# Multi-Site Randomized Controlled Trial of a Child-Centered Physical Activity Program, a Parent-Centered Dietary-Modification Program, or Both in Overweight Children: The HIKCUPS Study

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**Objective** To evaluate whether a child-centered physical activity program, combined with a parent-centered dietary program, was more efficacious than each treatment alone, in preventing unhealthy weight-gain in overweight children.

**Study design** An assessor-blinded randomized controlled trial involving 165 overweight/obese 5.5- to 9.9-year-old children. Participants were randomly assigned to 1 of 3 interventions: a parent-centered dietary program (Diet); a child-centered physical activity program (Activity); or a combination of both (Diet + Activity). All groups received 10 weekly face-to-face sessions followed by 3 monthly relapse-prevention phone calls. Analysis was by intention-to-treat. The primary outcome was change in body mass index *z*-score at 6 and 12 months (n = 114 and 106, respectively).

**Results** Body mass index *z*-scores were reduced at 12-months in all groups, with the Diet (mean [95% confidence interval]) (−0.39 [−0.51 to 0.27]) and Diet + Activity (−0.32, [−0.36, −0.23]) groups showing a greater reduction than the Activity group (−0.17 [−0.28, −0.06]) ($P = .02$). Changes in other outcomes (waist circumference and metabolic profile) were not statistically significant among groups.

**Conclusion** Relative body weight decreased at 6 months and was sustained at 12 months through treatment with a child-centered physical activity program, a parent-centered dietary program, or both. The greatest effect was achieved when a parent-centered dietary component was included. *(J Pediatr 2010;157:388-94)*.

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Overweight and obesity in childhood have been described as a global epidemic, with 10% of the world's children currently affected and the prevalence increasing.[1] Obesity in children is associated with a range of immediate and long-term comorbidities.[2,3] The development and implementation of prevention and treatment strategies presents a formidable challenge for researchers and practitioners.[4]

This challenge has been articulated in recent systematic reviews of treatment interventions, which showed poor long-term and, at best, modest short-term success.[5-7] Many of the studies had methodologic limitations such as small sample sizes, high attrition rates, limited outcome data, no intention-to-treat analyses, and insufficient follow-up periods. Furthermore, many were highly resource-intensive and performed in tertiary environments, limiting their potential reach and subsequent impact on regional/national child obesity prevalences.

In response to this, our research team has developed 2 group programs. These were designed to be of modest intensity and suitable for delivery in community settings. The first focused on changing family eating behaviors through a dietary modification program targeted at parents. The second aimed to promote physical activity and reduce sedentary behaviors by enhancing the obese child's movement skill proficiency, social support, and self-esteem. Given the minimal resources required to implement each program, it was also of interest to examine whether combining the 2 was more efficacious. The aim of this study was to assess the efficacy of each community-based program, separately and combined, for improving clinical outcomes among overweight and obese prepubertal, school-aged children. Our primary hypothesis was that a combined program would be more efficacious than either program alone for improving adiposity and metabolic profiles among overweight and obese children.

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| BMI | Body mass index |

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Trial Registration: clinicaltrials.gov (NCT00107692)

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## Methods

The HIKCUPS (Hunter and Illawarra Kids Challenge Using Parent Support) study was a 3-arm parallel group, randomized controlled trial conducted at the Universities of Wollongong and Newcastle, New South Wales, Australia. These community venues were chosen to maximize accessibility for all participants. Participants were provided with parking vouchers for the face-to-face sessions, and travel costs were reimbursed for those who did not have private transport. Eligibility criteria included the child being overweight or obese (referred to hereafter as "overweight") according to International Obesity Task Force cut points,[8] aged 5.5 to 9.9 years, prepubertal (Tanner Stage I) and generally healthy. Exclusion criteria included extreme obesity (body mass index [BMI] *z*-score >4), known syndromal obesity, a chronic illness, following a therapeutic diet, and taking medications associated with weight gain or long-term steroids. Participants were recruited from the local communities, primarily through print media and advertisements placed in school newsletters. The Human Research Ethics Committees at both sites approved the study protocol. Written informed consent was obtained from each child's parent or care provider, as well as child assent. The study was registered at clinicaltrials.gov (NCT00107692).

Eligible participants were randomized to 1 of 3 intervention arms described below, using a computer-based random number–producing algorithm. Randomization was stratified by sex and site. To ensure concealment, the sequence was generated by a statistician and given to only one researcher at each site, who assigned participants to their groups and informed a member of the research team at each site (who enrolled participants) of group allocation.

HIKCUPS involved 3 intervention arms: a Dietary-Modification Program (Diet), a Physical Activity Skill Development Program (Activity), and a combination of the Dietary-Modification and Physical Activity Skill Development Programs (Diet + Activity). Details of these interventions have been previously published.[9] Briefly, each intervention was designed to be inexpensive and sustainable in a community setting and was conducted on a separate, predesignated afternoon of the week. Each had 3 major components: (1) a weekly 2-hour face-to-face session for 10 weeks; (2) homework activities, designed to be completed in between each face-to-face session; and (3) a 3-month relapse prevention program where short- to medium-term goals set by parents were reviewed over the phone following a standard study procedure,[9] by a trained facilitator once a month for 3 months.

Outcome measures were assessed at baseline and at 6 and 12 months by trained assessors who were blinded to group assignment. Primary outcome was BMI *z*-score at 12-month follow-up. Other outcomes reported here include waist circumference, metabolic profiles, and blood pressure.

Height, weight, and waist circumference were measured by use of standardized procedures.[9] To enhance the quality of the anthropometric measurements, 2 assessors were involved and each measurement was taken in an entire sequence once (height, weight, waist), then the sequence was repeated. The *z*-scores for BMI were calculated by use of reference data from the United Kingdom.[10]

Blood pressure was measured by use of an automated blood pressure monitor (Critikon, Tampa, Florida) following standardized procedures. Blood was collected after the children had fasted overnight and was analyzed for glucose, insulin, lipids (total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides) and high sensitivity C-reactive protein at a single accredited pathology service (National Association of Testing Authorities, Australia, accredited).

To have an 80% chance of detecting as significant (at the 2-sided 5% level), a 0.26 standard deviation difference from baseline to 12-months (initial end point) in BMI *z*-score, with an anticipated loss to follow-up of 20%, 72 participants in each of the 3 groups (216 in total) were required to be recruited.

The $\chi^2$ tests and *t*-tests were used to assess differences in BMI and BMI *z*-score between the dropout and continuation groups. Linear mixed models were used to assess all outcomes for the impact of group, time, and the group-by-time interaction, with these 3 terms forming the base model. This approach was preferred to use of baseline scores as covariates, because the baseline scores for subjects who dropped out at 6 months or 12 months were retained to be consistent with an intention-to-treat analysis. The adjusted models contained any additional significant effects due to main effects and two-way interactions between base model terms of sex, site, and age (treated as continuous). Mixed models were fitted by use of SAS PROC MIXED[11] (SAS Institute, Cary, North Carolina) and restricted maximum likelihood estimation with an unstructured covariance structure and the Kenward-Roger adjustment for downward bias in the variance-covariance matrix. The effects of lack of normality and influential observations were evaluated but were not severe enough to impact the results. Differences of means and 95% confidence intervals were estimated by use of the mixed models.

## Results

The flow of participants is shown in the **Figure** (available at www.jpeds.com). Anthropometric data were collected for 165 children at baseline (**Table I**) and 114 (69%) and 106 (64%) children at 6- and 12-month follow-ups, respectively. There was no difference in retention rates among the 3 groups at 6-month follow-up, although at 12 months more participants from the Diet + Activity group (72%) and Diet group (71%) were retained compared with the Activity group (52%), ($\chi^2 = 6.24$, $P = .04$).

There were no differences between participants who were followed up compared with those who were not with regard to sex, age, or BMI *z*-score ($P > .05$). For waist circumference,