Evaluating the transferability of a hospital-based childhood obesity clinic to primary care: a randomised controlled trial

**INTRODUCTION**

While the prevalence of childhood obesity may be levelling off, one in five 11 year olds remain obese. A recent Cochrane Review highlighted the lack of evidence for effective weight-management programmes for childhood obesity. The Care Of Childhood Obesity (COCO) clinic at the Bristol Royal Hospital for Children (BRHC) is an established service that uses a multicomponent-team approach in consultations with children and families. This clinic has previously reported that 83% of children improve their body mass index standard deviation scores (BMI SDS) during 12 months therapy. Similar clinic models for managing childhood obesity remain scarce, and most children with obesity have limited or no access to services able to address their health needs. Primary care clinics (PCCs) are likely to be more accessible and would reduce pressure on greatly oversubscribed hospital clinics, allowing secondary care physicians to deal with children with associated comorbidities or requiring pharmacotherapy. However, research among primary care practitioners has identified a degree of ambivalence as to whether primary care has the resources or expertise to deal with this problem.

This pilot randomised controlled trial (RCT) examined the clinical efficacy of a nurse-led PCC compared with a consultant-led secondary care service at BRHC. The feasibility for a fully powered trial was assessed using a number of outcomes, including: (a) the clinical suitability of patients referred to receive PCC-based care; (b) the willingness of families to be randomised to PCCs; and (c) the degree to which families randomised to PCCs engaged with the service.

**METHOD**

Participants and setting

Children aged 5–16 years with a body mass index (BMI) ≥98th centile were referred by GPs to the consultant in charge of the COCO clinic at BRHC. Referred children were clinically screened for suitability and invited into the study. Consenting families were randomised to BRHC or a primary care clinic (PCC) and offered five appointments over 12 months. Clinical effectiveness was measured by change in body mass index standard deviation score (BMI SDS) at 12 months. Other measures included: treatment adherence, quality of life (QOL), and satisfaction. Feasibility was examined by assessing referral, screening, and recruitment data.

**RESULTS**

A total of 152 patients were referred by GPs: 31 (20%) were screened out; 45 (30%) declined to participate. Seventy-six (50%) patients were randomised and 68 provided baseline data (PCC = 42; BRHC = 26). S2 provided outcome data (PCC = 29; BRHC = 23). Mean change in BMI SDS was PCC: –0.17 (95% confidence interval [CI] = –0.27 to –0.07), BRHC: –0.15 [95% CI] = –0.26 to –0.03. QOL, adherence, and satisfaction data indicated similar positive patterns in both trials.

**Conclusion**

Screening and recruitment data indicate that primary care is a clinically appropriate setting and acceptable to families. The primary clinical outcome measure (reduction in BMI SDS) along with secondary outcome measures, indicate that primary care has the potential to be effective in providing weight management for children, using the COCO model.

**Keywords**

obesity; childhood; general practice; primary care; body weight, management.
the local primary care research network. The surgery was paid NHS service support cost rates for room use. The south Bristol clinic was based in a community health park, where recruitment was facilitated through the close relationship between the health park and an adjoining GP surgery which is part of the local primary care research network. As child obesity was one of the strategic targets of the health park, the room space was provided free of charge.

Randomisation
A ‘minimisation method’ was used to balance groups with respect to sex and age (primary or secondary school age at entry), with separate lists for the designated north and south Bristol participants. The initial allocation ratio was 1:1 but was changed to 2:1 after 5 months to ensure more patients were assigned to PCC rather than hospital, thus ensuring maximum information was obtained regarding transferring the service to PCC. New randomisation lists were set up at this point. Randomisation was undertaken by an independent statistician.

Intervention
The PCCs were led by practice nurses employed by Bristol PCT, who also provided governance for the PCCs. Nurse salaries and training costs were paid by NHS service support costs.

Nurse training involved: (1) shadowing the clinical team at the COCO outpatient clinic at BRHC on three occasions [each clinic ran for 4 hours], thus enabling the nurses to sit in with all members of the multidisciplinary team (doctor, specialist obesity nurse, dietitian, exercise specialist) on each of their three visits; (2) attendance at a one-off, secondary care workshop run by a specialist obesity nurse; (3) study packs given to nurses, to read in their own time, which included guidance on obesity management from the National Institute for Health and Clinical Excellence,7 and the Department of Health care pathway for primary care management,8 along with other literature and the background to the COCO clinic itself.4,10 and (4) familiarisation with standard operating procedures for clinical practice written by COCO clinicians and research staff.

During the first year of the study, the nurse based at the north clinic moved away from the area and the nurse from the south clinic then covered both clinics for the remainder of the study. The nurse-led clinics included an exercise specialist and a dietitian, both of whom also worked in the COCO clinic at BRHC; their time at the PCCs was paid as a research cost. PCCs were largely autonomous but clinical responsibility resided with the COCO consultant and project principal investigator. In practice, clinical advice was minimal (<10 contacts between nurses and consultant throughout the study).

PCC patients were offered five appointments over 12 months: an initial visit and four further appointments at 3-monthly intervals. At each appointment, the family saw the practice nurse, who weighed and measured the child, plotting the data on growth charts. The nurse discussed overall progress, focusing on factors that facilitated or inhibited weight reduction. The family then saw the dietitian and exercise consultant for specialist advice.

Patients attending the BRHC clinic had an initial consultation with the COCO consultant. They were offered a further four COCO appointments over a 1-year period at 3-monthly intervals, where they would also see a dietitian and/or exercise specialist as directed by the consultant.

Weight in kilograms and height in centimetres were recorded to one decimal place. In PCCs, measures were taken with portable Tanita floor scales (WB 100 S MA, Tanita Europe BV, The Netherlands) and the Seca Leicester stadiometer (Seca UK). In BRHC, measures were recorded on Seca scales (model M861, Seca UK).

Exercise and dietetic consultations
These followed the same pattern in both arms. Exercise consultations were underpinned by a sociocognitive approach,11 taking into account social factors and specific family issues, along with the needs/wishes of the child. The emphasis was on developing strategies and activities that were enjoyable, fostered an effort–benefit return, and developed confidence that could be supported by the
family. Age-specific approaches were used in recognition of developmental stage, with parents being the key determinants of behaviour in children aged under 10 years; the role of peers coming to the fore in early adolescence; and independent decision making in later adolescence. Dietetic consultations used a similar approach and made use of educational tools such as the ‘Eatwell plate’.

Outcomes
A range of process measures were monitored, including: criteria for patients being screened out; reasons for study non-participation (to establish whether a significant number of families preferred to be seen in secondary care); reasons for non-adherence to treatment; and did-not-attend rates between the study arms.

The primary outcome measure was change in BMI SDS at 12 months. BMI was adjusted for age and sex to give a BMI SDS score using the LMSGrowth, a Microsoft Excel add-in based on 1990 growth reference data from the Child Growth Foundation.

Secondary outcomes were: (1) quality-of-life scores using the Pediatric Quality of Life Scale (PedsQL); (2) satisfaction with care using an adapted instrument, developed from a similar study in primary care, and the General Practice Assessment Questionnaire. Satisfaction was measured in relation to ‘consultations’ (six-item scale that considered interaction of clinical team with participants), ‘appointments’ (four-item scale that considered organisation of appointments including waiting time), and ‘access’ (six-item scale that considered how easy the clinics were to access in terms of travel and location). Each scale was scored from 1 = excellent to 6 = very poor.

Sample size
As this was a feasibility study, it was not powered to achieve statistical significance for the primary clinical outcome. It was anticipated that 100 participants could be recruited over a 1-year period.

Statistical methods
The primary clinical outcome was the change in BMI SDS at 12 months. Mean (standard deviation) of the changes was calculated for each group, together with the difference between the mean changes and a two-sided 95% confidence interval (CI) for the difference. Linear models were used to explore the influence of other factors on the group mean difference.

Table 1. Reasons for exclusions and declining participation

<table>
<thead>
<tr>
<th>Screening for clinical comorbidity and recruitment criteria</th>
<th>Excluded, n (%)</th>
<th>Declined participation</th>
<th>Declined, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetic</td>
<td>8 (5)</td>
<td>Unable to contact</td>
<td>17 (11)</td>
</tr>
<tr>
<td>Endocrine</td>
<td>9 (6)</td>
<td>Declined via contact reply form</td>
<td>13 (9)</td>
</tr>
<tr>
<td>Type 2 diabetes, parental</td>
<td>7 (5)</td>
<td>Preference to see doctor/attend hospital</td>
<td>6 (4)</td>
</tr>
<tr>
<td>Obesity comorbidity</td>
<td>2 (1)</td>
<td>Access problems at PCC</td>
<td>4 (3)</td>
</tr>
<tr>
<td>Overt eating disorder</td>
<td>2 (1)</td>
<td>Unwilling to participate in research</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Iatrogenic</td>
<td>1 (&lt;1)</td>
<td>Unwilling to attend any clinic</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Outside age range</td>
<td>2 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>31 (20)</td>
<td>Total</td>
<td>45 (30)</td>
</tr>
</tbody>
</table>

*Denominator for percentages is total referred, n = 152. PCC = primary care clinic.
With baseline differences in BMI SDS observed between the groups (Table 2), 12-month comparisons were explored further using covariate adjustment for baseline, rather than calculating simple changes; results were very similar (data are not shown). A $\chi^2$ test was used to compare withdrawal rates between the two groups, and a two-sample t-test was used to compare change in mean PedsQL.

### RESULTS

Recruitment took place between April 2008 and May 2009. Figure 1 shows participant flow through the trial.

**Recruitment**

One-hundred and fifty-two children were referred by GPs. Thirty-one (20%) patients were screened out: 29 for suspected clinical comorbidities and two were outside the age range for the study (Table 1, Figure 1). Between 1 April 2008 and 1 November 2008, patients whose referral form indicated parental type 2 diabetes were not invited into the study but received usual care, which included a full oral glucose tolerance test at BRHC. Following a clinical review of the COCO clinic, the investigators concluded that the risk of type 2 diabetes for such children was minimal, and children referred subsequently were invited into the study and, if allocated to PCC, given an appointment at BRHC for an oral glucose tolerance test. Two patients allocated to PCC subsequently had negative tests and continued in the PCC arm.

One hundred and twenty-one (80%) patients were suitable for primary care management and invited into the study. Forty-five families (30%) declined to participate (Table 1). The majority were categorised as: unable to contact ($n = 17$, 11%), or declined via the contact reply form without giving a reason ($n = 13$, 9%). Six (4%) stated a clear preference to attend hospital.

**Allocation and baseline comparisons**

The distribution between study arms (PCC =

### Table 2. Allocation and baseline comparisons

<table>
<thead>
<tr>
<th>Allocation (n = 76)</th>
<th>BRHC (n = 31)</th>
<th>PCC (n = 45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>North-south</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male:female</td>
<td>16:15</td>
<td>21:24</td>
</tr>
<tr>
<td>Primary-secondary school</td>
<td>15:16</td>
<td>22:23</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline (n = 68)</th>
<th>BRHC (n = 26)</th>
<th>PCC (n = 42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years: mean (SD), range</td>
<td>11.5 (2.5), 5.8 to 14.9</td>
<td>11.4 (2.8), 5.7 to 17.0</td>
</tr>
<tr>
<td>BMI SDS: mean (SD), range</td>
<td>2.86 (0.40), 2.15 to 3.60</td>
<td>3.17 (0.57), 2.05 to 4.74</td>
</tr>
</tbody>
</table>

Eight children did not provide baseline data. BRHC = Bristol Royal Hospital for Children. BMI SDS = body mass index standard deviation scores. PCC = primary care clinic. SD = standard deviation.

### Table 3. Changes in body mass index standard deviation scores (BMI SDS)

<table>
<thead>
<tr>
<th>BMI SDS, n(%)</th>
<th>Reduced more than 0.5</th>
<th>Reduced between 0.25 and 0.5</th>
<th>Reduced between 0 and 0.25</th>
<th>Increased between 0.25 and 0.5</th>
<th>Increased more than 0.25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total (n = 52)</td>
<td>6 (12)</td>
<td>9 (17)</td>
<td>25 (48)</td>
<td>11 (21)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>BRHC (n = 23)</td>
<td>2 (9)</td>
<td>5 (22)</td>
<td>11 (48)</td>
<td>5 (22)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>PCC (n = 29)</td>
<td>4 (14)</td>
<td>4 (14)</td>
<td>14 (48)</td>
<td>6 (21)</td>
<td>1 (3)</td>
</tr>
</tbody>
</table>

*Range includes these end points. BRHC = Bristol Royal Hospital for Children. PCC = primary care clinic.

### Table 4. Comparison of BMI SDS changes between BRHC and PCC (North and South Bristol)

<table>
<thead>
<tr>
<th>Mean change</th>
<th>North and South combined</th>
<th>BRHC (n = 23)</th>
<th>PCC (n = 29)</th>
<th>South</th>
<th>BRHC (n = 11)</th>
<th>PCC (n = 15)</th>
<th>North</th>
<th>BRHC (n = 12)</th>
<th>PCC (n = 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI SDS SDS</td>
<td>-0.15 (0.25)</td>
<td>-0.17 (0.26)</td>
<td>-0.07 (0.16)</td>
<td>-0.26 (0.26)</td>
<td>-0.21 (0.30)</td>
<td>-0.08 (0.24)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>two-sided 95% CI</td>
<td>-0.26 to -0.05</td>
<td>-0.27 to 0.07</td>
<td>-0.17 to 0.16</td>
<td>-0.26 to 0.26</td>
<td>-0.21 to 0.30</td>
<td>-0.08 to 0.24</td>
<td></td>
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<tr>
<td>Mean difference (SE) BRHC minus PCC</td>
<td>0.02 (0.07)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>two-sided 95% CI</td>
<td>-0.12 to 0.17</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

BRHC = Bristol Royal Hospital for Children. BMI SDS = body mass index standard deviation scores. PCC = primary care clinic. SD = standard deviation. SE = standard error.
Withdrawals were higher in PCC (19/42 = 45%) compared with BRHC (10/26 = 38%) but the difference was not statistically significant (P = 0.77). Phone interviews with non-adhering families highlighted a number of issues. Motivation was the most prominent theme: parents struggled to motivate children between appointments, often leading to conflict between parent and child, thus disrupting family life. Some families felt clinic advice to be impractical or overambitious, and some felt it was not age appropriate. Families also cited family events that overrode their commitment to participate in the programme. The overall did-not-attend rate [total did-not-attend/total appointments offered] was 23%, which was similar in both arms (BRHC = 24%; PCC = 22%).

Quality of life
PedsQL scores rose in both arms over the 12 months: 10 points in PCC (95% CI = 3 to 18 points, n = 23) compared with 8 points in BRHC (95% CI = −2 to 18 points, n = 14), two-sample t-test P = 0.65.

Satisfaction
The satisfaction questionnaire considered the consultation, timing, and frequency of appointments, and access and convenience of the clinic. The PCCs scored slightly higher for each aspect of satisfaction: consultations, appointments, and access (Table 5), although all mean scores were between 1 and 3, equivalent to ratings from ‘excellent’ to ‘good’.

DISCUSSION
Summary
The original target was to recruit 100 children into the study. With 76 patients randomised and 68 starting the trial, this original target was not met, but the 152 patients referred provided a substantive body of data by which to assess the referral and recruitment process. GP assessment for referral using the Bristol Online Obesity Screening Tool showed that the majority of patients referred (80%) were suitable for the usual care pathway at BRHC (95% CI = −3 to −2). Thirty patients (30%) patients referred declined to participate. However, it should be noted that only 21 (14%) expressed a clear preference for the usual care pathway at BRHC (six preferred to see a doctor, 13 declined without reason, and two were unwilling to participate in research). This does not suggest widespread opposition to a primary-care-based service.

The 1-year reduction in children’s BMI...
SDS does not appear compromised, with similar results in PCC compared to BRHC. The overall BMI SDS improvements are better than those described in the recent Cochrane meta-analysis of randomised trials in childhood obesity. However, a BMI SDS change of between –0.15 and –0.17 is too small to be certain of an improvement in metabolic health, which requires a change of ≥–0.25.

Obesity in children is associated with low self-esteem, behavioural problems, and bullying. The data from this study suggest an equivalent improvement in quality of life between PCC and BRHC over the course of the trial.

The PCCs were unable to improve on the non-adherence rate in BRHC, and qualitative data (paper in preparation) indicated non-adherence was not linked to clinic type. The main issue was that patients lacked motivation and proved unresponsive to the efforts of clinic staff and parents. Alongside this, it is worth noting that a number of families stopped attending due to individual/family events, indicating that obesity management is perceived as an optional service, with non-attendance being thought to have little medical consequence. The reasons provided for non-adherence in the present study, particularly patient unpreparedness for change, were noted in another report by Barlow and Ohlemeyer examining non-adherence to a weight-management intervention programme. However, those families completing treatment in the current study were satisfied with service provision in either care site.

Strengths and limitations
At a time when policy makers and practitioners are searching for effective methods to reduce the health burden represented by childhood obesity, this study has taken a proven model of care and adapted it to a primary care setting, with promising results.

The authors recognise that as a pilot RCT the study is not statistically powered and the data must therefore be interpreted with caution. The authors are also aware that establishing two primary care clinics to cover the whole of Bristol and neighbouring PCTs does not test the locality aspect of the clinics, as only a small proportion of patients were registered with the practices where the clinics were sited. It is entirely plausible that clinics that are recognised by patients as local could improve adherence, and this is something that should be factored into a full trial design.

Comparison with existing literature
An Australian PCC-based trial, where treatment was based on four GP consultations with each family and child over a 12-week period, was unable to show a significant reduction in BMI compared with controls, and overall BMI change (not BMI SDS) was –0.12 at 12 months. Qualitative research has found a degree of uncertainty among primary care practitioners about taking on child obesity treatment. However, the present results do suggest a potential role for primary care, utilising nursing staff instead of doctors in locality-based, community clinics serving groups of practices, with overall clinical responsibility residing with the original referring GP.

A recent study has evaluated the MEND (Mind, Exercise, Nutrition … Do it!) programme, which runs from local authority community settings as well as primary care sites. The programme is based on 18 sessions of group advice and exercise over 9 weeks. BMI SDS reductions in the intervention group were significantly better than in the control group, with an overall reduction of 0.24. This study highlights the potential for managing obesity in community settings. However, this programme involves a much higher level of contact with the patient and family over a shorter period, and its success is dependent on group participation, which will not be suitable for all children.

Implications for practice and research
The data from this study suggest that there is scope to develop child obesity services in primary care. The prevalence of child obesity, along with the growing recognition that it is a critical public health problem, means that the few existing secondary care services are likely to be overwhelmed by demand. The study shows that, with appropriate training and support, primary care has the potential to be an effective site for weight management for children. Improving the proportion of suitable patients engaging and accessing services, patient retention, and the identification of interventions accruing a proportionally larger effect on BMI SDS remain unresolved issues for both primary and secondary care.
REFERENCES


