative data did suggest
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7 parents/carers made changes to their own PA levels and to the whole family's dietary habits. The
8
9 potential for social desirability in these parent/carer reports is acknowledged, although it is
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1 noteworthy that parent-proxy report has proved a reliable and valid measure of obesity-specific
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3 health-related quality of life elsewhere[65]. Further research is required to understand how
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5 interventions can best promote long-term behavioural change in families.
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3 Through mapping the GOALS intervention onto the TIDieR checklist[40], this paper provided a
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5 transparent account of the intervention modifications that were necessary during the study period.
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7 Such “teething problems” are a natural process of complex intervention implementation[39], and
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9 flexibility is important to tailor interventions to local needs[66]. Yet delivery challenges are rarely
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1 acknowledged in the research literature, nor consideration given to the potential impact of
2
3 modifications on intervention outcomes. In the current study, the proportion of children who
4
5 reduced BMI z-score during GOALS increased each year (43%, 63% and 80% respectively) and service
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7 audit data suggests these figures continued to rise after the study period. Whilst there is
8
9 insufficient data to link these improvements to intervention refinements, it is plausible that results
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1 from the first year did not reflect the true potential of the intervention. GOALS staff turnover during
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3 the study period was low (by the final year 12/14 staff had been delivering GOALS for at least two
4
5 years), therefore knowledge and experience increased substantially during the three years and it is
6
7 likely the intervention improved as a result.

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9 Whilst this study provides an important insight into childhood obesity treatment in practice, some
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1 limitations must be acknowledged. The service level agreement required that GOALS was available
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3 for all children who were obese within Liverpool, therefore a randomised controlled trial was not
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5 possible. Whilst other studies of childhood obesity treatment have employed a waiting-list control
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7 (e.g. [7,19]), GOALS was funded on a year-by-year basis thus there was insufficient time to allow for
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9 participant recruitment plus two cycles of the intervention (which would be required for a waiting
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1 list design). Therefore it is acknowledged that the pre-post design provides no information about
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3 how children’s BMI z-scores might have changed without intervention (although the qualitative data
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5 does provide some support to suggest GOALS played a role in changing family PA and dietary
6
7 behaviours). Future research conducted under service level conditions should consider a non-
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9 randomised comparison group, such as children from neighbouring regions not eligible for the
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1 intervention (see[36] for a discussion of the challenges of conducting research within a service
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3 delivery setting). Furthermore, there was a high attrition rate from the intervention and it is not
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3 known whether those who dropped out achieved any benefits. It was not always possible to attain
4 reasons for drop out, but reasons cited included difficulty with transport, clashes with other
5 commitments (e.g. sports clubs), and adverse life events (e.g. relationship breakdown, family illness).
6
7 The observed attrition rate (48%) is comparable to that observed in other childhood obesity
8 treatment interventions[67] and as the children who completed did not differ from the baseline
9 population, a complete case analysis was conducted to explore the impact of the intervention for
0 children who completed GOALS. However it is acknowledged these children represented less than
1 50% of the baseline cohort therefore the current results must be interpreted with caution. Finally,
2 the sample was predominantly White-British. Results cannot therefore be generalised to other
3 ethnic populations living in the UK, for whom engagement with childhood obesity treatment
4 interventions may be differentially influenced by cultural perceptions of obesity[68].
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Conclusions

A key strength of service evaluation is its high ecological validity and capacity to investigate intervention impact as it is delivered in practice. This study shows the GOALS childhood obesity treatment intervention supported families to change their PA and dietary behaviours, resulting in small improvements to children's BMI z-scores. Delivery challenges are inevitable when implementing a complex intervention, and it is possible the current results were diluted by early implementation difficulties. Therefore commissioners are encouraged to dedicate long-term funding to allow childhood obesity treatment interventions time to embed before evaluating their worth[44]. To support the translation of evidence to practice, researchers are urged to draw on relevant reporting guidelines (e.g.[40, 69, 70]) to ensure transparency of intervention components, necessary modifications and evaluation methods. Doing so will enable comparison between studies and provide vital information for policy-makers and practitioners wishing to implement a childhood obesity treatment intervention in their locality.

FIGURE LEGENDS

Figure 1: Participant flow through study

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CONTRIBUTORS

PW conducted the study as part of her doctoral degree and drafted the article. TC and LD conceived the study, secured funding and contributed to the analysis and interpretation of data. TC managed the overall project and supervised PW's doctoral programme, along with RM and ZK who both contributed to the analysis and interpretation of data. KP, SO, JH and LS designed the intervention and worked alongside PW to develop it according to ongoing feedback. All authors critically reviewed and contributed to the writing of the paper.

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COMPETING INTERESTS

PW, KP, SO, JH and LS were employed by Liverpool John Moores University to design, deliver and evaluate the GOALS intervention.

ETHICS APPROVAL

Ethical approval was received from the Liverpool NHS Paediatric Research Ethics Committee [05/Q1502/28]. Written informed consent was obtained from parents/carers, and written assent from children over 8 years and deemed capable of understanding.

DATA SHARING STATEMENT

There is descriptive data available for the overweight siblings who completed the intervention, plus other measures that were piloted with subgroups of the study population (e.g. waist-to-height ratio). The authors are willing to share this data with practitioners or researchers interested in the evaluation of family-based childhood obesity treatment interventions (please request from the first author, p.m.watson@ljmu.ac.uk).

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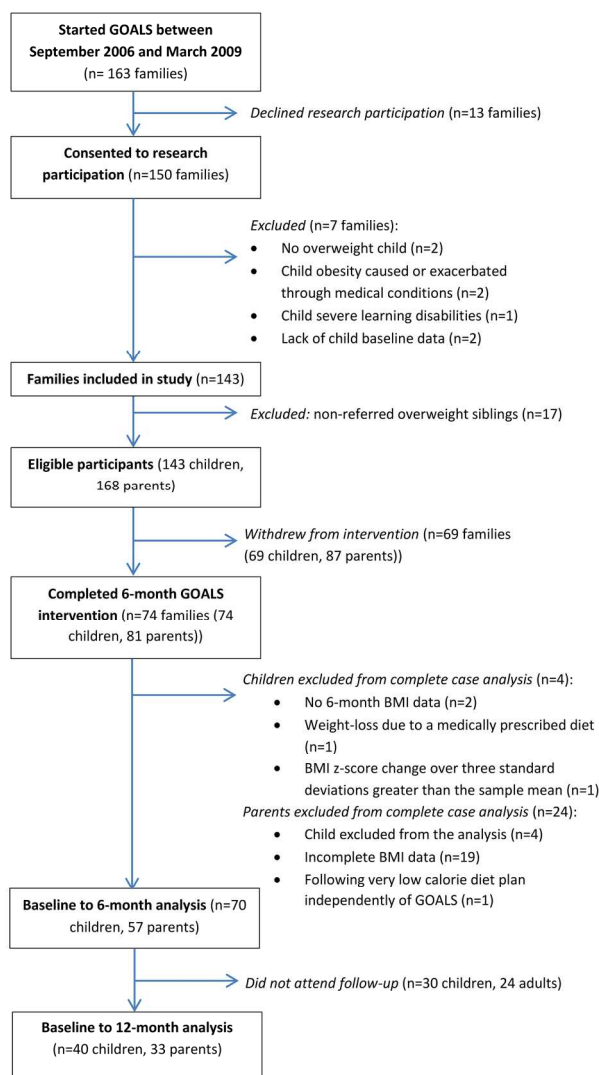


Figure 1: Participant flow through study

Figure 1: Participant flow through study
139x233mm (300 x 300 DPI)

Supplementary Online Resource 1

Most frequently used behaviour change techniques (BCTs) at GOALS and examples of their application. Figures refer to the corresponding number on Michie et al.'s (2011) CALO-RE taxonomy[1].

BCT	Examples of application
Provide information about consequences of behaviour in general (1)	Written information about benefits of physical activity/healthy eating and dangers of being overweight in handbooks; Giving verbal information about physical activity/diet and health during group and one to one sessions.
Provide information on consequences of behaviour to the individual (2)	Going through the BMI and growth charts, showing parents the extent of their child's obesity and explaining the risks their child faces unless something changes; Decisional balance during Target Time session; Talking about positive outcomes of change during mentor/goal setting sessions (e.g. "eating breakfast will give you more energy in the morning").
Provide normative information about others' behaviour (4)	Giving messages during group and one to one sessions to help families understand they are not alone (e.g. "most children in the UK do not get enough physical activity") and support the health messages given (e.g. "we have seen most success with families who really put in the effort at home").
Goal setting (5, 6)	Setting long and medium-term goals with families. These may focus both on outcomes and behaviours.
Action planning (7)	Setting specific weekly goals with each family (i.e. what will be done, where and when).
Barrier identification/problem solving (8)	Target Time session on addressing barriers to healthy lifestyles; Problem solving when setting goals with families, e.g. If someone is struggling asking "what is stopping you doing this and how can it be overcome?"
Set graded tasks (9)	Breaking medium and long-term goals down into small manageable steps (e.g. if target is to reduce from 2 bags of crisps a day to 1 bag a week, the first step might be to reduce to 1 bag a day).
Prompt review of goals (10, 11)	Following up families to review their goals on a weekly basis; Six-weekly mentor sessions to review weight outcomes and overall progress.
Provide rewards contingent on successful behaviour (13)	Allocating points when a weekly goal is achieved (points add up to earn tangible rewards).

BCT	Examples of application
Prompting generalisation of a target behaviour (15)	Mastering new cooking skills at GOALS, then setting a goal to try cooking the same meal at home; Signposting families to local physical activity sessions.
Prompt self-monitoring of behaviour (16)	Food diaries as part of initial assessment; Asking families to write down their progress towards their weekly goals.
Prompting focus on past success (18)	Increasing confidence by asking families to think of a time they have successfully carried out a behaviour or made a change. Used particularly during Target Time sessions towards start of programme.
Provide feedback on performance (19)	Feedback from food diaries; Providing specific verbal feedback when reviewing weekly goals; Providing feedback during Move It or Fun Foods sessions to correct technique, or confirm that an action is being performed correctly.
Provide instruction on how to perform the behaviour (21)	Teaching people how to read food labels or plan meals; Providing written advice and tips in handbooks; Teaching skills related to physical activity.
Model/demonstrate the behaviour (22)	Demonstrating technique and showing how to play games during Move It; Staff as role-models.e.g. Showing a willingness to try new foods, joining in Move It.
Environmental restructuring (24)	Discuss ways of restructuring the home environment to support change – e.g. put gym clothes out ready for the morning, have bowl of fruit on the table, remove tempting foods from house etc.
Agree behavioural contract (25)	Asking families to sign a “promise sheet” during their final mentor session, outlining specific behaviours they will continue.
Prompt practice (26)	Weekly goal setting is aimed at habit formation. Each goal is continued to prompt practice until it comes more easily.
Use of follow up prompts (27)	Post-intervention family follow ups; Newsletters and invites to events or to take part in GOALS activities; Ad hoc phone calls to families.
Facilitate social comparison (28)	Weekly group sessions provide opportunity to mix with others “in the same boat”; Move It sessions – comparison of own sporting/PA ability with that of others. Also provides opportunity for parents to compare their own children to other overweight children (visually and behaviourally).

BCT	Examples of application
Plan social support/social change (29)	Whole family approach; Weekly goals aimed at involving non-attending family members (particularly if their actions are acting as a barrier to progress); Encouraging group to attend local activities together and help each other out (e.g. Provision of lifts).
Prompt identification as a role model (30)	Parents encouraged to look at their own physical activity, diet and weight-related behaviours; Target Time session on positive role-modelling and supporting information in handbook; Parent discussion groups to allow sharing of ideas (i.e. “what worked for them”).
Prompt anticipated regret (31)	Managing expectations during group and one to one sessions – e.g. 18 weeks sounds a long time now but it will pass quickly so it is important to make the most of this opportunity, it is only going to become more difficult to address the obesity as children get older etc.
Fear arousal (32)	Visual demonstration of amount of fat and sugar in popular foods; Use of replica fat and models of clogging arteries to explain risks of obesity and physical inactivity.
Prompt self-talk (33)	Encouraging families to replace negative thoughts with more helpful thoughts (e.g. “I may not feel like exercising now, but I know it’ll make me feel better”). Used particularly during Target Time session about addressing barriers.
Relapse prevention/coping planning (35)	Discussions during mentor chats to identify potential challenges in maintaining changed behaviours, identifying coping strategies throughout programme.
Motivational interviewing (37)*	<i>Trained staff used core skills of motivational interviewing throughout (e.g. empathy, rolling with resistance), particularly during one to one sessions.</i>
Time management (38)	Discussing how families can free up time for physical activity; Group session with parents on planning meals in advance.

*Target Time staff were trained in motivational interviewing, but no formal training was provided for other staff.

Reference

1. Michie S, Ashford S, Sniehotta FF, Dombrowski SU, Bishop A, French DP. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy. *Psychol Health* 2011;26(11):1479-98.

Supplementary Online Resource 2

Parent feedback questions asked post-intervention and at 12-month follow up (via written questionnaire)

Theme	Post-intervention	12-month follow up
Parent physical activity	How do your activity levels <u>now</u> compare to your activity levels <u>before you came to GOALS</u> ? Please describe anything that is different.	How do your activity levels <u>now</u> compare to your activity levels <u>before you came to GOALS</u> ? Please describe anything that is different. How do your activity levels <u>now</u> compare to your activity levels <u>immediately after GOALS finished</u> ? If there are differences, what are the reasons for these?
Child physical activity	How do you feel <u>your child's</u> activity levels compare to their activity levels before GOALS?	How do you feel <u>your child's</u> activity levels compare to their activity levels before, and immediately after, GOALS?
Child confidence	Have you noticed any changes in your child's confidence and attitude to physical activity since coming to GOALS (either positive or negative)?	Have you noticed any changes in your child's confidence and attitude to physical activity since finishing GOALS (either positive or negative)?
Family diet	How do your family's eating habits <u>now</u> compare to your eating habits <u>before you came to GOALS</u> ? Please describe anything that is different.	How do your family's eating habits <u>now</u> compare to your eating habits <u>before you came to GOALS</u> ? Please describe anything that is different. How do your family's eating habits <u>now</u> compare to your eating habits <u>immediately after GOALS finished</u> ? If there are differences, what are the reasons for these?
Facilitators/barriers		If you have continued with your healthy lifestyle, what was it about GOALS that prepared you to do this? If you have not managed to keep up as healthy a lifestyle as you'd have liked, what do you feel has prevented you? If there are differences, how could we have helped?



Template for Intervention
Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME	(refer to page numbers on revised Word manuscript)	
1.	Provide the name or a phrase that describes the intervention. WHY	p.9 (table 1)	_____
2.	Describe any rationale, theory, or goal of the elements essential to the intervention. WHAT	p.9 (table 1)	_____
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	p.10 (table 1)	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities. WHO PROVIDED	p.9 (table 1) & p.11 (table 2)	_____
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	p.10 (table 1) & p.11-12 (table 2)	_____
6.	HOW Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	p.10 (table 1)	_____

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WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	p.10 (table 1) & p.11 (table 2)
WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	p.10 (table 1) & p.12 (table 2)
TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	p.10 (table 1) & p.12 (table 2)
MODIFICATIONS		
10.*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	p.11-12 (table 2)
HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	p.10 (table 1)
12.*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	p.10 (table 1)

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

TREND Statement Checklist

Paper Section/Topic	Item No.	Descriptor	Reported?	
			✓	Pg #
TITLE and ABSTRACT				(refer to page numbers on revised Word manuscript)
Title and Abstract	1	• Information on how units were allocated to interventions	n/a	
		• Structured abstract recommended	✓	p. 3
		• Information on target population or study sample	✓	p. 3
INTRODUCTION				
Background	2	• Scientific background and explanation of rationale	✓	p. 5-7
		• Theories used in designing behavioral interventions	✓	p. 5
METHODS				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	✓	p.7-8
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	✓	p.7-8 & p.9 (table 1)
		• Recruitment setting	✓	p. 9 (table 1)
		• Settings and locations where the data were collected		Not specified due to space limitations. Data was collected at intervention sites.
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	✓	p.9-10 (table 1) See TIDieR checklist also.
		○ Content: what was given?	✓	
		○ Delivery method: how was the content given?	✓	
		○ Unit of delivery: how were subjects grouped during delivery?	✓	
		○ Deliverer: who delivered the intervention?	✓	
		○ Setting: where was the intervention delivered?	✓	
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	✓	
		○ Time span: how long was it intended to take to deliver the intervention to each unit?	✓	
○ Activities to increase compliance or adherence (e.g., incentives)	✓			
Objectives	5	• Specific objectives and hypotheses	✓	p.7
Outcomes	6	• Clearly defined primary and secondary outcome measures	✓	p.7 & p.12-13
		• Methods used to collect data and any methods used to enhance the quality of measurements	✓	p.12-13
		• Information on validated instruments such as psychometric and biometric properties	✓	p.12-13
Sample size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	n/a	
Assignment method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	n/a	
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	n/a	
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	n/a	
Blinding (masking)	9	• Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed	n/a	
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	✓	p.13-14
		• If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)	n/a	

TREND Statement Checklist

Statistical methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods for correlated data	✓	p.13-14
		• Statistical methods used for additional analyses, such as subgroup analyses and adjusted analysis	n/a	
		• Methods for imputing missing data, if used	n/a	
		• Statistical software or programs used	✓	p.13-14
RESULTS				
Participant flow	12	• Flow of participants through each stage of the study: enrollment, assignment, allocation and intervention exposure, follow-up, analysis (a diagram is strongly recommended)	✓	p.15 & figure 1
		○ Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	✓	
		○ Assignment: the numbers of participants assigned to a study condition	n/a	
		○ Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	n/a	
		○ Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition	✓	
		○ Analysis: the number of participants included in or excluded from the main analysis, by study condition	✓	
		• Description of protocol deviations from study as planned, along with reasons	n/a	
Recruitment	13	• Dates defining the periods of recruitment and follow-up	✓	Figure 1
Baseline data	14	• Baseline demographic and clinical characteristics of participants in each study condition	✓	p.14-15
		• Baseline characteristics for each study condition relevant to specific disease prevention research	n/a	
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	✓	p.15
		• Comparison between study population at baseline and target population of interest	n/a	
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	n/a	
Numbers analyzed	16	• Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	✓	p.17 (table 3)
		• Indication of whether the analysis strategy was "intention to treat" or, if not, description of how non-compliers were treated in the analyses	✓	p.15
Outcomes and estimation	17	• For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision	✓	p.17 (table 3) – p values rather than confidence intervals
		• Inclusion of null and negative findings	✓	p.17 (table 3)
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	✓	p.18-20
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	n/a	
Adverse events	19	• Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)	n/a	
DISCUSSION				
Interpretation	20	• Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study	✓	p. 20-24
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	✓	p. 20-24
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	✓	p.22-24
		• Discussion of research, programmatic, or policy implications	✓	p.24
Generalizability	21	• Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other	✓	p.23-24 (limitations acknowledged)

TREND Statement Checklist

		contextual issues		
Overall evidence	22	<ul style="list-style-type: none"> General interpretation of the results in the context of current evidence and current theory 	✓	p.20-24

From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: <http://www.cdc.gov/trendstatement/>

For peer review only

BMJ Open

Service evaluation of the GOALS family-based childhood obesity treatment intervention during the first three years of implementation

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-006519.R2
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ABSTRACT

Objectives: To evaluate the impact of the GOALS family-based childhood obesity treatment intervention during the first three years of implementation.

Design: Single-group repeated measures with qualitative questionnaires.

Setting: Community venues in a socio-economically deprived, urban location in the North-West of England.

Participants: 70 overweight or obese children (mean age 10.5 years, 46% boys) and their parents/carers who completed GOALS between September 2006 and March 2009.

Interventions: GOALS was a childhood obesity treatment intervention that drew on social cognitive theory to promote whole family lifestyle change. Sessions covered physical activity (PA), diet and behaviour change over 18 two-hour weekly group sessions (lasting approximately 6 months). A TiDiR checklist of intervention components is provided.

Primary and secondary outcome measures: The primary outcome measure was child BMI z-score, collected at baseline, post-intervention and 12 months. Secondary outcome measures were child self-perceptions, parent/carer BMI and qualitative changes in family diet and PA (parent/carer questionnaire).

Results: Child BMI z-score reduced by 0.07 from baseline to post-intervention ($p < 0.001$) and was maintained at 12 months ($p < 0.05$). There was no change in parent/carer BMI or child self-perceptions, other than an increase in perceived social acceptance from baseline to post-intervention ($p < 0.05$). Parents/carers reported positive changes to family PA and dietary behaviours after completing GOALS.

Conclusions: GOALS completion was associated with small improvements in child BMI z-score and improved family PA and dietary behaviours. Several intervention modifications were necessary

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3 during the implementation period and it is suggested childhood obesity treatment interventions
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5 need time to embed before a definitive evaluation is conducted. Researchers are urged to use the
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7 TIDieR checklist to ensure transparent reporting of interventions and facilitate the translation of
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9 evidence to practice.
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STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study reports ecologically valid data from a childhood obesity treatment intervention as it was delivered in practice. It is the first paper to use the TIDieR checklist to describe a childhood obesity treatment intervention, providing valuable information to assist policy-makers and practitioners wishing to implement interventions in practice.
- As with many service evaluations, this study is limited by a lack of control group and a high attrition rate. It is not therefore known what change might have occurred without intervention or what impact the intervention had for those who did not complete.

INTRODUCTION

Currently 28% of children aged 2-15 years in England are overweight or obese[1]. Children who are obese face psychological[2] and physical[3] health complications in the short-term and are more likely to become obese adults[4]. Since adult obesity is a key risk factor for lifestyle-related morbidity and mortality[5], it is important to develop effective interventions for treating obesity in childhood. Growing evidence supports a family-based approach to childhood obesity treatment that focusses on physical activity (PA), diet and behaviour change (e.g. [6-11]). Bandura's social cognitive theory[12] provides a framework within which to understand the importance of family involvement in children's PA and eating behaviours. The theory posits that behaviour interacts in an ongoing reciprocal manner with personal cognitions and the surrounding environment (triadic reciprocal causation). In children, the cognitions and behaviours of parents/carers also form part of this reciprocal interaction[13], as parents/carers play a key role in both child PA[14] and child eating behaviours[15]. Therefore for children who are overweight to make healthy changes to their PA and diet, changes may also be required in their parents/carers' weight-related cognitions and behaviours.

Despite many childhood obesity treatment interventions using the term "family-based", interventions vary in their level of parent/carer involvement[16]. Some interventions have focussed on parents/carers as the exclusive agents of change[17, 18], others have promoted parent/carer support of the child's behaviour change[7, 19] and others have aimed to change both parent/carer and child behaviours together[20, 21]. Despite the theorised importance of parental role-modelling in child behaviour however[13], none of the aforementioned childhood obesity treatment interventions have involved practical PA sessions for both children and parents/carers together. Evidence from other health promotion settings shows joint parent/carer and child PA sessions can lead to improvements in children's PA levels, both in preschool[22] and primary-school[23] age groups.

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3 Children who are overweight often suffer low self-esteem[2], and one of the key reasons for
4 parents/carers seeking treatment is to improve children's psychological wellbeing[24]. Despite
5 early concerns that an increased focus on weight, diet and PA might heighten weight-related
6 concerns in children[25], recent reviews have found overall positive effects of childhood obesity
7 treatment on self-esteem[6,26]. However the evidence exploring the relationship between child
8 weight change and self-esteem change remains inconclusive, with some studies (e.g.[27]) showing
9 an association between child BMI reduction and increases in self-esteem and others (e.g.[10])
0 finding no association.
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2 Although systematic review evidence supports a multidisciplinary family-based approach to
3 childhood obesity treatment[6], the controlled studies on which systematic reviews are based often
4 lack the external validity and process information required for implementing interventions in
5 practice[28]. During recent years evidence from UK childhood obesity treatment interventions has
6 increased rapidly (e.g.[29-31]), including qualitative insights into reasons for engagement[32,33],
7 comparisons of parent, child and practitioner views[24, 34] and discussions of evaluation
8 methods[35,36]. The poor reporting of intervention components in childhood obesity treatment
9 studies however makes it difficult for decision makers to a) assess transferability of interventions for
0 their local context and b) learn how interventions can feasibly be implemented in practice[37].
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2 Transparent reporting is particularly important during the early stages of a complex intervention, as
3 challenges of delivery and implementation may impact the intervention's effectiveness[38]. Use of
4 tools such as the Template for Intervention Description and Replication (TIDieR) checklist[39] have
5 been advocated to support comparison between studies and facilitate the translation of evidence to
6 practice.
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8 The aim of the current paper is to evaluate a community-based childhood obesity treatment
9 intervention (Getting Our Active Lifestyles Started (GOALS)[9,35,40,41]) that drew on social cognitive
0 theory[12] to encourage healthy lifestyle changes for the whole family. The intervention included
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3 weekly practical PA sessions that involved children, parents/carers, siblings, and other family
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5 members. Previous findings from GOALS showed a positive association between child and
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7 parent/carer Body Mass Index (BMI) reduction, whereby children attending GOALS were more likely
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9 to lose weight if their attending parent/carer also lost weight[9]. This study will evaluate the
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1 impact of GOALS during the first three years of implementation, applying the TIDieR checklist[39] to
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3 describe intervention components. We will report post-intervention (6-month) and 12-month
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5 outcomes, explore qualitative reports of lifestyle changes from parents/carers and assess the
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7 relationship between child BMI z-score change and child self-perception change.
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METHODS

Participants

All families attending GOALS between September 2006 and March 2009 were invited to take part in the study. Children who attended GOALS but were not overweight, had obesity caused or exacerbated through medical conditions or syndromes, had severe learning disabilities, or did not provide baseline data were excluded from the study. Where there was more than one eligible overweight child in the family only the data from the child who was referred to GOALS was included. Demographic information (age, gender, ethnicity, socio-economic status by postcode, parent/carer relationship to child) was collected from participants at baseline.

Intervention (GOALS)

Between 2006 and 2013, Liverpool John Moores University, UK, was commissioned annually (through government grants, local authority and National Health Service (NHS) public health funds) to deliver a childhood obesity treatment service (GOALS) for socio-economically deprived communities in Liverpool. The aim of GOALS was to support families to increase PA and make healthy dietary changes. GOALS was targeted at families with children aged 4-16 years who were

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3 obese (BMI \geq 98th percentile according to the UK 1990 BMI reference charts[42]), although children
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5 were occasionally included who were overweight (BMI \geq 91st percentile). Minimal family unit was
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7 one child plus one adult carer, although siblings and other adult family members were encouraged
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9 to attend.
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2 Twenty-two GOALS interventions were delivered between September 2006 and March 2009. One
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4 intervention was excluded from the study because the children received an additional weekly PA
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6 session, leaving 21 eligible cohorts. Table 1 provides key intervention details, mapped to the TIDieR
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8 checklist[39]. The intervention framework in table 1 remained constant throughout the study.
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0 However the implementation process presented several delivery challenges, and some modifications
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2 were necessary. These included changes to recruitment and assessment processes, delivery venues,
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4 staff roles, counselling support, provision of childcare for younger siblings, support with transport to
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6 venues and support for children who had finished the intervention. Full details of these delivery
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8 issues and resulting modifications are provided in table 2 (TIDieR item 10).
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Table 1. GOALS intervention details. Numbers in parentheses refer to the item number on the TIDieR checklist[39].

Item	Description
Name (1)	GOALS (Getting Our Active Lifestyles Started!)
Why (2)	<p>The aim of GOALS was to promote a healthy weight trajectory in children who were obese, with a focus on supporting the whole family to become more physically active and make healthy changes to their diet.</p> <p>Due to the lack of available evidence when GOALS was founded in 2003, a continuous improvement methodology was used to develop and evaluate the intervention (see[35] for a full outline of this process). The whole family, multidisciplinary approach is supported by international evidence (e.g. [6, 43]).</p> <p>Intervention topics were informed by social cognitive theory ([12, 13]) and the theorised triadic reciprocal causation between environmental, behavioural and cognitive factors. Sessions aimed to enhance the self-efficacy of children and parents/carers for PA and healthy eating by providing positive mastery experiences, reciprocal modelling opportunities, and positive encouragement (see[41] for further details).</p> <p>Dietary objectives:</p> <p>To encourage families to:</p> <ul style="list-style-type: none"> - eat a healthy balanced diet - reduce portion sizes - consume fewer processed foods - cook more meals from fresh - increase fruit and vegetable intake - replace snacks high in fat and sugar with healthier alternatives - reduce the amount of salt and sugar added to food and drink - reduce the frequency of takeaways - increase water consumption - eat regular meals, focussing on breakfast in particular - read food labels and become more aware of what they are eating <p>Physical activity objectives:</p> <p>To encourage families to increase their physical activity through:</p> <ul style="list-style-type: none"> - active transport (e.g. walking to school) - lifestyle activity (e.g. taking stairs instead of lift) - active play (at home, out or with friends) - structured exercise (e.g. Zumba) - sport participation
What – procedure (4)	<p>Children were referred to GOALS through multiple routes, including self-referral in response to promotional activities (e.g. press articles, leaflets, whole school letters) and referral from health professionals in primary or secondary care. In addition from April 2007 children aged 9-10 years were recruited via letters to their parents/carers following participation in a local health and fitness programme in schools (<i>SportsLinx</i>,[44]).</p> <p>Approximately one week before the intervention each family attended a “lifestyle assessment” with an intervention delivery staff member. The purpose of these sessions was to build rapport with families, complete paperwork such as consent and monitoring forms, and to gather information about the family’s PA and dietary habits through an informal interview.</p> <p>The intervention sessions focussed on diet (<i>Fun Foods</i>), physical activity (<i>Move It</i>) and behaviour change and wellbeing (<i>Target Time</i>).</p> <p>Fun Foods: Aimed to equip families with the knowledge and practical skills to incorporate a healthy balanced diet into their lifestyle, based on the NHS Choices <i>eatwell plate</i>[45]. A range of classroom-based and practical sessions addressed topics such as portion sizes, reading food labels and healthy snacking. Families were provided with practical opportunities to develop their cooking skills, and to try out new recipes and foods.</p> <p>Move It: Involved a practical PA session with the aim of improving self-efficacy to be physically active outside the weekly sessions. Sessions aimed to engage the whole family, with a focus on enjoyment and personal achievement rather than competition.</p> <p>Target Time: Supported families to make their lifestyle changes easier through the use of multiple behaviour change techniques (full description of techniques used is available here (INSERT LINK TO SUPPLEMENTARY ONLINE RESOURCE 1) and through promoting and enhancing psychosocial wellbeing. Classroom-based sessions focussed on topics such as hunger and craving, raising self-esteem, dealing with bullying, and parental role-modelling. Each week families were supported to set small, realistic goals focussed on changing their PA and dietary behaviours outside of the structured GOALS sessions.</p> <p>Specific content evolved according to ongoing evaluation. An example timetable is available from the first author (p.m.watson@ljamu.ac.uk).</p>

Item	Description
What - materials (3)	Sessions were supported by a number of informative materials, such as parent/carer and child handbooks, personal log books to track progress and a GOALS cookbook containing healthy recipes to cook at home. Delivery staff were supplied with weekly session plans. Copies of all informative materials are available from the first author (p.m.watson@ljmu.ac.uk). Growth charts and BMI charts were used to monitor child height and weight (available from http://www.childgrowthfoundation.org/).
Who provided (5)	GOALS was designed, delivered and evaluated by a team from Liverpool John Moores University (LJMU), operationally led by the project manager/principal researcher (PW). The team consisted of one senior staff member and several sessional staff for each section (<i>Fun Foods, Move It, Target Time</i>). Both senior and sessional staff were involved in delivering the intervention. Senior staff held postgraduate qualifications in public health nutrition (SB – Fun Foods lead), exercise physiology (KP – Move It lead), health psychology (JH – Target Time lead to April 2008) and sport and exercise psychology (LS – Target Time lead from September 2008) and were responsible for developing the intervention content, delivering sessions and supervising sessional staff in the delivery of sessions. Sessional staff were recruited from a range of backgrounds and were employed part-time to deliver the intervention. For the sessional staff, the following skills and attributes were pre-requisites: <ul style="list-style-type: none"> - minimal vocational qualification for their subject area - an interest in promoting healthy lifestyles - interpersonal skills and the ability to engage groups of different ages and abilities - experience of delivering activities to groups of children and/or families.
How (6)	Interventions were delivered to groups of families, arranged where possible by child age (e.g. 4-7 years, 8-11 years, 12-16 years). Groups ranged from 5-12 families at baseline. Some sessions included parents/carers and children together, but topics involving sensitive discussion (e.g. dealing with bullying) or aimed specifically at parents/carers (e.g. meal planning) were delivered to children and/or parents/carers separately.
Where (7)	Sessions were delivered after school in primary and secondary schools across Liverpool. Liverpool is a city in the North-West of England with approximately 470,780 residents[46] and high levels of socio-economic deprivation[47]. Despite indications that childhood obesity rates have begun to plateau[48], prevalence of childhood obesity in Liverpool remains higher than the national average with 28.6% of 4-5 year olds and 39% of 10-11 year olds overweight or obese[49].
When and how much (8)	<p>Sessions lasted for 2 hours and ran once a week after school (usually 5.30-7.30pm or 6-8pm) during term-time only. During year 1 (Sep 2006-Mar 2007), contact varied between 17,18 and 19 sessions. During years 2 and 3 (April 2007-Mar 2009), the intervention included 18 sessions.</p> <p>Due to the term-time only delivery, interventions varied in duration depending on whether they started during autumn/winter (approximately 5 months) or during spring/summer (approximately 6 months due to the long summer holiday break).</p> <p>Families were invited to individual follow-up sessions 9 months (from April 2007 only) and 12 months after they had started GOALS. These sessions lasted approximately 45 minutes and involved a progress review and height and weight measurements.</p>
Tailoring (9)	<p>Each family was assigned a personal mentor who they met with every few weeks to track their progress. The use of social cognitive theory allowed staff mentors to set weekly goals with families that focussed on either the home environment, parental behaviours/cognitions or child behaviours/cognitions, depending on the underlying cause of the target behaviour. For example, the goal for a family where the child was overeating in response to being bullied might focus on developing coping skills for the child (child cognitions), whereas the goal for a family where the child was overeating because their portions were too large might be for the parent/carer to learn about appropriate child portion sizes (parent/carer cognitions).</p> <p>Provision was made for childcare of younger siblings where required.</p> <p>Taxis were provided for families without transport in 8 of the 21 intervention cohorts.</p>
How well - planned and actual (11, 12)	During the first year, reflective staff meetings were held weekly to ensure the intervention was delivered as intended and to agree actions for the following week. Staff completed a written evaluation after each session to note what worked well, challenges they had faced and ideas for improvement. During the later stages, meetings continued on a six-weekly basis with regular session visits from the project manager. Regular training ensured the GOALS ethos and core framework was understood and practised by all staff.

Table 2. Modifications to the GOALS delivery mechanisms during the study period and lessons learned.

Numbers in parentheses in the first column refer to the item number on the TiDieR checklist[39].

TiDieR item	Modification	Rationale and lessons learned
What – procedure (4)	During Year 1 every child was assessed for underlying causes of obesity and co-morbidities by a community paediatrician. In Year 2, this was replaced with an assessment with a school nurse and later a self-completion form by the parent/carer with recommendations to visit the family GP before starting the intervention.	The available guidelines for treating childhood obesity recommended all children with a BMI \geq 99.6 th percentile be referred to hospital or community paediatric consultants before treatment was considered[50] and a medical assessment be undertaken of presenting symptoms and underlying causes of overweight and obesity, comorbidities and risk factors, and growth and pubertal status[51]. As the majority of children registering for GOALS had a BMI \geq 99.6 th percentile, assessment by community paediatricians proved a time-consuming and costly arrangement, and research suggested these assessments may not be necessary for all obese children[52]. The protocol was therefore replaced by an assessment with a school health practitioner and later a self-completion form by the parent/carer, in which they were signposted to the GP.
Where (7)	Year 1 interventions were delivered in both primary (n=4) and secondary schools (n=3). Year 2 & 3 interventions were delivered in secondary schools only.	Due to the multidisciplinary nature of the intervention, each site required space for PA, facilities for cooking and classrooms for general activities. Primary schools were rarely open during evening hours (and thus incurred costs for site management) and cooking facilities were often limited to the school kitchens. By contrast, secondary schools provided ideal space for group cooking sessions in food technology rooms and were often open during the evening for adult education classes (thus allowing free access).
Who provided (5)	During Year 1, Fun Foods was led by community dietitians (theory-based sessions) and community food workers (practical sessions) employed by the NHS in Liverpool. From Year 2, the employment of all Fun Foods staff was transferred to Liverpool John Moores University. A public health nutritionist delivered the theory-based sessions and food workers continued to deliver practical elements. In September 2008 (mid-Year 3) all food workers were trained to be “nutrition mentors”, responsible for the delivery of both theory-based and practical sessions with ongoing training and supervision from the public health nutritionist.	Little guidance was available outlining the skills required for delivery of healthy eating sessions in the community. Since the intervention focussed on general healthy eating advice rather than individually-prescribed diets, it was established that a public health nutritionist possessed the relevant skills for supervision and quality assurance of the Fun Foods element of the intervention.

TIDieR item	Modification	Rationale and lessons learned
Who provided (5)	A qualified counsellor began working with GOALS in February 2007 (end of Year 1) to provide additional support for children and families where appropriate.	The group session provided little opportunity for children or families to discuss personal issues that may have been affecting their lifestyle change (e.g. if children were being bullied). The GOALS lifestyles counsellor provided an impartial source of support for children or families who needed to talk something through that went beyond the remit of the GOALS staff. Several different ways of working were explored, ranging from informal drop-ins during the weekly session, group sessions about feelings, and fixed appointment times for families either during or outside of the weekly session. Whilst the support was deemed beneficial for families, it proved difficult to sustain financially and the counsellor's involvement ceased a short time after the study period.
Tailoring (9)	During Years 1 & 2, a mobile crèche was provided on site for younger siblings (if required). During Year 3, younger siblings were included in the main programme.	To allow whole families to attend, it was important provision was made for the childcare of younger siblings. Therefore a free crèche was provided for families at the intervention site. However the mobile crèche proved costly given the small number of children who used it, and children often expressed a wish to join in the main group's activities. The option of arranging local child-minders was explored but the families concerned were reluctant to leave their children with an unknown adult. Therefore the most appropriate solution was to accommodate young children within the main session, with an allocated staff member to take them aside for age-appropriate activities where necessary.
Tailoring (9)	The number of interventions in which taxis were provided for families increased with each year (1/7 in Year 1; 3/7 in Year 2; 4/7 in Year 3).	As it was not possible to provide intervention sites in every district of the city, consideration was given to the provision of transport for families who lived further afield. Several options were explored, including reimbursement of public transport expenses for families without a car and arrangement of taxis to and from sessions. It was however a challenge to develop objective criteria for offering these services and there was some concern the arrangement of taxis hindered the lifestyle change process for families. Financial support for transport was ceased after the study period, and staff instead supported families to identify appropriate public transport solutions.
When and how much (8)	A family-based weekly PA session for "GOALS graduates" was piloted between May 2007 (start of Year 2) and July 2008 (mid-Year 3).	Families expressed a wish for continued support beyond the 18-week intervention. However sessions later ceased due to poor attendance and pressure to allocate financial resources to the main intervention.

Key: Year 1 = September 2006-March 2007; Year 2 = April 2007-March 2008; Year 3 = April 2008-March 2009

Outcome measures

BMI (collected from children and parents/carers at baseline, post-intervention and 12 months)

Height and weight measures were taken by PW and senior staff (KP, SO, JH, LS). Weight was recorded to the nearest 0.1kg using a Tanita WB/100MA floor scale. Height was recorded to the nearest 0.1cm using a portable Leicester Height Measure. To control for measurement error staff took two height measures and calculated the mean. If these two measures differed by 1% or more a third measure was taken and the median used. BMI was calculated using the equation $\text{weight(kg)/height(m)}^2$. To account for change in children's ages from baseline, BMI was converted to z-scores based on the 1990 UK Growth Reference curves[42] using LMS Growth Software[53].

Child self-perceptions (collected from children over 8 years at baseline, post-intervention and 12 months)

Child self-perceptions were measured using the Self-Perception Profile for Children (SPPC)[54]. The SPPC is a 36-item validated questionnaire consisting of six subscales measuring global self-esteem plus five specific domains of self-esteem in children. The SPPC is validated for use in children aged over 8 years and has acceptable internal consistency reliabilities for all six subscales (Cronbach's Alpha range .71 to .86). To reduce participant burden, four subscales that have been shown to change through healthy lifestyle intervention[26] were used in the current study (*Social acceptance; Athletic competence; Physical appearance; Global self-esteem*), yielding a questionnaire with 24 items in total (6 in each subscale).

Changes in PA and diet (collected from parents/carers who attended after April 2007 at post-intervention and 12 months)

Parents/carers completed a questionnaire containing four qualitative feedback items that explored changes in their own PA levels, their child's PA levels, their child's confidence and their family's diet. At 12 months, parents/carers were also asked questions about their facilitators and barriers to change. Full questionnaire schedules are available [here](#) (LINK TO SUPPLEMENTARY ONLINE

RESOURCE 2).

Analysis

To account for clustering of children within intervention cohorts, data were first entered into MLwiN version 2.24 (Centre for Multilevel Modelling, Bristol, 2011) to explore the variance contributed by between-cohort differences (comparison of a two-level model (time; child) with a three-level model (time; child; cohort), BMI z-score change as the outcome variable). As inclusion of cohort as a random variable did not improve the fit of the model, data were treated as independent and pooled for analysis in SPSS version 17 (SPSS Inc., 2008). Outcome data is presented for complete cases only. Data was tested for normality using the Kolmogorov-Smirnov test. Paired samples t-tests (normally distributed data) and Wilcoxon signed rank tests (non-parametric data) were used to assess within-subjects change from baseline to post-intervention, and from baseline to 12-month follow up. Pearson correlations were used to measure relationships between child BMI z-score change and child self-perception change, and child BMI z-score change and age. Independent t-tests were used to compare results by gender. Responses to the feedback questionnaires were first coded as "improved", "unchanged" or "declined" (stage 1), then analysed against the GOALS intervention objectives (see table 1) with subsequent inductive analysis to allow new themes to emerge (stage 2). To enhance the credibility of findings, stage 1 analysis was carried out independently by two members of the research team (PW and RM). Inter-rater agreement ranged from 0.80 to 0.91. Stage 2 analysis was carried out by PW, followed by a process of peer scrutiny and discussion to reach a consensus on the final themes.

RESULTS

Baseline characteristics

One hundred and forty-three families were included in the study (143 children (63 boys), 168 parents/carers). According to the 2007 indices of deprivation[55], 92 families lived within the most

Child outcomes

Table 3 shows the BMI z-score and self-perception scores for children at baseline, post-intervention and 12 months. There was a significant decrease in BMI z-score from baseline to post-intervention (-0.07, $p < 0.001$) that was maintained at 12 months for the children who attended follow up (baseline to post -0.09, $p = 0.004$; baseline to 12 months -0.09, $p = 0.041$). Forty-five children provided complete baseline and post-intervention self-perception data (exclusions were due to incomplete questionnaires ($n = 10$), age under 8 years ($n = 6$) and absence when the questionnaires were completed ($n = 9$)). There were small improvements in all self-esteem domains from baseline to post-intervention, though the only change to reach significance was in the social acceptance domain (0.26, $p = 0.028$). There were no significant differences in child outcomes by gender or age.

Correlations between BMI z-score and self-perceptions

There were no correlations between baseline BMI z-score and baseline self-perceptions, or between BMI z-score change and self-perception change at either post-intervention or 12 months. However, the correlation between baseline BMI z-score and perceived social acceptance change from baseline to post-intervention approached significance ($r = .288$, $p = 0.055$), suggesting the most obese children experienced the greatest increase in perceived social acceptance. There were also significant correlations between baseline to *post-intervention* BMI z-score change and baseline to *12-month* self-perception change in two domains (global self-esteem, $r = -.433$, $p < 0.05$; physical appearance, $r = -.423$, $p < 0.05$) and correlations that approached significance in the other two domains (social acceptance, $r = -.380$, $p = 0.061$; athletic competence, $r = -.390$, $p = 0.060$). This indicates the children who lost the most weight during the intervention had the most improved self-perceptions at 12 months.

Parent/carer outcomes

Median BMI did not change between baseline (29.42, interquartile range (IQR) 27.10-35.19, $n = 57$), post-intervention (29.89, IQR 27.12-35.24, $n = 57$) and 12 months (30.91, IQR 26.73-34.63, $n = 33$).

Table 3. Baseline, post-intervention and 12-month child outcomes following completion of GOALS. Means and standard deviations are reported for children with complete baseline and post-intervention data. Outcomes for the subsample who attended 12-month follow up are reported separately.

Measure		n	Baseline	Post-intervention	12 months	Baseline to post-intervention	p	Baseline to 12 months	p
BMI z-score	Complete	70	3.02 (0.60)	2.95 (0.62)	n/a	-0.07*** (0.16)	<0.001	n/a	n/a
	Complete with 12-month follow up	40	2.88 (0.60)	2.79 (0.60)	2.79 (0.66)	-0.09** (0.18)	0.004	-0.09* (0.26)	0.041
PSPP Social Acceptance	Complete	45	2.99 (0.74)	3.26 (0.57)	n/a	0.26* (0.78)	0.028	n/a	n/a
	Complete with 12-month follow up	22	2.97 (0.70)	3.23 (0.57)	2.99 (0.69)	0.26 (0.75)	0.112	0.02 (0.62)	0.905
PSPP Athletic Competence	Complete	45	2.35 (0.66)	2.46 (0.76)	n/a	0.11 (0.65)	0.244	n/a	n/a
	Complete with 12-month follow up	21	2.49 (0.55)	2.65 (0.59)	2.55 (0.66)	0.16 (0.70)	0.315	0.06 (0.63)	0.661
PSPP Physical Appearance	Complete	45	2.04 (0.81)	2.20 (0.77)	n/a	0.16 (0.74)	0.165	n/a	n/a
	Complete with 12-month follow up	21	2.05 (0.64)	2.33 (0.70)	2.35 (0.73)	0.28 (0.74)	0.102	0.31 (0.78)	0.087
PSPP Global Self-Esteem	Complete	45	2.72 (0.80)	2.85 (0.69)	n/a	0.13 (0.74)	0.253	n/a	n/a
	Complete with 12-month follow up	21	2.70 (0.72)	2.89 (0.71)	2.87 (0.69)	0.18 (0.76) [#]	0.218	0.17 (0.98) [#]	0.727

*p value of within-subject effect (paired samples *t*-test) <0.05

**p value of within-subject effect (paired samples *t*-test) <0.01

***p value of within-subject effect (paired samples *t*-test) <0.001

[#]Data not normally distributed, *Wilcoxon signed rank* test used.

Parent/carer-reported changes in family PA and diet

Of 56 parents/carers who completed GOALS after April 2007, 44 completed questionnaires post-intervention and 19 completed questionnaires at 12 months. In some families (two at post-intervention, two at 12 months) two parents/carers completed a questionnaire. Therefore for items related to child or family changes the data from both parents/carers was either combined (where there was agreement) or excluded (where there was disagreement).

Post-intervention changes

A summary of the post-intervention questionnaire responses with example quotes is provided in table 4. None of the parents/carers reported declines in their family's PA and diet behaviours, although there were a few cases where no change was reported (six for parent/carer PA levels, one each for child PA levels, child confidence and family diet). Improvements to parents/carers' own PA levels focussed mostly on structured exercise and walking, whereas in their children they reported examples related to sport participation, active transport, exercise and active play. The majority of parents/carers commented on their child's improved confidence and increased willingness to get involved in PA, although some noted their child still lacked confidence outside of the GOALS setting. In terms of diet, many responses focussed on a healthy balanced diet in general and an increase in fruit and vegetable intake. Examples of healthy choices were provided, such as switching to healthier varieties of foods, introducing new foods or removing high fat foods. Several parents/carers described their child's increased willingness to try new foods.

12-month changes

Positive changes were reported for all children's PA levels, though in one case this was a delayed change not attributed to GOALS (*"my child's activity levels have gone up since moving into high school"*). Improvements in child confidence were maintained for all families (e.g. *"[my son] is more confident in himself and I feel the change he has made will be forever"*). Maintenance levels were slightly lower for parent/carer PA (13/19) and family dietary changes (11/17); although there were a

Table 4. Post-intervention parent/carer-reported changes in family PA and diet. Eligible responses represent the number of responses for each item after accounting for agreement/disagreement between parents/carers from within the same family. For the parent/carer PA levels item, only 41 responses were provided (3 were left blank). Example quotes are provided to illustrate the range of responses for each item in the improved (I) category, plus single examples for the unchanged (U) and un-coded (n/a) categories where applicable.

Questionnaire item	Eligible responses	I	U	D	n/a	Example quotes (category in parentheses)
Parent/carer PA levels	41	34	6	-	1	<p>"[I] regularly attend the gym" (I)</p> <p>"I am a lot more active, I always walk instead of getting a taxi" (I)</p> <p>"[My PA levels have] stayed the same" (U)</p> <p>"Doing Move It has made me realise just how unfit I really am" (n/a)</p>
Child PA levels	42	41	1	-	-	<p>"[My child is] more active, swimming has improved, little more running" (I)</p> <p>"[My son] now goes to cricket, football" (I)</p> <p>"Walk home from school most nights" (I)</p> <p>"[My daughter] plays more physical games" (I)</p> <p>"My son tries much harder now without giving up too soon" (I)</p> <p>"[My child] has increased [PA] to some degree, but have found it difficult to fit in around school/homework" (I)</p> <p>"[My child's PA levels are] the same" (U)</p>
Child confidence	40	36	1	-	3	<p>"[My grandson] doesn't seem to worry so much now about his weight and looks more confident" (I)</p> <p>"[My daughter] is more positive and confident towards exercise" (I)</p> <p>"[My son] has become more involved and will try most things" (I)</p> <p>"My son has always been confident so there has been no change" (U)</p> <p>"My child is positive when he is at GOALS, but still not so in school and around people he doesn't really know" (n/a)</p>
Family diet	40	38	1	-	1	<p>"[We make] a lot more healthier choices at the same cost as before" (I)</p> <p>"[We] eat far more fruit and veg" (I)</p> <p>"Sausage rolls or pies are now a definite 'no no'" (I)</p> <p>"Kids more adventurous with trying new foods" (I)</p> <p>"Not much change as we have always ate fairly healthy" (U)</p> <p>"I have been conscious of eating healthily for some time, but found it difficult to control what [my son] ate outside" (n/a)</p>

Key: I: improved; U: unchanged; D: declined; n/a: un-coded (was not possible to deduce from the response whether there was any change)

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3 further three parents/carers who reported keeping up some, but not all, of their dietary changes (e.g.
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5 *"We have changed a lot of eating habits, but sometimes will fall back and have to start again"*). The
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7 parents/carers who had maintained changes provided examples of healthy behaviours that had
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9 become a way of life for them (e.g. *"we now think before we eat "rubbish" and our diet has improved*
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1 *vastly without too many big changes and it's become a way of life"*), described the acquisition of
2
3 coping skills to prevent relapse (e.g. *"I can feel when I'm getting lazy and I up my walking"*) and the
4
5 formation of healthy routines (e.g. *"we always do an activity as a family once a week"*).

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7 In response to the question about facilitators, parents/carers commented on the importance of
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9 education (e.g. *"GOALS helped me in choosing healthy options and checking labels on food"*), small
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1 attainable changes (e.g. *"the idea that small changes that can be maintained more easily can make a*
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3 *difference to your weight and shape"*), making exercise fun (e.g. *"showing you how to enjoy yourself*
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5 *with your family during exercise"*) and coping skills for maintaining change (e.g. *"the GOALS methods*
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7 *kick in when I start to feel unhealthy"*). Parents/carers also mentioned the enthusiasm and
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9 encouragement from staff, and specific sessions that had helped them such as the portion sizes and
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1 practical cooking sessions.
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7 As most of the families had maintained some changes, very little information was provided on
8
9 barriers. Those who had relapsed said they had done so because of poor health, lack of
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1 time/planning and other commitments. One parent who had struggled to keep up his PA levels
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3 noted the GOALS group session finishing had been a big challenge.
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DISCUSSION

The aim of this paper was to evaluate the impact of the GOALS family-based childhood obesity treatment intervention during the first three years of implementation, applying the TiDieR[39] checklist to describe intervention components. Children completing GOALS demonstrated improvements in BMI z-score that were maintained at 12-month follow up. There was also a small

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3 improvement in perceived social acceptance that was most marked in the children with the highest
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5 baseline BMI z-score, and a moderate correlation between BMI z-score reduction during the
6
7 intervention and improved self-perceptions at 12 months. Whilst there was no change in parental
8
9 BMI, parents/carers reported positive changes to their own and their child's PA and diet.

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12 The mean BMI z-score change (-0.07) for children completing GOALS is consistent with the outcomes
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14 of other evaluations carried out in a service-delivery setting (e.g. [10,56]), yet smaller than that
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16 reported in published randomised controlled trials (RCTs) of UK community-based childhood obesity
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18 treatment interventions (e.g. [7, 11]). Whilst discussion surrounds what constitutes a clinically
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20 important BMI z-score reduction[57], evidence shows that even small reductions in BMI z-score are
21
22 associated with positive improvements to cardiovascular risk factors in obese children[58, 59] and as
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24 such any improvement in BMI z-score should be viewed as a positive intervention outcome[60].

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27 While reviews have found overall positive effects of childhood obesity treatment on self-esteem [6,
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29 26], authors have expressed concern that the increased focus on weight-related behaviours could
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31 have adverse effects on children's self-perceptions[25]. Quantitative data in this study showed little
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33 change in children's self-perceptions, although parents/carers did report qualitative increases in
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35 children's confidence. Whilst children's perceived social acceptance scores were comparable with a
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37 UK-sample of mixed-weight children[61], their scores on the perceived athletic competence and
38
39 physical appearance scales remained low. It is important obesity treatment interventions help
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41 parents/carers understand how they can promote a healthy body image in children, for example
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43 through focussing on healthy behaviours rather than weight and encouraging children to adopt an
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45 identity that goes beyond physical appearance[62].

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48 Whilst child weight loss has previously been linked to increases in self-esteem[27], it is not clear
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50 whether child weight loss increases self-esteem or increased self-esteem facilitates child weight loss,
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52 or both[26]. In the present study BMI z-score change during the intervention was not linked to self-
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54 perception changes over the same period (as also found in[10]), but was inversely associated with
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3 self-perception change from baseline to *12-month follow up*. The fact this relationship was found in
4
5 only one direction (i.e. there was no correlation between self-perception change during the
6
7 intervention and baseline to 12-month BMI z-score change) suggests that weight-loss in the short-
8
9 term may lead to improvements in children's self-perceptions over the longer-term.
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2 A key challenge for childhood obesity treatment is the transition from the safe and supportive group
3
4 environment to long-term behaviour change at home[34]. Although most parents/carers reported
5
6 positive changes to PA and diet that were maintained after finishing GOALS, many parents/carers
7
8 spoke of the tendency to fall back into old habits from time to time. Such cycles of change are
9
0 well-established in the health behaviour literature[63], and data from the current study suggests the
1
2 skills learned at GOALS were used as an effective coping mechanism to prevent full relapse. As
3
4 theorised by the social cognitive framework on which GOALS was based[12,13], family support may
5
6 be important in maintaining healthy behaviours. Previous research from childhood obesity
7
8 treatment shows the most successful families are those who work together to achieve healthy
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0 lifestyle changes[9,24]. GOALS placed a strong emphasis on family involvement through inclusive
1
2 PA sessions for children, parents/carers and siblings and a focus on changing the whole family's
3
4 lifestyle. The success of this whole family engagement was evidenced by the proportion of children
5
6 who attended with at least two other family members (approximately 60%). Although the whole
7
8 family focus did not result in a change in parental BMI (possibly due to the lack of emphasis on
9
0 parental weight loss), the qualitative data suggested parents/carers made changes to their own PA
1
2 levels and to the whole family's dietary habits. The potential for social desirability in these
3
4 parent/carer reports is acknowledged, although it is noteworthy that parent-proxy report has
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6 proved a reliable and valid measure of obesity-specific health-related quality of life elsewhere[64].
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8 Further research is required to understand how interventions can best promote long-term
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0 behavioural change in families.
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3 By mapping the GOALS intervention onto the TIDieR checklist[39], this paper provides a transparent
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5 account of the intervention modifications that were necessary during the study period. Such
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7 “teething problems” are a natural process of complex intervention implementation[38], and
8
9 flexibility is important to tailor interventions to local needs[65]. Yet delivery challenges are rarely
0
1 acknowledged in the research literature, nor consideration given to the potential impact of
2
3 modifications on intervention outcomes. In the current study, the proportion of children who
4
5 reduced BMI z-score during GOALS increased each year (43%, 63% and 80% respectively) and service
6
7 audit data suggests these figures continued to rise after the study period. Whilst there is
8
9 insufficient data to link these improvements to intervention refinements, it is possible that results
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1 from the first year did not reflect the true potential of the intervention. GOALS staff turnover during
2
3 the study period was low (by the final year 12/14 staff had been delivering GOALS for at least two
4
5 years), therefore it is plausible that an increase in staff knowledge and experience positively
6
7 impacted intervention delivery.
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1 Whilst this study provides an important insight into childhood obesity treatment in practice, some
2
3 limitations must be acknowledged. The service level agreement required that GOALS was available
4
5 for all children who were obese within Liverpool, therefore a randomised controlled trial was not
6
7 possible. Whilst other studies of childhood obesity treatment have employed a waiting-list control
8
9 (e.g. [7,19]), GOALS was funded on a year-by-year basis and there was insufficient time to allow for
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1 participant recruitment plus two cycles of the intervention (which would be required for a waiting
2
3 list design). Therefore it is acknowledged that the pre-post design provides no information about
4
5 how children’s BMI z-scores might have changed without intervention (although qualitative data
6
7 does suggest GOALS played a role in changing family PA and dietary behaviours). Future research
8
9 conducted under service level conditions should consider a non-randomised comparison group, such
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1 as children from neighbouring regions not eligible for the intervention (see[35] for a discussion of
2
3 the challenges of conducting research within a service delivery setting). Furthermore, there was a
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5 high attrition rate from the intervention and it is not known whether those who dropped out
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3 achieved any benefits. It was not always possible to attain reasons for drop out, but reported issues
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5 included difficulty with transport, clashes with other commitments (e.g. sports clubs), and adverse
6
7 life events (e.g. relationship breakdown, family illness). The observed attrition rate (48%) is
8
9 comparable to that observed in other childhood obesity treatment interventions[66] and as the
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1 children who completed did not differ from the baseline population, a complete case analysis was
2
3 conducted to explore the impact of the intervention for children who completed GOALS. However it
4
5 is acknowledged these children represented less than 50% of the baseline cohort therefore the
6
7 current results must be interpreted with caution. Finally, the sample was predominantly White-
8
9 British. Results cannot therefore be generalised to other ethnic populations living in the UK, for
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1 whom engagement with childhood obesity treatment interventions may be differentially influenced
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3 by cultural perceptions of obesity[67].
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Conclusions

A key strength of service evaluation is its high ecological validity and capacity to investigate
intervention impact as it is delivered in practice. This study shows the GOALS childhood obesity
treatment intervention supported families to change their PA and dietary behaviours, resulting in
small improvements to children's BMI z-scores. Delivery challenges are inevitable when
implementing a complex intervention, and it is possible the current results were diluted by early
implementation difficulties. Therefore commissioners are encouraged to dedicate long-term
funding to allow childhood obesity treatment interventions time to embed before evaluating their
worth[43]. To support the translation of evidence to practice, researchers are urged to draw on
relevant reporting guidelines (e.g.[39, 68, 69]) to ensure transparency of intervention components,
necessary modifications and evaluation methods. Doing so will enable comparison between
studies and provide vital information for policy-makers and practitioners wishing to implement a
childhood obesity treatment intervention in their locality.

FIGURE LEGENDS

Figure 1: Participant flow through study

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CONTRIBUTORS

PW conducted the study as part of her doctoral degree and drafted the article. TC and LD conceived the study, secured funding and contributed to the analysis and interpretation of data. TC managed the overall project and supervised PW's doctoral programme, along with RM and ZK who both contributed to the analysis and interpretation of data. KP, SO, JH and LS designed the intervention and worked alongside PW to develop it according to ongoing feedback. All authors critically reviewed and contributed to the writing of the paper.

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COMPETING INTERESTS

PW, KP, SO, JH and LS were employed by Liverpool John Moores University to design, deliver and evaluate the GOALS intervention.

ETHICS APPROVAL

Ethical approval was received from the Liverpool NHS Paediatric Research Ethics Committee [05/Q1502/28]. Written informed consent was obtained from parents/carers, and written assent from children over 8 years and deemed capable of understanding.

DATA SHARING STATEMENT

There is descriptive data available for the overweight siblings who completed the intervention, plus other measures that were piloted with subgroups of the study population (e.g. waist-to-height ratio). The authors are willing to share this data with practitioners or researchers interested in the evaluation of family-based childhood obesity treatment interventions (please request from the first author, p.m.watson@ljmu.ac.uk).

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ABSTRACT

Objectives: To evaluate the impact of the GOALS family-based childhood obesity treatment intervention during the first three years of implementation.

Design: Single-group repeated measures with qualitative questionnaires.

Setting: Community venues in a socio-economically deprived, urban location in the North-West of England.

Participants: 70 overweight or obese children (mean age 10.5 years, 46% boys) and their parents/carers who completed GOALS between September 2006 and March 2009.

Interventions: GOALS was a childhood obesity treatment intervention that drew on social cognitive theory to promote whole family lifestyle change. Sessions covered physical activity (PA), diet and behaviour change over 18 two-hour weekly group sessions (lasting approximately 6 months). A TiDiR checklist of intervention components is provided.

Primary and secondary outcome measures: The primary outcome measure was child BMI z-score, collected at baseline, post-intervention and 12 months. Secondary outcome measures were child self-perceptions, parent/carer BMI and qualitative changes in family diet and PA (parent/carer questionnaire).

Results: Child BMI z-score reduced by 0.07 from baseline to post-intervention ($p < 0.001$) and was maintained at 12 months ($p < 0.05$). There was no change in parent/carer BMI or child self-perceptions, other than an increase in perceived social acceptance from baseline to post-intervention ($p < 0.05$). Parents/carers reported positive changes to family PA and dietary behaviours after completing GOALS.

Conclusions: GOALS completion was associated with small improvements in child BMI z-score and improved family PA and dietary behaviours. Several intervention modifications were necessary

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3 during the implementation period and it is suggested childhood obesity treatment interventions
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5 need time to embed before a definitive evaluation is conducted. Researchers are urged to use the
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7 TIDieR checklist to ensure transparent reporting of interventions and facilitate the translation of
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9 evidence to practice.
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STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study reports ecologically valid data from a childhood obesity treatment intervention as it was delivered in practice. It is the first paper to use the TIDieR checklist to describe a childhood obesity treatment intervention, providing valuable information to assist policy-makers and practitioners wishing to implement interventions in practice.
- As with many service evaluations, this study is limited by a lack of control group and a high attrition rate. It is not therefore known what change might have occurred without intervention or what impact the intervention had for those who did not complete.

INTRODUCTION

Currently 28% of children aged 2-15 years in England are overweight or obese[1]. Children who are obese face psychological[2] and physical[3] health complications in the short-term and are more likely to become obese adults[4]. Since adult obesity is a key risk factor for lifestyle-related morbidity and mortality[5], it is important to develop effective interventions for treating obesity in childhood. Growing evidence supports a family-based approach to childhood obesity treatment that focusses on physical activity (PA), diet and behaviour change (e.g. [6-11]). Bandura's social cognitive theory[12] provides a framework within which to understand the importance of family involvement in children's PA and eating behaviours. The theory posits that behaviour interacts in an ongoing reciprocal manner with personal cognitions and the surrounding environment (triadic reciprocal causation). In children, the cognitions and behaviours of parents/carers also form part of this reciprocal interaction[13], as parents/carers play a key role in both child PA[14] and child eating behaviours[15]. Therefore for children who are overweight to make healthy changes to their PA and diet, changes may also be required in their parents/carers' weight-related cognitions and behaviours.

Despite many childhood obesity treatment interventions using the term "family-based", interventions vary in their level of parent/carer involvement[16]. Some interventions have focussed on parents/carers as the exclusive agents of change[17, 18], others have promoted parent/carer support of the child's behaviour change[7, 19] and others have aimed to change both parent/carer and child behaviours together[20, 21]. Despite the theorised importance of parental role-modelling in child behaviour however[13], none of the aforementioned childhood obesity treatment interventions have involved practical PA sessions for both children and parents/carers together. Evidence from other health promotion settings shows joint parent/carer and child PA sessions can lead to improvements in children's PA levels, both in preschool[22] and primary-school[23] age groups.

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3 Children who are overweight often suffer low self-esteem[2], and one of the key reasons for
4 parents/carers seeking treatment is to improve children's psychological wellbeing[24]. Despite
5 early concerns that an increased focus on weight, diet and PA might heighten weight-related
6 concerns in children[25], recent reviews have found overall positive effects of childhood obesity
7 treatment on self-esteem[6,26]. However the evidence exploring the relationship between child
8 weight change and self-esteem change remains inconclusive, with some studies (e.g.[27]) showing
9 an association between child BMI reduction and increases in self-esteem and others (e.g.[10])
0 finding no association.

1 Although systematic review evidence supports a multidisciplinary family-based approach to
2 childhood obesity treatment[6], the controlled studies on which systematic reviews are based often
3 lack the external validity and process information required for implementing interventions in
4 practice[28]. During recent years evidence from UK childhood obesity treatment interventions has
5 increased rapidly (e.g.[29-31]), including qualitative insights into reasons for engagement[32,33],
6 comparisons of parent, child and practitioner views[24, 34] and discussions of evaluation
7 methods[35,36]. The poor reporting of intervention components in childhood obesity treatment
8 studies however makes it difficult for decision makers to a) assess transferability of interventions for
9 their local context and b) learn how interventions can feasibly be implemented in practice[37].

0 Transparent reporting is particularly important during the early stages of a complex intervention, as
1 challenges of delivery and implementation may impact the intervention's effectiveness[38]. Use of
2 tools such as the Template for Intervention Description and Replication (TIDieR) checklist[39] have
3 been advocated to support comparison between studies and facilitate the translation of evidence to
4 practice.

5 The aim of the current paper is to evaluate a community-based childhood obesity treatment
6 intervention (Getting Our Active Lifestyles Started (GOALS)[9,35,40,41]) that drew on social cognitive
7 theory[12] to encourage healthy lifestyle changes for the whole family. The intervention included
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3 weekly practical PA sessions that involved children, parents/carers, siblings, and other family
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5 members. Previous findings from GOALS showed a positive association between child and
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7 parent/carer Body Mass Index (BMI) reduction, whereby children attending GOALS were more likely
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9 to lose weight if their attending parent/carer also lost weight[9]. This study will evaluate the
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1 impact of GOALS during the first three years of implementation, applying the TIDieR checklist[39] to
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3 describe intervention components. We will report post-intervention (6-month) and 12-month
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5 outcomes, explore qualitative reports of lifestyle changes from parents/carers and assess the
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7 relationship between child BMI z-score change and child self-perception change.
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METHODS

Participants

All families attending GOALS between September 2006 and March 2009 were invited to take part in the study. Children who attended GOALS but were not overweight, had obesity caused or exacerbated through medical conditions or syndromes, had severe learning disabilities, or did not provide baseline data were excluded from the study. Where there was more than one eligible overweight child in the family only the data from the child who was referred to GOALS was included. Demographic information (age, gender, ethnicity, socio-economic status by postcode, parent/carer relationship to child) was collected from participants at baseline.

Intervention (GOALS)

Between 2006 and 2013, Liverpool John Moores University, UK, was commissioned annually (through government grants, local authority and National Health Service (NHS) public health funds) to deliver a childhood obesity treatment service (GOALS) for socio-economically deprived communities in Liverpool. The aim of GOALS was to support families to increase PA and make healthy dietary changes. GOALS was targeted at families with children aged 4-16 years who were

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3 obese (BMI \geq 98th percentile according to the UK 1990 BMI reference charts[42]), although children
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5 were occasionally included who were overweight (BMI \geq 91st percentile). Minimal family unit was
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7 one child plus one adult carer, although siblings and other adult family members were encouraged
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9 to attend.
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2 Twenty-two GOALS interventions were delivered between September 2006 and March 2009. One
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4 intervention was excluded from the study because the children received an additional weekly PA
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6 session, leaving 21 eligible cohorts. Table 1 provides key intervention details, mapped to the TIDieR
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8 checklist[39]. The intervention framework in table 1 remained constant throughout the study.
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0 However the implementation process presented several delivery challenges, and some modifications
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2 were necessary. These included changes to recruitment and assessment processes, delivery venues,
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4 staff roles, counselling support, provision of childcare for younger siblings, support with transport to
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6 venues and support for children who had finished the intervention. Full details of these delivery
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8 issues and resulting modifications are provided in table 2 (TIDieR item 10).
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Table 1. GOALS intervention details. Numbers in parentheses refer to the item number on the TIDieR checklist[39].

Item	Description
Name (1)	GOALS (Getting Our Active Lifestyles Started!)
Why (2)	<p>The aim of GOALS was to promote a healthy weight trajectory in children who were obese, with a focus on supporting the whole family to become more physically active and make healthy changes to their diet.</p> <p>Due to the lack of available evidence when GOALS was founded in 2003, a continuous improvement methodology was used to develop and evaluate the intervention (see[35] for a full outline of this process). The whole family, multidisciplinary approach is supported by international evidence (e.g. [6, 43]).</p> <p>Intervention topics were informed by social cognitive theory ([12, 13]) and the theorised triadic reciprocal causation between environmental, behavioural and cognitive factors. Sessions aimed to enhance the self-efficacy of children and parents/carers for PA and healthy eating by providing positive mastery experiences, reciprocal modelling opportunities, and positive encouragement (see[41] for further details).</p> <p>Dietary objectives:</p> <p>To encourage families to:</p> <ul style="list-style-type: none"> - eat a healthy balanced diet - reduce portion sizes - consume fewer processed foods - cook more meals from fresh - increase fruit and vegetable intake - replace snacks high in fat and sugar with healthier alternatives - reduce the amount of salt and sugar added to food and drink - reduce the frequency of takeaways - increase water consumption - eat regular meals, focussing on breakfast in particular - read food labels and become more aware of what they are eating <p>Physical activity objectives:</p> <p>To encourage families to increase their physical activity through:</p> <ul style="list-style-type: none"> - active transport (e.g. walking to school) - lifestyle activity (e.g. taking stairs instead of lift) - active play (at home, out or with friends) - structured exercise (e.g. Zumba) - sport participation
What – procedure (4)	<p>Children were referred to GOALS through multiple routes, including self-referral in response to promotional activities (e.g. press articles, leaflets, whole school letters) and referral from health professionals in primary or secondary care. In addition from April 2007 children aged 9-10 years were recruited via letters to their parents/carers following participation in a local health and fitness programme in schools (<i>SportsLinx</i>,[44]).</p> <p>Approximately one week before the intervention each family attended a “lifestyle assessment” with an intervention delivery staff member. The purpose of these sessions was to build rapport with families, complete paperwork such as consent and monitoring forms, and to gather information about the family’s PA and dietary habits through an informal interview.</p> <p>The intervention sessions focussed on diet (<i>Fun Foods</i>), physical activity (<i>Move It</i>) and behaviour change and wellbeing (<i>Target Time</i>).</p> <p>Fun Foods: Aimed to equip families with the knowledge and practical skills to incorporate a healthy balanced diet into their lifestyle, based on the NHS Choices <i>eatwell plate</i>[45]. A range of classroom-based and practical sessions addressed topics such as portion sizes, reading food labels and healthy snacking. Families were provided with practical opportunities to develop their cooking skills, and to try out new recipes and foods.</p> <p>Move It: Involved a practical PA session with the aim of improving self-efficacy to be physically active outside the weekly sessions. Sessions aimed to engage the whole family, with a focus on enjoyment and personal achievement rather than competition.</p> <p>Target Time: Supported families to make their lifestyle changes easier through the use of multiple behaviour change techniques (full description of techniques used is available here (INSERT LINK TO SUPPLEMENTARY ONLINE RESOURCE 1) and through promoting and enhancing psychosocial wellbeing. Classroom-based sessions focussed on topics such as hunger and craving, raising self-esteem, dealing with bullying, and parental role-modelling. Each week families were supported to set small, realistic goals focussed on changing their PA and dietary behaviours outside of the structured GOALS sessions.</p> <p>Specific content evolved according to ongoing evaluation. An example timetable is available from the first author (p.m.watson@ljmu.ac.uk).</p>

Item	Description
What - materials (3)	Sessions were supported by a number of informative materials, such as parent/carer and child handbooks, personal log books to track progress and a GOALS cookbook containing healthy recipes to cook at home. Delivery staff were supplied with weekly session plans. Copies of all informative materials are available from the first author (p.m.watson@ljmu.ac.uk). Growth charts and BMI charts were used to monitor child height and weight (available from http://www.childgrowthfoundation.org/).
Who provided (5)	GOALS was designed, delivered and evaluated by a team from Liverpool John Moores University (LJMU), operationally led by the project manager/principal researcher (PW). The team consisted of one senior staff member and several sessional staff for each section (<i>Fun Foods, Move It, Target Time</i>). Both senior and sessional staff were involved in delivering the intervention. Senior staff held postgraduate qualifications in public health nutrition (SB – Fun Foods lead), exercise physiology (KP – Move It lead), health psychology (JH – Target Time lead to April 2008) and sport and exercise psychology (LS – Target Time lead from September 2008) and were responsible for developing the intervention content, delivering sessions and supervising sessional staff in the delivery of sessions. Sessional staff were recruited from a range of backgrounds and were employed part-time to deliver the intervention. For the sessional staff, the following skills and attributes were pre-requisites: <ul style="list-style-type: none"> - minimal vocational qualification for their subject area - an interest in promoting healthy lifestyles - interpersonal skills and the ability to engage groups of different ages and abilities - experience of delivering activities to groups of children and/or families.
How (6)	Interventions were delivered to groups of families, arranged where possible by child age (e.g. 4-7 years, 8-11 years, 12-16 years). Groups ranged from 5-12 families at baseline. Some sessions included parents/carers and children together, but topics involving sensitive discussion (e.g. dealing with bullying) or aimed specifically at parents/carers (e.g. meal planning) were delivered to children and/or parents/carers separately.
Where (7)	Sessions were delivered after school in primary and secondary schools across Liverpool. Liverpool is a city in the North-West of England with approximately 470,780 residents[46] and high levels of socio-economic deprivation[47]. Despite indications that childhood obesity rates have begun to plateau[48], prevalence of childhood obesity in Liverpool remains higher than the national average with 28.6% of 4-5 year olds and 39% of 10-11 year olds overweight or obese[49].
When and how much (8)	<p>Sessions lasted for 2 hours and ran once a week after school (usually 5.30-7.30pm or 6-8pm) during term-time only. During year 1 (Sep 2006-Mar 2007), contact varied between 17,18 and 19 sessions. During years 2 and 3 (April 2007-Mar 2009), the intervention included 18 sessions.</p> <p>Due to the term-time only delivery, interventions varied in duration depending on whether they started during autumn/winter (approximately 5 months) or during spring/summer (approximately 6 months due to the long summer holiday break).</p> <p>Families were invited to individual follow-up sessions 9 months (from April 2007 only) and 12 months after they had started GOALS. These sessions lasted approximately 45 minutes and involved a progress review and height and weight measurements.</p>
Tailoring (9)	<p>Each family was assigned a personal mentor who they met with every few weeks to track their progress. The use of social cognitive theory allowed staff mentors to set weekly goals with families that focussed on either the home environment, parental behaviours/cognitions or child behaviours/cognitions, depending on the underlying cause of the target behaviour. For example, the goal for a family where the child was overeating in response to being bullied might focus on developing coping skills for the child (child cognitions), whereas the goal for a family where the child was overeating because their portions were too large might be for the parent/carer to learn about appropriate child portion sizes (parent/carer cognitions).</p> <p>Provision was made for childcare of younger siblings where required.</p> <p>Taxis were provided for families without transport in 8 of the 21 intervention cohorts.</p>
How well - planned and actual (11, 12)	During the first year, reflective staff meetings were held weekly to ensure the intervention was delivered as intended and to agree actions for the following week. Staff completed a written evaluation after each session to note what worked well, challenges they had faced and ideas for improvement. During the later stages, meetings continued on a six-weekly basis with regular session visits from the project manager. Regular training ensured the GOALS ethos and core framework was understood and practised by all staff.

Table 2. Modifications to the GOALS delivery mechanisms during the study period and lessons learned.

Numbers in parentheses in the first column refer to the item number on the TiDieR checklist[39].

TiDieR item	Modification	Rationale and lessons learned
What – procedure (4)	During Year 1 every child was assessed for underlying causes of obesity and co-morbidities by a community paediatrician. In Year 2, this was replaced with an assessment with a school nurse and later a self-completion form by the parent/carer with recommendations to visit the family GP before starting the intervention.	The available guidelines for treating childhood obesity recommended all children with a BMI \geq 99.6 th percentile be referred to hospital or community paediatric consultants before treatment was considered[50] and a medical assessment be undertaken of presenting symptoms and underlying causes of overweight and obesity, comorbidities and risk factors, and growth and pubertal status[51]. As the majority of children registering for GOALS had a BMI \geq 99.6 th percentile, assessment by community paediatricians proved a time-consuming and costly arrangement, and research suggested these assessments may not be necessary for all obese children[52]. The protocol was therefore replaced by an assessment with a school health practitioner and later a self-completion form by the parent/carer, in which they were signposted to the GP.
Where (7)	Year 1 interventions were delivered in both primary (n=4) and secondary schools (n=3). Year 2 & 3 interventions were delivered in secondary schools only.	Due to the multidisciplinary nature of the intervention, each site required space for PA, facilities for cooking and classrooms for general activities. Primary schools were rarely open during evening hours (and thus incurred costs for site management) and cooking facilities were often limited to the school kitchens. By contrast, secondary schools provided ideal space for group cooking sessions in food technology rooms and were often open during the evening for adult education classes (thus allowing free access).
Who provided (5)	During Year 1, Fun Foods was led by community dietitians (theory-based sessions) and community food workers (practical sessions) employed by the NHS in Liverpool. From Year 2, the employment of all Fun Foods staff was transferred to Liverpool John Moores University. A public health nutritionist delivered the theory-based sessions and food workers continued to deliver practical elements. In September 2008 (mid-Year 3) all food workers were trained to be “nutrition mentors”, responsible for the delivery of both theory-based and practical sessions with ongoing training and supervision from the public health nutritionist.	Little guidance was available outlining the skills required for delivery of healthy eating sessions in the community. Since the intervention focussed on general healthy eating advice rather than individually-prescribed diets, it was established that a public health nutritionist possessed the relevant skills for supervision and quality assurance of the Fun Foods element of the intervention.

TIDieR item	Modification	Rationale and lessons learned
Who provided (5)	A qualified counsellor began working with GOALS in February 2007 (end of Year 1) to provide additional support for children and families where appropriate.	The group session provided little opportunity for children or families to discuss personal issues that may have been affecting their lifestyle change (e.g. if children were being bullied). The GOALS lifestyles counsellor provided an impartial source of support for children or families who needed to talk something through that went beyond the remit of the GOALS staff. Several different ways of working were explored, ranging from informal drop-ins during the weekly session, group sessions about feelings, and fixed appointment times for families either during or outside of the weekly session. Whilst the support was deemed beneficial for families, it proved difficult to sustain financially and the counsellor's involvement ceased a short time after the study period.
Tailoring (9)	During Years 1 & 2, a mobile crèche was provided on site for younger siblings (if required). During Year 3, younger siblings were included in the main programme.	To allow whole families to attend, it was important provision was made for the childcare of younger siblings. Therefore a free crèche was provided for families at the intervention site. However the mobile crèche proved costly given the small number of children who used it, and children often expressed a wish to join in the main group's activities. The option of arranging local child-minders was explored but the families concerned were reluctant to leave their children with an unknown adult. Therefore the most appropriate solution was to accommodate young children within the main session, with an allocated staff member to take them aside for age-appropriate activities where necessary.
Tailoring (9)	The number of interventions in which taxis were provided for families increased with each year (1/7 in Year 1; 3/7 in Year 2; 4/7 in Year 3).	As it was not possible to provide intervention sites in every district of the city, consideration was given to the provision of transport for families who lived further afield. Several options were explored, including reimbursement of public transport expenses for families without a car and arrangement of taxis to and from sessions. It was however a challenge to develop objective criteria for offering these services and there was some concern the arrangement of taxis hindered the lifestyle change process for families. Financial support for transport was ceased after the study period, and staff instead supported families to identify appropriate public transport solutions.
When and how much (8)	A family-based weekly PA session for "GOALS graduates" was piloted between May 2007 (start of Year 2) and July 2008 (mid-Year 3).	Families expressed a wish for continued support beyond the 18-week intervention. However sessions later ceased due to poor attendance and pressure to allocate financial resources to the main intervention.

Key: Year 1 = September 2006-March 2007; Year 2 = April 2007-March 2008; Year 3 = April 2008-March 2009

Outcome measures

BMI (collected from children and parents/carers at baseline, post-intervention and 12 months)

Height and weight measures were taken by PW and senior staff (KP, SO, JH, LS). Weight was recorded to the nearest 0.1kg using a Tanita WB/100MA floor scale. Height was recorded to the nearest 0.1cm using a portable Leicester Height Measure. To control for measurement error staff took two height measures and calculated the mean. If these two measures differed by 1% or more a third measure was taken and the median used. BMI was calculated using the equation $\text{weight(kg)/height(m)}^2$. To account for change in children's ages from baseline, BMI was converted to z-scores based on the 1990 UK Growth Reference curves[42] using LMS Growth Software[53].

Child self-perceptions (collected from children over 8 years at baseline, post-intervention and 12 months)

Child self-perceptions were measured using the Self-Perception Profile for Children (SPPC)[54]. The SPPC is a 36-item validated questionnaire consisting of six subscales measuring global self-esteem plus five specific domains of self-esteem in children. The SPPC is validated for use in children aged over 8 years and has acceptable internal consistency reliabilities for all six subscales (Cronbach's Alpha range .71 to .86). To reduce participant burden, four subscales that have been shown to change through healthy lifestyle intervention[26] were used in the current study (*Social acceptance; Athletic competence; Physical appearance; Global self-esteem*), yielding a questionnaire with 24 items in total (6 in each subscale).

Changes in PA and diet (collected from parents/carers who attended after April 2007 at post-intervention and 12 months)

Parents/carers completed a questionnaire containing four qualitative feedback items that explored changes in their own PA levels, their child's PA levels, their child's confidence and their family's diet. At 12 months, parents/carers were also asked questions about their facilitators and barriers to change. Full questionnaire schedules are available [here \(LINK TO SUPPLEMENTARY ONLINE](#)

RESOURCE 2).

Analysis

To account for clustering of children within intervention cohorts, data were first entered into MLwiN version 2.24 (Centre for Multilevel Modelling, Bristol, 2011) to explore the variance contributed by between-cohort differences (comparison of a two-level model (time; child) with a three-level model (time; child; cohort), BMI z-score change as the outcome variable). As inclusion of cohort as a random variable did not improve the fit of the model, data were treated as independent and pooled for analysis in SPSS version 17 (SPSS Inc., 2008). Outcome data is presented for complete cases only.

Data was tested for normality using the Kolmogorov-Smirnov test. Paired samples t-tests (normally distributed data) and Wilcoxon signed rank tests (non-parametric data) were used to assess within-subjects change from baseline to post-intervention, and from baseline to 12-month follow up. Pearson correlations were used to measure relationships between child BMI z-score change and child self-perception change, and child BMI z-score change and age. Independent t-tests were used to compare results by gender. Responses to the feedback questionnaires were first coded as "improved", "unchanged" or "declined" (stage 1), then analysed against the GOALS intervention objectives (see table 1) with subsequent inductive analysis to allow new themes to emerge (stage 2). To enhance the credibility of findings, stage 1 analysis was carried out independently by two members of the research team (PW and RM). Inter-rater agreement ranged from 0.80 to 0.91. Stage 2 analysis was carried out by PW, followed by a process of peer scrutiny and discussion to reach a consensus on the final themes.

RESULTS

Baseline characteristics

One hundred and forty-three families were included in the study (143 children (63 boys), 168 parents/carers). According to the 2007 indices of deprivation[55], 92 families lived within the most

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3 10% deprived neighbourhoods in England, 34 in the 11-50% most deprived and 17 in the least 50%
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5 deprived. Mean child age was 10.4±2.2 years (range 4.7-16.0 years) and mean BMI z-score was
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7 3.0±0.57 (range 1.53-4.73). One hundred and eight children were superobese (BMI ≥ 99.6th
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9 percentile), 29 children were obese (BMI ≥ 98th percentile) and 6 children were overweight (BMI ≥
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1 91st percentile) according to the 1990 UK Growth Reference data[42]. Ethnicity data was provided
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3 for 79 children, 67 of whom were white-British, 2 white-other background, 3 mixed race, 3 black-
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5 British, 1 Asian and 3 from other backgrounds. Whilst this ethnic profile is representative of the
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7 Liverpool population, it is less diverse than the national population in England and Wales, where
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9 there is a higher proportion of ethnic minority groups[46]. Of the 168 parents/carers taking part,
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1 120 were mothers, 34 fathers, 13 other relations (7 grandmothers, 3 adult siblings, 1 aunt, 2 other
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3 carers) and 1 unknown.
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Participant flow through study (see figure 1)

Seventy-four families (74 children, 81 parents/carers) completed the intervention (at least 50% attendance and still attending at the end of the intervention). Median attendance for these families was 83.3%. Families were included in the complete case analysis if the overweight child in the family had complete baseline and post-intervention (6-month) BMI data. If a child was excluded from the analysis, their parents/carers were also excluded. Of the 74 children who completed, three were excluded (two had no post-BMI data, the third lost weight due to a medically-prescribed diet), leaving 71 children for analysis. One further child's data was removed, as his BMI z-score change from baseline to post-intervention (-0.71) was over three standard deviations greater than the sample mean. Therefore the complete case analysis included 70 children (32 boys), with 58 parents/carers (43 mothers, 13 fathers, 2 other) providing complete baseline and post-intervention BMI data. One father was excluded due to following a very low calorie diet plan independent of GOALS, leaving 57 parents/carers in the BMI analysis (6 healthy weight, 24 overweight, 27 obese). The characteristics of the 70 complete child cases were comparable to those of the whole cohort at baseline, with a mean age of 10.5±2.1 years and a mean BMI z-score of 3.02±0.60.

Child outcomes

Table 3 shows the BMI z-score and self-perception scores for children at baseline, post-intervention and 12 months. There was a significant decrease in BMI z-score from baseline to post-intervention (-0.07, $p < 0.001$) that was maintained at 12 months for the children who attended follow up (baseline to post -0.09, $p = 0.004$; baseline to 12 months -0.09, $p = 0.041$). Forty-five children provided complete baseline and post-intervention self-perception data (exclusions were due to incomplete questionnaires ($n = 10$), age under 8 years ($n = 6$) and absence when the questionnaires were completed ($n = 9$)). There were small improvements in all self-esteem domains from baseline to post-intervention, though the only change to reach significance was in the social acceptance domain (0.26, $p = 0.028$). There were no significant differences in child outcomes by gender or age.

Correlations between BMI z-score and self-perceptions

There were no correlations between baseline BMI z-score and baseline self-perceptions, or between BMI z-score change and self-perception change at either post-intervention or 12 months. However, the correlation between baseline BMI z-score and perceived social acceptance change from baseline to post-intervention approached significance ($r = .288$, $p = 0.055$), suggesting the most obese children experienced the greatest increase in perceived social acceptance. There were also significant correlations between baseline to *post-intervention* BMI z-score change and baseline to *12-month* self-perception change in two domains (global self-esteem, $r = -.433$, $p < 0.05$; physical appearance, $r = -.423$, $p < 0.05$) and correlations that approached significance in the other two domains (social acceptance, $r = -.380$, $p = 0.061$; athletic competence, $r = -.390$, $p = 0.060$). This indicates the children who lost the most weight during the intervention had the most improved self-perceptions at 12 months.

Parent/carer outcomes

Median BMI did not change between baseline (29.42, interquartile range (IQR) 27.10-35.19, $n = 57$), post-intervention (29.89, IQR 27.12-35.24, $n = 57$) and 12 months (30.91, IQR 26.73-34.63, $n = 33$).

Table 3. Baseline, post-intervention and 12-month child outcomes following completion of GOALS. Means and standard deviations are reported for children with complete baseline and post-intervention data. Outcomes for the subsample who attended 12-month follow up are reported separately.

Measure		n	Baseline	Post-intervention	12 months	Baseline to post-intervention	p	Baseline to 12 months	p
BMI z-score	Complete	70	3.02 (0.60)	2.95 (0.62)	n/a	-0.07*** (0.16)	<0.001	n/a	n/a
	Complete with 12-month follow up	40	2.88 (0.60)	2.79 (0.60)	2.79 (0.66)	-0.09** (0.18)	0.004	-0.09* (0.26)	0.041
PSPP Social Acceptance	Complete	45	2.99 (0.74)	3.26 (0.57)	n/a	0.26* (0.78)	0.028	n/a	n/a
	Complete with 12-month follow up	22	2.97 (0.70)	3.23 (0.57)	2.99 (0.69)	0.26 (0.75)	0.112	0.02 (0.62)	0.905
PSPP Athletic Competence	Complete	45	2.35 (0.66)	2.46 (0.76)	n/a	0.11 (0.65)	0.244	n/a	n/a
	Complete with 12-month follow up	21	2.49 (0.55)	2.65 (0.59)	2.55 (0.66)	0.16 (0.70)	0.315	0.06 (0.63)	0.661
PSPP Physical Appearance	Complete	45	2.04 (0.81)	2.20 (0.77)	n/a	0.16 (0.74)	0.165	n/a	n/a
	Complete with 12-month follow up	21	2.05 (0.64)	2.33 (0.70)	2.35 (0.73)	0.28 (0.74)	0.102	0.31 (0.78)	0.087
PSPP Global Self-Esteem	Complete	45	2.72 (0.80)	2.85 (0.69)	n/a	0.13 (0.74)	0.253	n/a	n/a
	Complete with 12-month follow up	21	2.70 (0.72)	2.89 (0.71)	2.87 (0.69)	0.18 (0.76) [#]	0.218	0.17 (0.98) [#]	0.727

*p value of within-subject effect (paired samples *t*-test) <0.05

**p value of within-subject effect (paired samples *t*-test) <0.01

***p value of within-subject effect (paired samples *t*-test) <0.001

[#]Data not normally distributed, *Wilcoxon signed rank* test used.

Parent/carer-reported changes in family PA and diet

Of 56 parents/carers who completed GOALS after April 2007, 44 completed questionnaires post-intervention and 19 completed questionnaires at 12 months. In some families (two at post-intervention, two at 12 months) two parents/carers completed a questionnaire. Therefore for items related to child or family changes the data from both parents/carers was either combined (where there was agreement) or excluded (where there was disagreement).

Post-intervention changes

A summary of the post-intervention questionnaire responses with example quotes is provided in table 4. None of the parents/carers reported declines in their family's PA and diet behaviours, although there were a few cases where no change was reported (six for parent/carer PA levels, one each for child PA levels, child confidence and family diet). Improvements to parents/carers' own PA levels focussed mostly on structured exercise and walking, whereas in their children they reported examples related to sport participation, active transport, exercise and active play. The majority of parents/carers commented on their child's improved confidence and increased willingness to get involved in PA, although some noted their child still lacked confidence outside of the GOALS setting. In terms of diet, many responses focussed on a healthy balanced diet in general and an increase in fruit and vegetable intake. Examples of healthy choices were provided, such as switching to healthier varieties of foods, introducing new foods or removing high fat foods. Several parents/carers described their child's increased willingness to try new foods.

12-month changes

Positive changes were reported for all children's PA levels, though in one case this was a delayed change not attributed to GOALS (*"my child's activity levels have gone up since moving into high school"*). Improvements in child confidence were maintained for all families (e.g. *"[my son] is more confident in himself and I feel the change he has made will be forever"*). Maintenance levels were slightly lower for parent/carer PA (13/19) and family dietary changes (11/17); although there were a

Table 4. Post-intervention parent/carer-reported changes in family PA and diet. Eligible responses represent the number of responses for each item after accounting for agreement/disagreement between parents/carers from within the same family. For the parent/carer PA levels item, only 41 responses were provided (3 were left blank). Example quotes are provided to illustrate the range of responses for each item in the improved (I) category, plus single examples for the unchanged (U) and un-coded (n/a) categories where applicable.

Questionnaire item	Eligible responses	I	U	D	n/a	Example quotes (category in parentheses)
Parent/carer PA levels	41	34	6	-	1	<p>"[I] regularly attend the gym" (I)</p> <p>"I am a lot more active, I always walk instead of getting a taxi" (I)</p> <p>"[My PA levels have] stayed the same" (U)</p> <p>"Doing Move It has made me realise just how unfit I really am" (n/a)</p>
Child PA levels	42	41	1	-	-	<p>"[My child is] more active, swimming has improved, little more running" (I)</p> <p>"[My son] now goes to cricket, football" (I)</p> <p>"Walk home from school most nights" (I)</p> <p>"[My daughter] plays more physical games" (I)</p> <p>"My son tries much harder now without giving up too soon" (I)</p> <p>"[My child] has increased [PA] to some degree, but have found it difficult to fit in around school/homework" (I)</p> <p>"[My child's PA levels are] the same" (U)</p>
Child confidence	40	36	1	-	3	<p>"[My grandson] doesn't seem to worry so much now about his weight and looks more confident" (I)</p> <p>"[My daughter] is more positive and confident towards exercise" (I)</p> <p>"[My son] has become more involved and will try most things" (I)</p> <p>"My son has always been confident so there has been no change" (U)</p> <p>"My child is positive when he is at GOALS, but still not so in school and around people he doesn't really know" (n/a)</p>
Family diet	40	38	1	-	1	<p>"[We make] a lot more healthier choices at the same cost as before" (I)</p> <p>"[We] eat far more fruit and veg" (I)</p> <p>"Sausage rolls or pies are now a definite 'no no'" (I)</p> <p>"Kids more adventurous with trying new foods" (I)</p> <p>"Not much change as we have always ate fairly healthy" (U)</p> <p>"I have been conscious of eating healthily for some time, but found it difficult to control what [my son] ate outside" (n/a)</p>

Key: I: improved; U: unchanged; D: declined; n/a: un-coded (was not possible to deduce from the response whether there was any change)

further three parents/carers who reported keeping up some, but not all, of their dietary changes (e.g. *"We have changed a lot of eating habits, but sometimes will fall back and have to start again"*). The parents/carers who had maintained changes provided examples of healthy behaviours that had become a way of life for them (e.g. *"we now think before we eat "rubbish" and our diet has improved vastly without too many big changes and it's become a way of life"*), described the acquisition of coping skills to prevent relapse (e.g. *"I can feel when I'm getting lazy and I up my walking"*) and the formation of healthy routines (e.g. *"we always do an activity as a family once a week"*).

In response to the question about facilitators, parents/carers commented on the importance of education (e.g. *"GOALS helped me in choosing healthy options and checking labels on food"*), small attainable changes (e.g. *"the idea that small changes that can be maintained more easily can make a difference to your weight and shape"*), making exercise fun (e.g. *"showing you how to enjoy yourself with your family during exercise"*) and coping skills for maintaining change (e.g. *"the GOALS methods kick in when I start to feel unhealthy"*). Parents/carers also mentioned the enthusiasm and encouragement from staff, and specific sessions that had helped them such as the portion sizes and practical cooking sessions.

As most of the families had maintained some changes, very little information was provided on barriers. Those who had relapsed said they had done so because of poor health, lack of time/planning and other commitments. One parent who had struggled to keep up his PA levels noted the GOALS group session finishing had been a big challenge.

DISCUSSION

The aim of this paper was to evaluate the impact of the GOALS family-based childhood obesity treatment intervention during the first three years of implementation, applying the TIDieR[39] checklist to describe intervention components. Children completing GOALS demonstrated improvements in BMI z-score that were maintained at 12-month follow up. There was also a small

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3 improvement in perceived social acceptance that was most marked in the children with the highest
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5 baseline BMI z-score, and a moderate correlation between BMI z-score reduction during the
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7 intervention and improved self-perceptions at 12 months. Whilst there was no change in parental
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9 BMI, parents/carers reported positive changes to their own and their child's PA and diet.
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3 The mean BMI z-score change (-0.07) for children completing GOALS is consistent with the outcomes
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5 of other evaluations carried out in a service-delivery setting (e.g. [10,56]), yet smaller than that
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7 reported in published randomised controlled trials (RCTs) of UK community-based childhood obesity
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9 treatment interventions (e.g. [7, 11]). Whilst discussion surrounds what constitutes a clinically
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1 important BMI z-score reduction[57], evidence shows that even small reductions in BMI z-score are
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3 associated with positive improvements to cardiovascular risk factors in obese children[58, 59] and as
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5 such any improvement in BMI z-score should be viewed as a positive intervention outcome[60].
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0 While reviews have found overall positive effects of childhood obesity treatment on self-esteem [6,
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2 26], authors have expressed concern that the increased focus on weight-related behaviours could
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4 have adverse effects on children's self-perceptions[25]. Quantitative data in this study showed little
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6 change in children's self-perceptions, although parents/carers did report qualitative increases in
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8 children's confidence. Whilst children's perceived social acceptance scores were comparable with a
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0 UK-sample of mixed-weight children[61], their scores on the perceived athletic competence and
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2 physical appearance scales remained low. It is important obesity treatment interventions help
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4 parents/carers understand how they can promote a healthy body image in children, for example
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6 through focussing on healthy behaviours rather than weight and encouraging children to adopt an
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8 identity that goes beyond physical appearance[62].
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2 Whilst child weight loss has previously been linked to increases in self-esteem[27], it is not clear
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4 whether child weight loss increases self-esteem or increased self-esteem facilitates child weight loss,
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6 or both[26]. In the present study BMI z-score change during the intervention was not linked to self-
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8 perception changes over the same period (as also found in[10]), but was inversely associated with
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3 self-perception change from baseline to *12-month follow up*. The fact this relationship was found in
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5 only one direction (i.e. there was no correlation between self-perception change during the
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7 intervention and baseline to 12-month BMI z-score change) suggests that weight-loss in the short-
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9 term may lead to improvements in children's self-perceptions over the longer-term.
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3 A key challenge for childhood obesity treatment is the transition from the safe and supportive group
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5 environment to long-term behaviour change at home[34]. Although most parents/carers reported
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7 positive changes to PA and diet that were maintained after finishing GOALS, many parents/carers
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9 spoke of the tendency to fall back into old habits from time to time. Such cycles of change are
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1 well-established in the health behaviour literature[63], and data from the current study suggests the
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3 skills learned at GOALS were used as an effective coping mechanism to prevent full relapse. As
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5 theorised by the social cognitive framework on which GOALS was based[12,13], family support may
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7 be important in maintaining healthy behaviours. Previous research from childhood obesity
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9 treatment shows the most successful families are those who work together to achieve healthy
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1 lifestyle changes[9,24]. GOALS placed a strong emphasis on family involvement through inclusive
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3 PA sessions for children, parents/carers and siblings and a focus on changing the whole family's
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5 lifestyle. The success of this whole family engagement was evidenced by the proportion of children
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7 who attended with at least two other family members (approximately 60%). Although the whole
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9 family focus did not result in a change in parental BMI (possibly due to the lack of emphasis on
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1 parental weight loss), the qualitative data suggested parents/carers made changes to their own PA
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3 levels and to the whole family's dietary habits. The potential for social desirability in these
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5 parent/carer reports is acknowledged, although it is noteworthy that parent-proxy report has
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7 proved a reliable and valid measure of obesity-specific health-related quality of life elsewhere[64].
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9 Further research is required to understand how interventions can best promote long-term
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1 behavioural change in families.
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3 By mapping the GOALS intervention onto the TIDieR checklist[39], this paper provides a transparent
4 account of the intervention modifications that were necessary during the study period. Such
5 “teething problems” are a natural process of complex intervention implementation[38], and
6 flexibility is important to tailor interventions to local needs[65]. Yet delivery challenges are rarely
7 acknowledged in the research literature, nor consideration given to the potential impact of
8 modifications on intervention outcomes. In the current study, the proportion of children who
9 reduced BMI z-score during GOALS increased each year (43%, 63% and 80% respectively) and service
0 audit data suggests these figures continued to rise after the study period. Whilst there is
1 insufficient data to link these improvements to intervention refinements, it is possible that results
2 from the first year did not reflect the true potential of the intervention. GOALS staff turnover during
3 the study period was low (by the final year 12/14 staff had been delivering GOALS for at least two
4 years), therefore it is plausible that an increase in staff knowledge and experience positively
5 impacted intervention delivery.

6
7 Whilst this study provides an important insight into childhood obesity treatment in practice, some
8 limitations must be acknowledged. The service level agreement required that GOALS was available
9 for all children who were obese within Liverpool, therefore a randomised controlled trial was not
0 possible. Whilst other studies of childhood obesity treatment have employed a waiting-list control
1 (e.g. [7,19]), GOALS was funded on a year-by-year basis and there was insufficient time to allow for
2 participant recruitment plus two cycles of the intervention (which would be required for a waiting
3 list design). Therefore it is acknowledged that the pre-post design provides no information about
4 how children’s BMI z-scores might have changed without intervention (although qualitative data
5 does suggest GOALS played a role in changing family PA and dietary behaviours). Future research
6 conducted under service level conditions should consider a non-randomised comparison group, such
7 as children from neighbouring regions not eligible for the intervention (see[35] for a discussion of
8 the challenges of conducting research within a service delivery setting). Furthermore, there was a
9 high attrition rate from the intervention and it is not known whether those who dropped out
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3 achieved any benefits. It was not always possible to attain reasons for drop out, but reported issues
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5 included difficulty with transport, clashes with other commitments (e.g. sports clubs), and adverse
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7 life events (e.g. relationship breakdown, family illness). The observed attrition rate (48%) is
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9 comparable to that observed in other childhood obesity treatment interventions[66] and as the
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1 children who completed did not differ from the baseline population, a complete case analysis was
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3 conducted to explore the impact of the intervention for children who completed GOALS. However it
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5 is acknowledged these children represented less than 50% of the baseline cohort therefore the
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7 current results must be interpreted with caution. Finally, the sample was predominantly White-
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9 British. Results cannot therefore be generalised to other ethnic populations living in the UK, for
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1 whom engagement with childhood obesity treatment interventions may be differentially influenced
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3 by cultural perceptions of obesity[67].
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Conclusions

A key strength of service evaluation is its high ecological validity and capacity to investigate
intervention impact as it is delivered in practice. This study shows the GOALS childhood obesity
treatment intervention supported families to change their PA and dietary behaviours, resulting in
small improvements to children's BMI z-scores. Delivery challenges are inevitable when
implementing a complex intervention, and it is possible the current results were diluted by early
implementation difficulties. Therefore commissioners are encouraged to dedicate long-term
funding to allow childhood obesity treatment interventions time to embed before evaluating their
worth[43]. To support the translation of evidence to practice, researchers are urged to draw on
relevant reporting guidelines (e.g.[39, 68, 69]) to ensure transparency of intervention components,
necessary modifications and evaluation methods. Doing so will enable comparison between
studies and provide vital information for policy-makers and practitioners wishing to implement a
childhood obesity treatment intervention in their locality.

FIGURE LEGENDS

Figure 1: Participant flow through study

ACKNOWLEDGEMENTS

We would like to thank Liz Lamb, Jamuna Acharya and Ruwan De Soysa for their support in the strategic management of the GOALS project; Nicola Eccles, Shirley Judd, Lisa Newson, Hazel Cheung and Phil Casey for their contribution to the early development of the GOALS intervention (prior to the study period); and not least the families who participated in GOALS, staff who delivered the intervention, school health team who provided medical support and schools who provided use of their facilities.

CONTRIBUTORS

PW conducted the study as part of her doctoral degree and drafted the article. TC and LD conceived the study, secured funding and contributed to the analysis and interpretation of data. TC managed the overall project and supervised PW's doctoral programme, along with RM and ZK who both contributed to the analysis and interpretation of data. KP, SO, JH and LS designed the intervention and worked alongside PW to develop it according to ongoing feedback. All authors critically reviewed and contributed to the writing of the paper.

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COMPETING INTERESTS

PW, KP, SO, JH and LS were employed by Liverpool John Moores University to design, deliver and evaluate the GOALS intervention.

ETHICS APPROVAL

Ethical approval was received from the Liverpool NHS Paediatric Research Ethics Committee [05/Q1502/28]. Written informed consent was obtained from parents/carers, and written assent from children over 8 years and deemed capable of understanding.

DATA SHARING STATEMENT

There is descriptive data available for the overweight siblings who completed the intervention, plus other measures that were piloted with subgroups of the study population (e.g. waist-to-height ratio). The authors are willing to share this data with practitioners or researchers interested in the evaluation of family-based childhood obesity treatment interventions (please request from the first author, p.m.watson@ljmu.ac.uk).

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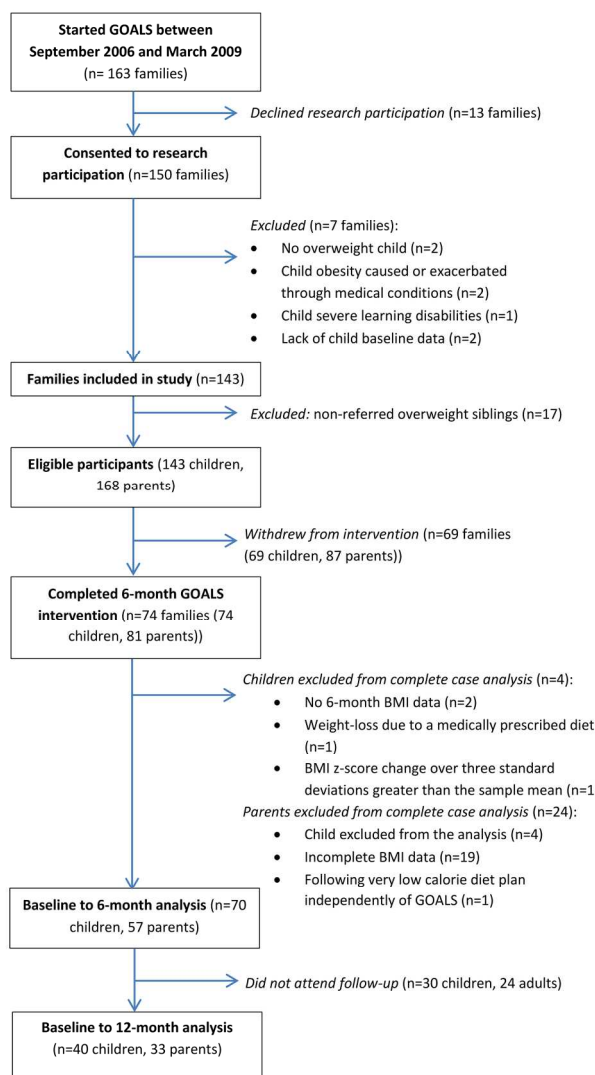


Figure 1: Participant flow through study

Figure 1: Participant flow through study
139x233mm (300 x 300 DPI)

Supplementary Online Resource 1

Most frequently used behaviour change techniques (BCTs) at GOALS and examples of their application. Figures refer to the corresponding number on Michie et al.'s (2011) CALO-RE taxonomy[1].

BCT	Examples of application
Provide information about consequences of behaviour in general (1)	Written information about benefits of physical activity/healthy eating and dangers of being overweight in handbooks; Giving verbal information about physical activity/diet and health during group and one to one sessions.
Provide information on consequences of behaviour to the individual (2)	Going through the BMI and growth charts, showing parents the extent of their child's obesity and explaining the risks their child faces unless something changes; Decisional balance during Target Time session; Talking about positive outcomes of change during mentor/goal setting sessions (e.g. "eating breakfast will give you more energy in the morning").
Provide normative information about others' behaviour (4)	Giving messages during group and one to one sessions to help families understand they are not alone (e.g. "most children in the UK do not get enough physical activity") and support the health messages given (e.g. "we have seen most success with families who really put in the effort at home").
Goal setting (5, 6)	Setting long and medium-term goals with families. These may focus both on outcomes and behaviours.
Action planning (7)	Setting specific weekly goals with each family (i.e. what will be done, where and when).
Barrier identification/problem solving (8)	Target Time session on addressing barriers to healthy lifestyles; Problem solving when setting goals with families, e.g. If someone is struggling asking "what is stopping you doing this and how can it be overcome?"
Set graded tasks (9)	Breaking medium and long-term goals down into small manageable steps (e.g. if target is to reduce from 2 bags of crisps a day to 1 bag a week, the first step might be to reduce to 1 bag a day).
Prompt review of goals (10, 11)	Following up families to review their goals on a weekly basis; Six-weekly mentor sessions to review weight outcomes and overall progress.
Provide rewards contingent on successful behaviour (13)	Allocating points when a weekly goal is achieved (points add up to earn tangible rewards).

BCT	Examples of application
Prompting generalisation of a target behaviour (15)	Mastering new cooking skills at GOALS, then setting a goal to try cooking the same meal at home; Signposting families to local physical activity sessions.
Prompt self-monitoring of behaviour (16)	Food diaries as part of initial assessment; Asking families to write down their progress towards their weekly goals.
Prompting focus on past success (18)	Increasing confidence by asking families to think of a time they have successfully carried out a behaviour or made a change. Used particularly during Target Time sessions towards start of programme.
Provide feedback on performance (19)	Feedback from food diaries; Providing specific verbal feedback when reviewing weekly goals; Providing feedback during Move It or Fun Foods sessions to correct technique, or confirm that an action is being performed correctly.
Provide instruction on how to perform the behaviour (21)	Teaching people how to read food labels or plan meals; Providing written advice and tips in handbooks; Teaching skills related to physical activity.
Model/demonstrate the behaviour (22)	Demonstrating technique and showing how to play games during Move It; Staff as role-models.e.g. Showing a willingness to try new foods, joining in Move It.
Environmental restructuring (24)	Discuss ways of restructuring the home environment to support change – e.g. put gym clothes out ready for the morning, have bowl of fruit on the table, remove tempting foods from house etc.
Agree behavioural contract (25)	Asking families to sign a “promise sheet” during their final mentor session, outlining specific behaviours they will continue.
Prompt practice (26)	Weekly goal setting is aimed at habit formation. Each goal is continued to prompt practice until it comes more easily.
Use of follow up prompts (27)	Post-intervention family follow ups; Newsletters and invites to events or to take part in GOALS activities; Ad hoc phone calls to families.
Facilitate social comparison (28)	Weekly group sessions provide opportunity to mix with others “in the same boat”; Move It sessions – comparison of own sporting/PA ability with that of others. Also provides opportunity for parents to compare their own children to other overweight children (visually and behaviourally).

BCT	Examples of application
Plan social support/social change (29)	Whole family approach; Weekly goals aimed at involving non-attending family members (particularly if their actions are acting as a barrier to progress); Encouraging group to attend local activities together and help each other out (e.g. Provision of lifts).
Prompt identification as a role model (30)	Parents encouraged to look at their own physical activity, diet and weight-related behaviours; Target Time session on positive role-modelling and supporting information in handbook; Parent discussion groups to allow sharing of ideas (i.e. “what worked for them”).
Prompt anticipated regret (31)	Managing expectations during group and one to one sessions – e.g. 18 weeks sounds a long time now but it will pass quickly so it is important to make the most of this opportunity, it is only going to become more difficult to address the obesity as children get older etc.
Fear arousal (32)	Visual demonstration of amount of fat and sugar in popular foods; Use of replica fat and models of clogging arteries to explain risks of obesity and physical inactivity.
Prompt self-talk (33)	Encouraging families to replace negative thoughts with more helpful thoughts (e.g. “I may not feel like exercising now, but I know it’ll make me feel better”). Used particularly during Target Time session about addressing barriers.
Relapse prevention/coping planning (35)	Discussions during mentor chats to identify potential challenges in maintaining changed behaviours, identifying coping strategies throughout programme.
Motivational interviewing (37)*	<i>Trained staff used core skills of motivational interviewing throughout (e.g. empathy, rolling with resistance), particularly during one to one sessions.</i>
Time management (38)	Discussing how families can free up time for physical activity; Group session with parents on planning meals in advance.

*Target Time staff were trained in motivational interviewing, but no formal training was provided for other staff.

Reference

1. Michie S, Ashford S, Sniehotta FF, Dombrowski SU, Bishop A, French DP. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy. *Psychol Health* 2011;26(11):1479-98.

Supplementary Online Resource 2

Parent feedback questions asked post-intervention and at 12-month follow up (via written questionnaire)

Theme	Post-intervention	12-month follow up
Parent physical activity	How do your activity levels <u>now</u> compare to your activity levels <u>before you came to GOALS</u> ? Please describe anything that is different.	How do your activity levels <u>now</u> compare to your activity levels <u>before you came to GOALS</u> ? Please describe anything that is different. How do your activity levels <u>now</u> compare to your activity levels <u>immediately after GOALS finished</u> ? If there are differences, what are the reasons for these?
Child physical activity	How do you feel <u>your child's</u> activity levels compare to their activity levels before GOALS?	How do you feel <u>your child's</u> activity levels compare to their activity levels before, and immediately after, GOALS?
Child confidence	Have you noticed any changes in your child's confidence and attitude to physical activity since coming to GOALS (either positive or negative)?	Have you noticed any changes in your child's confidence and attitude to physical activity since finishing GOALS (either positive or negative)?
Family diet	How do your family's eating habits <u>now</u> compare to your eating habits <u>before you came to GOALS</u> ? Please describe anything that is different.	How do your family's eating habits <u>now</u> compare to your eating habits <u>before you came to GOALS</u> ? Please describe anything that is different. How do your family's eating habits <u>now</u> compare to your eating habits <u>immediately after GOALS finished</u> ? If there are differences, what are the reasons for these?
Facilitators/barriers		If you have continued with your healthy lifestyle, what was it about GOALS that prepared you to do this? If you have not managed to keep up as healthy a lifestyle as you'd have liked, what do you feel has prevented you? If there are differences, how could we have helped?



Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME	(refer to page numbers on revised Word manuscript)	
1.	Provide the name or a phrase that describes the intervention.	p.9 (table 1)	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	p.9 (table 1)	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	p.10 (table 1)	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	p.9 (table 1) & p.11 (table 2)	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	p.10 (table 1) & p.11-12 (table 2)	_____
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	p.10 (table 1)	_____

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WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	p.10 (table 1) & p.11 (table 2)
WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	p.10 (table 1) & p.12 (table 2)
TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	p.10 (table 1) & p.12 (table 2)
MODIFICATIONS		
10.*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	p.11-12 (table 2)
HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	p.10 (table 1)
12.*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	p.10 (table 1)

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

1 * The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of
2 studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the
3 TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**.
4 When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013**
5 **Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see
6 www.equator-network.org).
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TREND Statement Checklist

Paper Section/Topic	Item No.	Descriptor	Reported?	
			✓	Pg #
TITLE and ABSTRACT				(refer to page numbers on revised Word manuscript)
Title and Abstract	1	• Information on how units were allocated to interventions	n/a	
		• Structured abstract recommended	✓	p. 3
		• Information on target population or study sample	✓	p. 3
INTRODUCTION				
Background	2	• Scientific background and explanation of rationale	✓	p. 5-7
		• Theories used in designing behavioral interventions	✓	p. 5
METHODS				
Participants	3	• Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)	✓	p.7-8
		• Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented	✓	p.7-8 & p.9 (table 1)
		• Recruitment setting	✓	p. 9 (table 1)
		• Settings and locations where the data were collected		Not specified due to space limitations. Data was collected at intervention sites.
Interventions	4	• Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:	✓	p.9-10 (table 1) See TIDieR checklist also.
		○ Content: what was given?	✓	
		○ Delivery method: how was the content given?	✓	
		○ Unit of delivery: how were subjects grouped during delivery?	✓	
		○ Deliverer: who delivered the intervention?	✓	
		○ Setting: where was the intervention delivered?	✓	
		○ Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?	✓	
		○ Time span: how long was it intended to take to deliver the intervention to each unit?	✓	
○ Activities to increase compliance or adherence (e.g., incentives)	✓			
Objectives	5	• Specific objectives and hypotheses	✓	p.7
Outcomes	6	• Clearly defined primary and secondary outcome measures	✓	p.7 & p.12-13
		• Methods used to collect data and any methods used to enhance the quality of measurements	✓	p.12-13
		• Information on validated instruments such as psychometric and biometric properties	✓	p.12-13
Sample size	7	• How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	n/a	
Assignment method	8	• Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)	n/a	
		• Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)	n/a	
		• Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)	n/a	
Blinding (masking)	9	• Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed	n/a	
Unit of Analysis	10	• Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)	✓	p.13-14
		• If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)	n/a	

TREND Statement Checklist

Statistical methods	11	• Statistical methods used to compare study groups for primary methods outcome(s), including complex methods for correlated data	✓	p.13-14
		• Statistical methods used for additional analyses, such as subgroup analyses and adjusted analysis	n/a	
		• Methods for imputing missing data, if used	n/a	
		• Statistical software or programs used	✓	p.13-14
RESULTS				
Participant flow	12	• Flow of participants through each stage of the study: enrollment, assignment, allocation and intervention exposure, follow-up, analysis (a diagram is strongly recommended)	✓	p.15 & figure 1
		○ Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study	✓	
		○ Assignment: the numbers of participants assigned to a study condition	n/a	
		○ Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention	n/a	
		○ Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition	✓	
		○ Analysis: the number of participants included in or excluded from the main analysis, by study condition	✓	
		• Description of protocol deviations from study as planned, along with reasons	n/a	
Recruitment	13	• Dates defining the periods of recruitment and follow-up	✓	Figure 1
Baseline data	14	• Baseline demographic and clinical characteristics of participants in each study condition	✓	p.14-15
		• Baseline characteristics for each study condition relevant to specific disease prevention research	n/a	
		• Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	✓	p.15
		• Comparison between study population at baseline and target population of interest	n/a	
Baseline equivalence	15	• Data on study group equivalence at baseline and statistical methods used to control for baseline differences	n/a	
Numbers analyzed	16	• Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	✓	p.17 (table 3)
		• Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	✓	p.15
Outcomes and estimation	17	• For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision	✓	p.17 (table 3) – p values rather than confidence intervals
		• Inclusion of null and negative findings	✓	p.17 (table 3)
		• Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any	✓	p.18-20
Ancillary analyses	18	• Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory	n/a	
Adverse events	19	• Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)	n/a	
DISCUSSION				
Interpretation	20	• Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study	✓	p. 20-24
		• Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	✓	p. 20-24
		• Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	✓	p.22-24
		• Discussion of research, programmatic, or policy implications	✓	p.24
Generalizability	21	• Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other	✓	p.23-24 (limitations acknowledged)

TREND Statement Checklist

		contextual issues		
Overall evidence	22	<ul style="list-style-type: none"> General interpretation of the results in the context of current evidence and current theory 	✓	p.20-24

From: Des Jarlais, D. C., Lyles, C., Crepaz, N., & the Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *American Journal of Public Health*, 94, 361-366. For more information, visit: <http://www.cdc.gov/trendstatement/>

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