The Memphis Girls’ health Enrichment Multi-site Studies (GEMS)

An Evaluation of the Efficacy of a 2-Year Obesity Prevention Program in African American Girls

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Objective: To determine the efficacy of a 2-year obesity prevention program in African American girls.

Design: Memphis GEMS (Girls’ health Enrichment Multi-site Studies) was a controlled trial in which girls were randomly assigned to an obesity prevention program or alternative intervention.

Setting: Local community centers and YWCAs (Young Women’s Christian Associations) in Memphis, Tennessee.

Participants: Girls aged 8 to 10 years (N = 303) who were identified by a parent or guardian as African American and who had a body mass index (BMI) at or higher than the 25th percentile for age or 1 parent with a BMI of 25 or higher.

Interventions: Group behavioral counseling to promote healthy eating and increased physical activity (obesity prevention program) or self-esteem and social efficacy (alternative intervention).

Main Outcome Measure: The BMI at 2 years.

Results: The BMI increased in all girls with no treatment effect (obesity prevention minus alternative intervention) at 2 years (mean, 0.09; 95% confidence interval [CI], −0.40 to 0.58). Two-year treatment effects in the expected direction were observed for servings per day of sweetened beverages (mean, −0.19; 95% CI, −0.39 to 0.09), water (mean, 0.21; 95% CI, 0.03 to 0.40), and vegetables (mean, 0.15; 95% CI, −0.02 to 0.30), but there were no effects on physical activity. Post hoc analyses suggested a treatment effect in younger girls (P for interaction = .08). The mean BMI difference at 2 years was −2.41 (95% CI, −4.83 to 0.02) in girls initially aged 8 years and −1.02 (95% CI, −2.31 to 0.27) in those initially aged 10 years.

Conclusions: The lack of significant BMI change at 2 years indicates that this intervention alone is insufficient for obesity prevention. Effectiveness may require more explicit behavior change goals and a stronger physical activity component as well as supportive changes in environmental contexts.

Trial Registration: clinicaltrials.gov Identifier: NCT00000615


CHILDHOOD OBESITY IS A worldwide health concern given its high incidence, increasing prevalence, and associated health consequences during childhood and later in adulthood. Among US children aged 6 to 11 years, obesity prevalence has increased almost 4-fold in the past 3 decades from about 5% to 19.4 The need for effective interventions targeting this high-risk population is therefore a particularly high public health priority. The Girls’ health Enrichment Multi-site Studies (GEMS) program sought to address this need through development and evaluation of culturally appropriate obesity prevention approaches in preadolescent African American girls. The GEMS program began in 1999 with a 3-year feasibility and pilot studies phase (phase 1) during which measurements and separate interventions were developed and pilot-tested (but not powered to detect significant effects on body mass index [BMI]) at 4 research centers. In phase 2, 2-year efficacy trials were conducted at 2 centers (Stanford, Arch Pediatr Adolesc Med. 2010;164(11):1007-1014

See also pages 995 and 1067

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California, and Memphis, Tennessee), which tested separate interventions in collaboration with the National Heart, Lung, and Blood Institute.14,15 This article reports the results of the Memphis GEMS phase 2 obesity prevention trial.

**METHODS**

**RESEARCH DESIGN**

Details of the Memphis GEMS trial design have been reported previously.14 GEMS evaluated an obesity prevention program in 303 preadolescent African American girls and their guardian compared with an alternative intervention that was not expected to affect diet, physical activity, or body weight. The primary outcome measure was BMI (calculated as weight in kilograms divided by height in meters squared) at 2 years. Secondary outcome measures were anthropometric and other measures of body composition, diet, and physical activity at 1 and 2 years of follow-up.

**RECRUITMENT AND ELIGIBILITY**

Recruitment occurred during 5 waves, primarily through television and radio advertisements and through flyers and presentations in the community. Advertisements described GEMS as a study of healthy growth. To be eligible, girls had to be identified as African American or black by their parent/guardian, be aged 8 to 10 years, and have a BMI at or higher than the 25th percentile for age and sex16 or have at least 1 parent with a BMI of 25 or higher. Girls were excluded if they had a BMI higher than 35 or conditions that would affect their growth or limit participation in the study.

Parents/guardians gave written informed consent, and girls provided assent. The protocol was reviewed by an independent data and safety monitoring board and approved by the University of Memphis Institutional Review Board and the National Heart, Lung, and Blood Institute.

**INTERVENTIONS**

The rationale and development of the GEMS obesity prevention program are described elsewhere.14,17 During the first year, both interventions were offered at 10 community centers or YWCAs (Young Women's Christian Associations), which had adequate facilities for health promotion programs (eg, flexible hours of operation, ample space for physical activity, and areas for basic food preparation).

Interventionists were African American women with experience teaching and working with children. Participants met in groups of 8 to 15 girls. Both intervention groups had the same number and frequency of sessions. To reduce potential contamination, obesity prevention groups met on weekday evenings and the alternative intervention groups met on Saturday afternoons. Meetings occurred weekly for 14 weeks and then monthly for 20 months (34 sessions in 2 years). Sessions lasted approximately 90 minutes. During the second year, both interventions transitioned to monthly field trips within the community to provide interactive learning experiences in accordance with the respective intervention goals. The obesity prevention program provided practical experience with nutrition and physical activity, and the alternative intervention focused on building social awareness and community responsibility. Both interventions contained techniques outlined by Michie et al18; namely, providing information, facilitating goal setting through demonstration and practical experience, and providing feedback and encouragement. The composition of the groups changed across time, with girls moving from one group to another based on scheduling considerations; however, girls never crossed from obesity prevention to the alternative intervention or vice versa. Makeup sessions were provided to girls who missed regularly scheduled sessions.

Girls and their parents/guardians participated in the obesity prevention program through a combination of separate and joint sessions. Girls developed behavioral goals to eat a nutritionally balanced diet; reduce consumption of sugar-sweetened beverages and high-fat, high-calorie foods; increase intake of water, vegetables, and fruits; increase moderate to vigorous physical activity; and decrease sedentary behavior. Behavioral strategies included skill building, self-monitoring, feedback and positive reinforcement, goal setting, problem solving, and social support. Parents/guardians were encouraged to make changes in the home food environment, such as increasing the availability of healthy foods.

The alternative intervention targeted the girls only and was designed to provide meaningful benefits with the goal of improving self-esteem and social efficacy. There was no focus on changing behaviors at home or activities related to diet, physical activity, or body weight.

Separate interventionists conducted the obesity prevention and alternative intervention groups, and they were trained only for their assigned intervention. All interventionists were masked to outcome measurements. The project director continuously evaluated treatment fidelity through direct observation and monitoring of both intervention groups. From the 10% randomly videotaped sessions, the project director determined whether the objectives were consistently implemented. The range of sessions judged acceptable was 92% to 100% (reflects ratings based on 1=strongly agree or 2=agree).

**RANDOMIZATION AND MEASUREMENTS**

Randomization was stratified by recruitment wave and within each wave, by community center. Eligible participants were randomly assigned to either the obesity prevention program or the self-esteem intervention. Randomization occurred initially in 2 mirror image blocks of 15 participants. Later, independent blocks of 5 participants at each center were used to ensure a better balance between the 2 intervention groups.

Trained staff performed all measurements at baseline and at the 1- and 2-year follow-up visits and were masked to group assignment. Baseline social and demographic information for the girl and her household was obtained from the parent/guardian.

**ANTHROPOMETRIC, BIOELECTRICAL IMPEDANCE, AND SEXUAL MATURATION MEASUREMENTS**

Height, weight, and waist circumference were measured twice while girls were barefoot and wore lightweight clothing. A stadiometer (Shorr Productions, Olney, Maryland) and electronic scale (model 5602; Scale-Tronix, White Plains, New York) were used to measure height and weight, respectively. Waist circumference was measured at the level of the umbilicus at end expiration with a physician’s tape measure (Moore Medical, Farmington, Connecticut). The BMI percentiles were calculated using the Centers for Disease Control and Prevention growth charts.18 Three measurements of triceps skinfold thickness were obtained (Harpenden Skinfold Caliper, model C-136; Creative Health Products, Inc, Plymouth, Michigan). The mean of all measurements was determined. Bioelectrical impedance measures (Tanita TBF-300A; Tanita Corp, Arlington Heights, Illinois) were used to measure impedance and body fat distribution. The Tanita TBF-300A (Tanita Corp) was validated against dual-energy x-ray absorptiometry at baseline,19 and was used at the 1- and 2-year visits.

Parents/guardians were invited to participate in the self-esteem intervention. Participation varied by wave and community center (range, 12.5% to 86.3%). Participation was not linked to any other aspect of the study (eg, BMI response or treatment fidelity).
illinois) were obtained using manufacturer protocol to estimate body composition. Sexual maturation was assessed by self-report using drawings and descriptions of pubertal stages.19

DIETARY ASSESSMENT

Trained interviewers obtained 24-hour dietary recall information (Nutrition Data System for Research, version 4.05-33; University of Minnesota, Minneapolis) on 3 consecutive days (including 1 weekend day) and analyzed the information according to 3-day means. The first 24-hour recall occurred face-to-face, and the subsequent 2 recalls were conducted by telephone. Standardized methods were used, and quality control procedures included a multiple-pass approach and probes.20,21

PHYSICAL ACTIVITY MONITORING

A validated accelerometer22 (Actigraph version 2.2; Manufacturing Technologies Inc, Pensacola, Florida) was used to assess physical activity for 3 consecutive days, typically including 1 weekend day; the mean of these measurements was determined. The number of minutes spent in moderate to vigorous physical activity was calculated, defined as 3000 counts or more per minute.23

STATISTICAL ANALYSIS

Unless otherwise indicated, all analyses and determinations of effect size followed the GEMS protocol14 and were evaluated at α = .05 (2-tailed). Because of the a priori distinction between the primary outcome analysis and all secondary analyses, no adjustment for multiple comparisons was made. Baseline comparisons between the 2 intervention groups for the primary and secondary outcomes were performed with t tests and χ² tests.

The primary analysis used analysis of covariance (ANCOVA) to assess differences between the 2 intervention groups in BMI at 2 years, with adjustment for baseline BMI. Data were analyzed according to intention-to-treat principles.22 In a preliminary step, multiple imputation was used to generate a predicted value to replace missing values in both intervention groups.22 A prediction equation was developed using data for girls in the alternative intervention group who provided both baseline and 2-year follow-up data. That equation was used to predict 2-year BMI values for girls in either intervention group who did not attend the 2-year follow-up visit, adding random error based on the distribution of the 2-year BMI. This procedure was repeated to create 5 complete data sets that were analyzed separately; the results were combined using SAS PROC MIANALYZE statistical software (SAS/STAT 9.1; SAS Institute Inc, Cary, North Carolina).

The same ANCOVA approach was used to evaluate treatment effects on primary and secondary outcomes at 1 year and on secondary outcomes at 2 years. The ANCOVAs for BMI were repeated separately with stratification on median baseline BMI (< 20.8 and ≥ 20.8), age tertiles (7.98 to < 8.73 years, 8.73 to 9.77 years, and > 9.77 to 11.0 years), and household income (< $40,000 and ≥ $40,000 per year) to evaluate treatment effects in these strata. In each case, the stratification factor was tested for interaction between it and the treatment group. Post hoc repeated-measures ANCOVA was used to evaluate treatment effects on BMI at 1 and 2 years of follow-up, with adjustment for baseline BMI; separate models evaluated the main effect for treatment group and the visit × treatment group interaction. Also post hoc, the repeated-measures ANCOVA for BMI was done separately with stratification on baseline age; in this model, age was modeled continuously and all 2- and 3-way interactions involving visit, treatment group, and age were included. The subgroups pertaining to baseline BMI, age, and household income were prespecified based on the extant literature. To gauge the effect of multiple imputation procedures, analyses were repeated for BMI separately for girls who completed the study, with no imputation for missing data. Results from these secondary analyses were generally similar to the results for the primary and secondary analyses with imputation.

RESULTS

RECRUITMENT, BASELINE CHARACTERISTICS, FOLLOW-UP, AND ATTENDANCE

Of 463 respondents, almost three-fourths (338 [73.0%]) were eligible and were scheduled for baseline assessment (Figure 1). A total of 303 girls enrolled in the trial. Mean values and distributions for the major demographic, anthropometric, dietary, and physical activity baseline measures were not significantly different between the 2 intervention groups14 (Table 1).

Mean (SD) session attendance during the 2 years was 27.8 (8.05) for the obesity prevention program and 27.9 (8.10) for the alternative intervention, including makeup sessions, which composed about 50% of all attendance (P = .94).

At the 1-year follow-up visit, 75.9% (230 of 303) of the baseline sample were available for assessment; 80.2% (243 of 303) were available at the 2-year follow-up visit (Figure 1). At the end of the study, 83.5% (253 of 303) had undergone at least a 1- or 2-year assessment and 71.3% (216 of 303) had completed both follow-up visits. Girls who did not complete follow-up visits were similar to those who did in terms of age (P = .43), BMI (P = .49), and pubertal maturation (P = .16 and P = .30 for breast develop-
opment and pubic hair growth, respectively). The only significant group difference was baseline vegetable intake among girls who did not complete the 1-year assessment. Mean daily vegetable intake among girls in the obesity prevention program was higher than that of girls in the alternative intervention (mean [SD], 1.16 [0.86] vs 0.76 [0.51] servings per day; \( P = .03 \)).

**BODY MASS INDEX**

Table 2 gives BMI and anthropometric findings from the a priori ANCOVA. Mean BMI and other anthropometric measures increased in both intervention groups each year. There were no significant differences between the 2 intervention groups in mean BMI or any other anthropometric measure at the 1- and 2-year follow-up visits.

**DIETARY INTAKE AND PHYSICAL ACTIVITY**

Table 3 indicates dietary and physical activity findings. Relative to baseline, all girls reported increases in mean intake of sweetened beverages, but at the 2-year visit, the obesity prevention group had 0.19 fewer servings per day than the alternative intervention group \( (P = .08) \). The obesity prevention group reported increased water consumption from baseline and at 2 years had 0.21 more servings per day than the alternative intervention group \( (P = .02) \). Vegetable intake decreased from baseline in both intervention groups, but at 2 years, the obesity prevention group reported a vegetable intake of 0.13 servings per day higher than the alternative intervention group \( (P = .07) \). At 2 years, energy intake was reported to be 78 kcal/d less for the obesity prevention group compared with the alternative intervention group, although this difference was not statistically significant \( (P = .16) \).

Girls in both groups decreased their physical activity across time. Physical activity did not differ significantly between the 2 groups at either the 1- or 2-year follow-up visit.

**POST HOC BMI ANALYSES**

Prespecified secondary analyses did not identify significant interactions for subgroups defined by baseline BMI, age, and household income. However, in the post hoc repeated-measures ANCOVA that included treatment group, age, visit, and all interactions, with adjustment for baseline BMI, the mean \( F \) test across 5 imputed data sets for the age \( \times \) treatment \( \times \) visit interaction term had a \( P \) value of .08. The pattern of the predicted means was suggestive of an intervention effect among younger girls at the 2-year follow-up visit (Figure 2).

**COMMENT**

The primary BMI analysis indicates that the obesity prevention program did not significantly reduce weight gain relative to the alternative intervention. Secondary analyses show no significant effects on other anthropometric measures. Statistically significant or marginally significant treatment effects were observed for reported intakes of sweetened beverages, water, and vegetables, but...
no effects were found for measured physical activity. Post hoc secondary analyses suggest an age difference in effects on BMI, indicating that treatment-related differences in BMI in the youngest girls were more than twice as large as those in the oldest girls: −2.41 vs −1.02. Although not a significant difference, as we were not powered to detect a 3-way interaction, the magnitude of this difference suggests clinical relevance.

Findings of no effect are common in obesity prevention trials, and a recent commentary estimated that 42%

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<th>Table 2. Adjusted Means and Treatment Effects for BMI and Anthropometric Measurements at 1 and 2 Years of Follow-up.a</th>
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Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CI, confidence interval.

a Determined using a priori analysis of covariance. Data are presented as mean (SE) unless otherwise indicated. Difference indicates treatment effects.

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Abbreviation: CI, confidence interval.

a Determined using a priori analysis of covariance. Data are presented as mean (SE) unless otherwise indicated. Difference indicates treatment effects.
b All measurements are expressed as units per day.
to 50% of trials are effective, depending on the study inclusion criteria and definitions of effectiveness used in systematic reviews. The lack of a significant effect on BMI is particularly disappointing when considering the need for interventions in this high-risk population and in light of the theoretical and empirical support for the cultural appropriateness and potential efficacy of the Memphis GEMS obesity prevention program.\(^{10,17}\) It may be challenging to identify effective obesity prevention strategies in high-risk populations such as African American girls because the difficulty of avoiding weight gain may be greater in the social and environmental contexts in which they live. GEMS targeted behaviors that are strongly influenced by school, neighborhood, and media context related to eating and physical activity,\(^{17,19,20}\) and these influences are more adverse for African Americans.

The types of food stores and restaurants available in predominantly African American neighborhoods are relatively less conducive to the purchase and consumption of healthful foods (eg, fewer supermarkets and more fast-food restaurants) compared with predominantly white neighborhoods.\(^{20}\) Promotion of high-calorie foods and beverages to African Americans through television, outdoor advertising, and other media is high relative to the intensity of such promotions to white individuals or the general population\(^{20,32}\) and may have greater salience because of ways in which ethnically distinctive populations respond to targeted advertising.\(^{33}\) A similarly adverse picture applies to physical activity options; namely, less access to safe and attractive options for outdoor physical activity in neighborhoods where African American children live.\(^{34,35}\) Some of these environmental challenges are especially applicable to children in lower-income communities, where most of the Memphis GEMS participants reside. Multilevel interventions may be needed in which both contextual and individual behaviors are targeted,\(^{20}\) although evidence for the effectiveness of such interventions is currently lacking.

Our findings suggest ways to strengthen the potential effectiveness of the GEMS intervention in directly facilitating behavior changes. Obesity prevention programs tend to differ from obesity treatment programs because they promote healthful eating and activity patterns without specific goal levels for caloric intake and expenditure. Consistent with a prevention approach, the GEMS obesity prevention program emphasized behaviors such as reducing sweetened beverage intake and increasing water intake. The intervention affected these behaviors but not total caloric intake, which was not directly emphasized. A more explicit emphasis on the need for caloric moderation may be warranted, even in elementary school–age children, to influence mean BMI, with appropriate precautions to avoid triggering inappropriate caloric restriction. Even more striking is the potential to improve intervention effectiveness with respect to physical activity and inactivity. Girls in both intervention groups became less physically active as they grew older, and their highest level of physical activity was at baseline. This observation reflects the well-known pattern of decreasing physical activity in adolescent girls, particularly among African American girls.\(^{36}\) The potential for physical activity to moderate weight gain across time is substantial. Findings from the National Heart, Lung, and Blood Institute Growth and Health Study showed that African American girls who were consistently physically active throughout adolescence (aged 9-19 years) had a mean BMI 3 kg/m\(^2\) lower than girls who were consistently inactive.\(^{37}\) However, attempts to increase physical activity or even to reduce the decline in physical activity that occurs during adolescence continue to pose a challenge.\(^{36,39}\)

Our findings may have implications for the developmental timing of preventive interventions. Stice et al\(^{40}\) noted that intervention effectiveness to reduce mean BMI was lowest among 9- to 11-year-old participants, an age range in which fat accumulation in girls occurs and continues relatively linearly through age 14 years.\(^{41,42}\) Instituting measures to prevent excess weight gain concurrent with pubertal growth will be difficult if hormonal processes overshadow potential intervention effects. Intervening with girls well before puberty to better moderate the trajectory of adiposity gain may be preferable.

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**Figure 2.** Predicted mean body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) from post hoc repeated-measures analysis of 3-way interactions for age, visit, and treatment group. Brackets show mean treatment group differences at 2 years with 95% confidence intervals.
and is consistent with our finding of a larger effect in girls who were youngest at enrollment (ie, age 8 years). There may also be behavioral explanations for differential treatment effects in younger girls, such as family environmental influences, that can be explored through the analysis of mediators of effects reported in this article.

The many strengths of Memphis GEMS include the randomized controlled trial design, the high degree of quality control built into intervention delivery and data collection, the large sample size, the relatively long (2-year) period of intervention and follow-up, the high-risk ethnic group and primarily low-income study population that is typically underserved, and the 80% follow-up rates at the 2-year visit. Sensitivity analyses indicate that imputation for missing data did not alter conclusions. In addition, the intervention materials can be readily disseminated to and adapted by community organizations. Limitations of the study include the narrow age range and the single race and sex; although appropriate to the development of a culturally targeted approach, this reduces the generalizability of the results. Another potential limitation, discussed elsewhere, is the somewhat high percentage of participants who required makeup sessions, which may have reduced the effect of the intervention as originally designed. Also, as is common with many obesity interventions, our significant effects were observed primarily for subjective (eg, diet) and not objective (eg, BMI) measures, suggesting the possibility of response bias. Finally, whereas the alternative intervention stressed self-esteem and never mentioned diet, exercise, or BMI, its intensity may have generated attention effects that influenced our results.

In conclusion, the Memphis GEMS obesity prevention program, which promoted healthy eating behaviors and increased physical activity targeted to low-income African American girls and their parents/guardians, did not reduce mean BMI relative to an alternative intervention after 2 years. A comparatively large effect was suggested in the youngest girls, indicating that preventive interventions may need to start well before puberty. The obesity prevention program was associated with improvements in several dietary behaviors—sweetened beverage consumption, water intake, and vegetable intake—but had no effect on physical activity levels, which showed a marked decline among girls in both groups. This aspect of the program requires strengthening. More fundamentally, success with individually oriented preventive interventions, especially those targeted to African Americans or low-income populations, may require concurrent environmental and policy changes to improve contexts for eating and physical activity behavior change.

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REFERENCES


