Summary Report: PC COCO

Evaluating the transferability of a successful, hospital-based, childhood obesity clinic to primary care: a pilot study

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INTRODUCTION

Obesity affects one in five children in the UK and undoubtedly causes increased ill health with rising levels of childhood and adolescent diabetes, obesity induced liver disease and increased risk of early heart disease. There are few clinics offering effective treatment for childhood obesity. However, the clinic for childhood obesity at Bristol Royal Hospital for Children (BCH) has been successful in around 83% of cases[1]. This pilot study examined the feasibility of transferring the success of the hospital clinic to a nurse led primary care (PC) setting in preparation for a full RCT.

Participating patients were randomly assigned to treatment at one of two PC clinics or the hospital clinic and were each offered 5 appointments over a one year period. At each visit the patients and their families received general lifestyle, diet and exercise advice. We collected weight, height and waist measurments along with lifestyle, diet and health economics data. We looked at how families felt about their experience at the clinics via face to face interviews and patient satisfaction questionnaires.

RECRUITMENT

Children were recruited to the trial by GPs via an electronic referral form designed by the study team. Referral forms were screened by the COCO consultant for clinical co-morbidities requiring secondary care support. Families of children fulfilling recruitment criteria (age: 5-16 with a BMI at or above the 98th centile of standard UK growth charts) were sent a study pack and reply form. Families declining participation followed a usual care pathway. Recruited families were randomised to one of two PC clinics or the BCH clinic.

METHODS

As a pilot study the primary outcome was the feasibility of transferring the BCH clinic into PC and running a full statistically powered trial. The main clinical measure used to assess this was change in body mass index (BMI) standard deviation score (SDS) over a one year period and comparing the results between the study arms. Body weight was recorded at each visit using clinically validated equipment. BMI was adjusted for age and sex to give a BMI SDS based on 1990 UK growth reference data[2]. We also compared non adherence to treatment and attendance rates between the two study arms along with a range of secondary outcome measures including: quality of life scores; satisfaction; changes in self reported diet and activity levels.

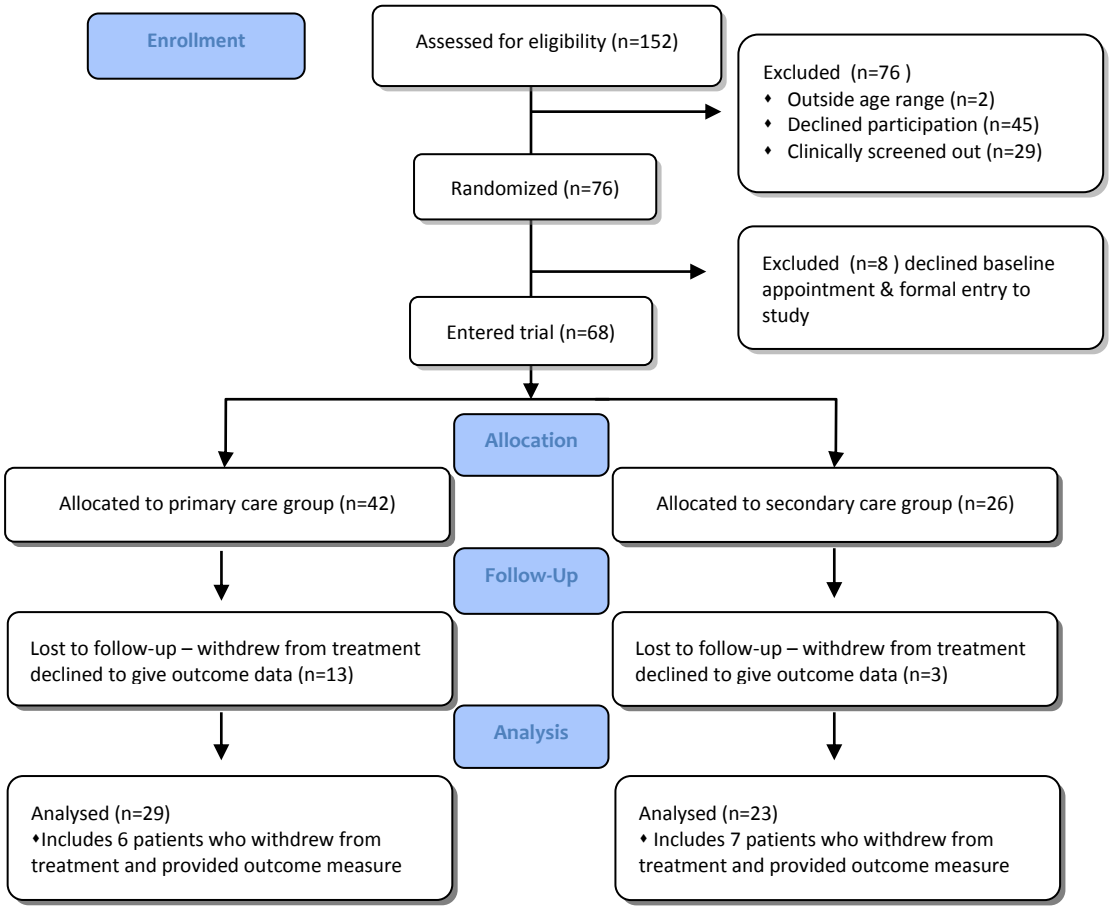
As a pilot the study was not statistically powered. Our aim was to recruit 100 patients to assess feasibility and plans for a full trial.

The trial follows the Consolidated Standards of Reporting Trials (CONSORT) and is registered with ClinicalTrials.gov, NCT00536536. Ethical approval for the study was granted by Southmead Research Ethics Committee on 18/07/2007.

RESULTS

Recruitment occurred between April 2008 and May 2010. The diagram below shows participant flow through the trial.

Figure 1: participant flow through the study



The distribution between the study arms (PC:45 and BCH:31) reflects the 2:1 randomisation schedule in favour of PC. A pragmatic decision was taken to change the allocation ratio from 1:1 to 1:2 with effect from 14/08/2008 to ensure more patients were assigned to PC. Recruitment at the beginning of the study was slow and those allocated to PC were being divided between two clinics. Changing the allocation in favour of PC gave the new clinics operational momentum, vital to a relatively small study. Table 1 shows the distribution of participants by gender, age and BMI SDS.

Sixty Eight patients entered the trial which was short of our target of 100. However, the process data we collected during recruitment are valuable in a pilot and will contribute to the next stage of developing and refining treatment and research programmes for managing child obesity.

Table 1: Allocation details

Allocation (n=76)	**BCH (n=31)**	**Primary Care (n=45)**
Male:Female	13:18	16:29
Primary:Secondary school	15:16	22:23
Baseline (n=68)	**BCH (n=26)**	**Primary Care (n=42)**
Age *mean (SD) range*	11.5(2.5) 5.8-14.9	11.4(2.8) 5.7-17.0
BMI SDS *mean (SD) range*	2.86(0.40) 2.15-3.60	3.17(0.57) 2.05-4.74

As table 2 shows the majority of patients across the two study arms, 40/52 (77%) improved their BMI SDS scores, with 15 (29%) showing reductions of more than 0.25 SDS. In BCH the mean BMI SDS reduction was 0.15, and in PC 0.17 (see table 3) giving a difference of only 0.02 indicating non inferiority of the PC clinics in terms of the main clinical outcome measure.

Table 2: Change in BMI SDS between baseline and outcome

Change in BMI SDS	***Total N=52***	***BCH N=23***	***PCN=29***
<-0.5	6 (12%)	2 (9%)	4 (14%)
≥-0.5 & <-0.25	9 (17%)	5 (22%)	4 (14%)
≥-0.25 & <0	25 (48%)	11 (48%)	14 (48%)
≥0 & <0.25	11 (21%)	5 (22%)	6 (21%)
≥0.25	1 (3%)	0 (0%)	1 (3%)

Table 3: Difference in BMI SDS change between the study arms

Mean Change	**BCH** $^{n=23}$	**PC** $^{n=29}$
BMISDS	-0.15	-0.17
(SD)	(0.25)	(0.26)
95% CI	0.05-0.26	0.07- 0.27
Mean difference BCH:PC	0.02 [two-sided 95% CI: -0.12- 0.17]	

Typically for obesity clinics[3,4] both arms of the study experienced high levels of non adherance with nearly half of those starting treatment withdrawing (29/68, 43%). There was a higher rate in PC (19/42=45%) compared to BCH (10/34=38%) but the difference was not statistically significant (Chi-squared test p=0.58). We recorded all the occasions patients did not attend (DNA), the overall DNA rate was 23% with the results being similar in the two study arms (BCH=24%; PC=22%).

Secondary outcome measures showed improvements during the period patients attended the clinics with no significant differences between the study arms: quality of life scores increased; opportunities for activity and attitudes to activity scores increased; there were marginal changes in food preference toward healthier foods but self reported consumption of fats and sugars decreased by around 11% across the study. Families completed a patient satisfaction questionnaire at the end of treatment which considered: consultations; appointments; access/convenience. PC clinics scored slightly higher but all scores were between 'good' and 'excellent'. Qualitative interviews explored families' experiences of the clinic in detail and these will be analysed shortly.

Mean NHS cost per participant showed the BCH clinic was marginally cheaper than PC sites (£200 vs £245). However, analysis of all NHS costs over the study period for each participant demonstrated a favourable picture for PC due to a higher usage of secondary care facilities for BCH participants (BCH total NHS cost £552 vs £436 for PC).

Conclusion

This trial has demonstrated equivalence in the primary clinical outcome of BMI SDS change over 12 months between a hospital and primary care based service. The overall BMI SDS improvements described for both hospital and primary care clinics are better than those described in the recent cochrane meta-analysis of randomised trials in childhood obesity[5]. Overall a BMI SDS change of between -0.15 and -0.17 is still too small to be certain of effecting improved metabolic health which requires a reduction of -0.25 or above[6].

Having demonstrated equivalence in terms of primary outcome and patient acceptability, we now plan to use this experience and that obtained from our work in a hospital based study recently published in the British Medical Journal[7] to evaluate an intervention to increase BMI SDS improvement to levels well over -0.25. This approach termed 'Mandometer therapy' provides a

behavioural modification programme to enable people who are obese or overweight to consume food more slowly thus enhancing satiety and gradually reducing self determined portion size. The proposed study is a two-arm, parallel, randomised controlled trial based in primary care. This proposal was submitted to the Health Technology Assessment Obesity Themed Call in November 2009 and was short-listed for a full application which was submitted in early September (Changing eating behaviours to treat childhood obesity in the community using Mandolean: the ComMando, (Community Mandolean) randomised trial).

PUBLICATIONS AND DISSEMINATION

In developing the primary care clinics we undertook interviews with patients at the BCH clinic to identify key aspects of clinical practice that would feed into the training of the primary care staff. The data also provided a valuable stream of qualitative data which were published in the following paper:

Owen SE, Sharp DJ, Shield JPH, Turner KT. Childrens' and parents' views and experiences of attending a childhood obesity clinic: a qualitative study. Primary Health Care Research & Development 2009;10:236–244.

We plan to publish research papers on the following themes:

1. A trial paper based on the main outcome data.
2. A qualitative paper based on the face to face interviews.
3. A paper based around the costing of self reported diet data compared with the cost of a 'healthy' diet
4. A paper reflecting on our experiences of identifying obese children via GP practice databases and recruiting via direct letters from the GP practice

We will develop a full dissemination strategy at the next full meeting of the PC-COCO research team on 06-10-2010.

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