

Multidisciplinary Approach To Clinical Research: Developing Collaborations

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Overview

- Why collaborate?
- How to collaborate
- Clinic-based example
- Community-based example

Why Collaborate?

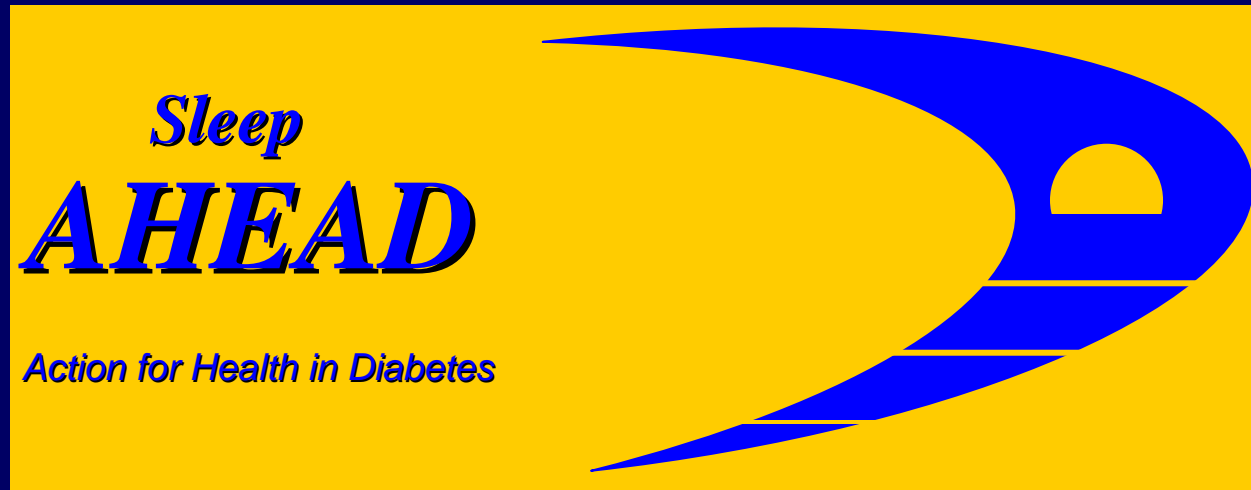
- Brings different perspectives to complex problems.
- Allows for a more integrated view.
- More appealing to funders.
- Facilitates personal learning.

How to Collaborate

- Search the literature.
- Assess your own strengths and weaknesses
- Identify productive collaborators
- Listen
- Compromise
- Be genuine about what you know and what you don't (including politics)

Clinic-Based Example

Sleep AHEAD:
Sleep Apnea in Look AHEAD
Participants



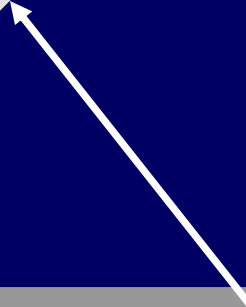
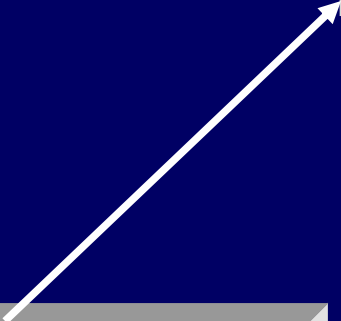
BROWN

Pittsburgh

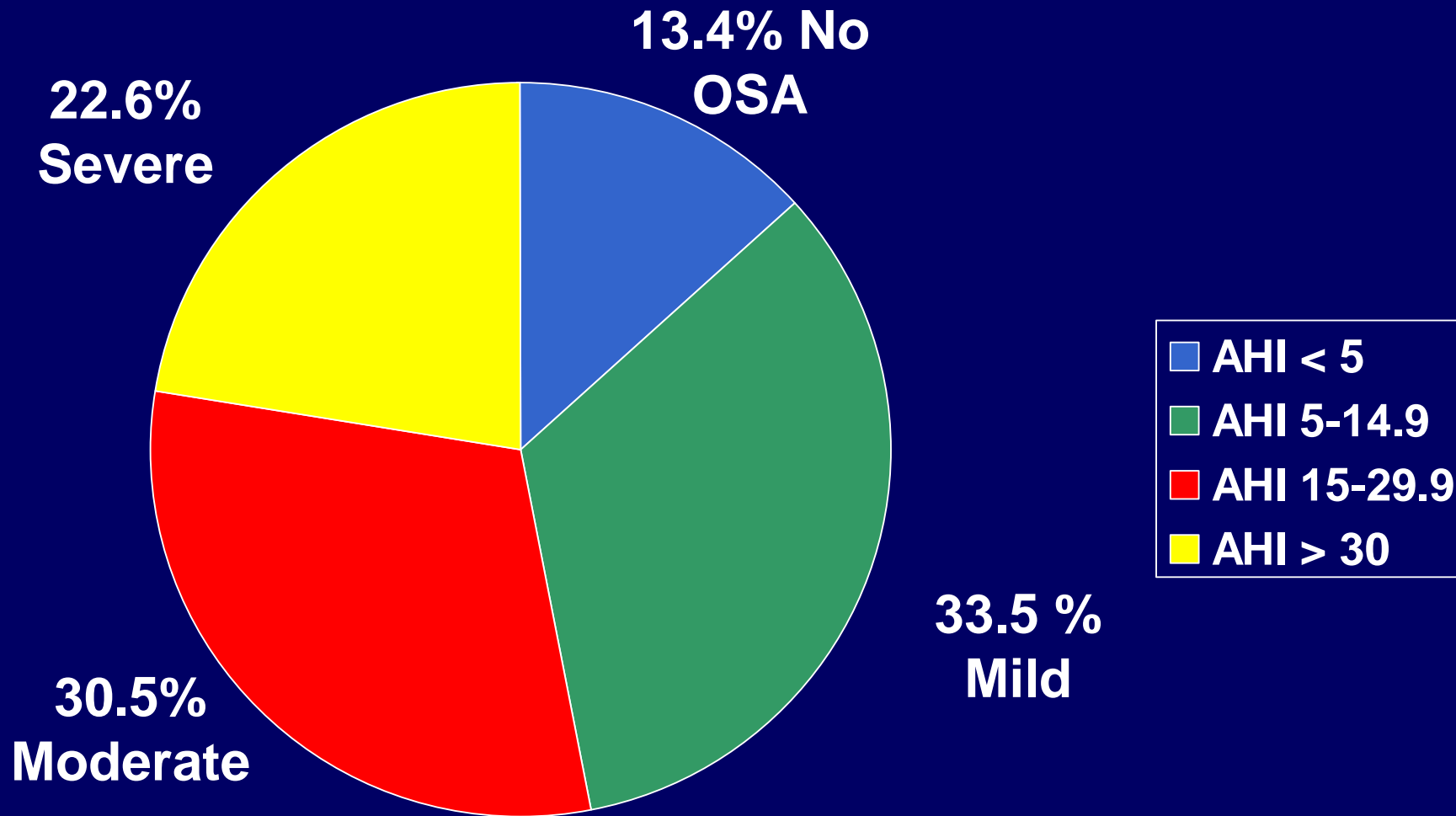
PSGRL

Columbia

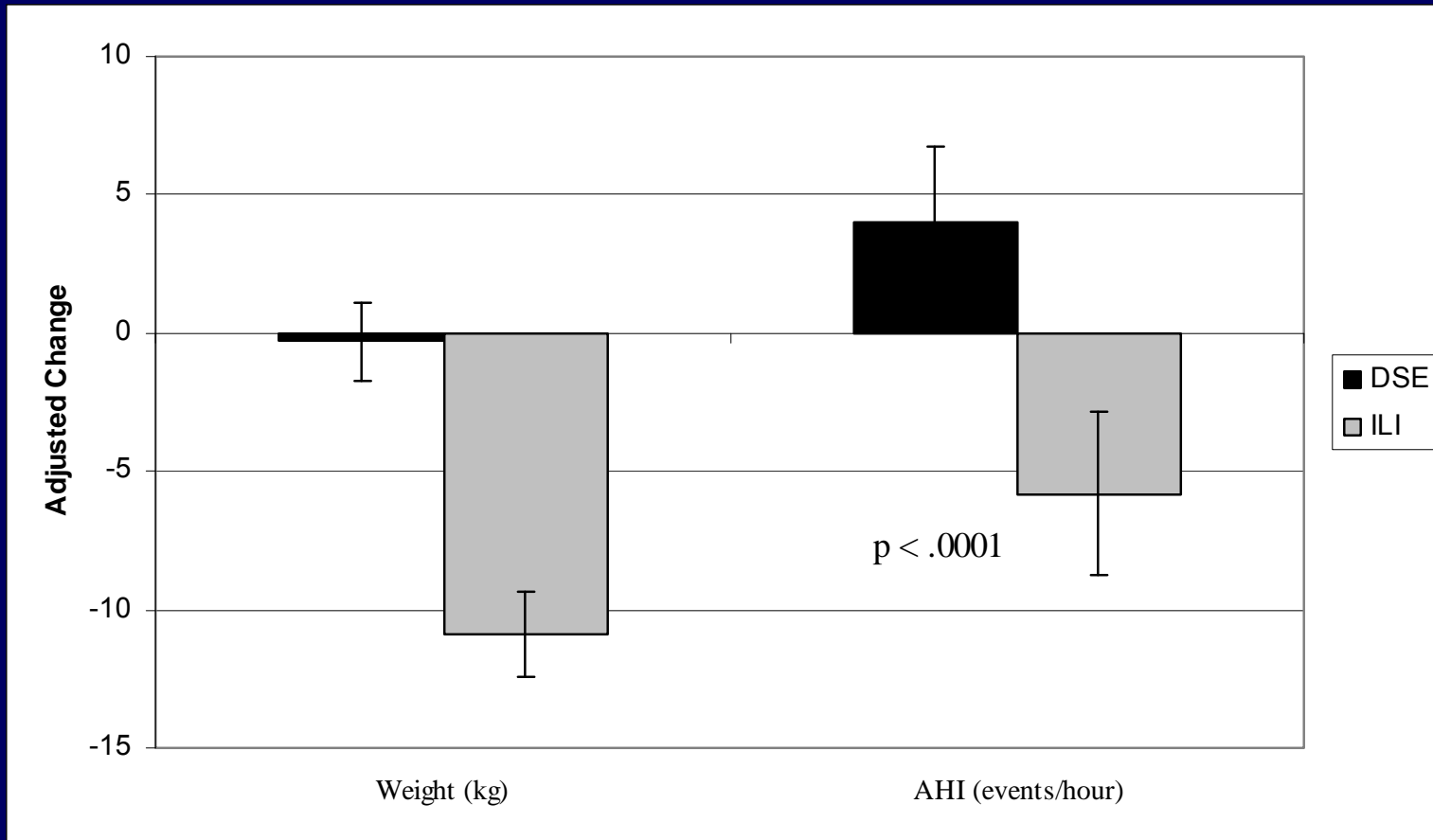
Penn



Sleep Disordered Breathing in Obese Patients with Type 2 Diabetes (N=305)

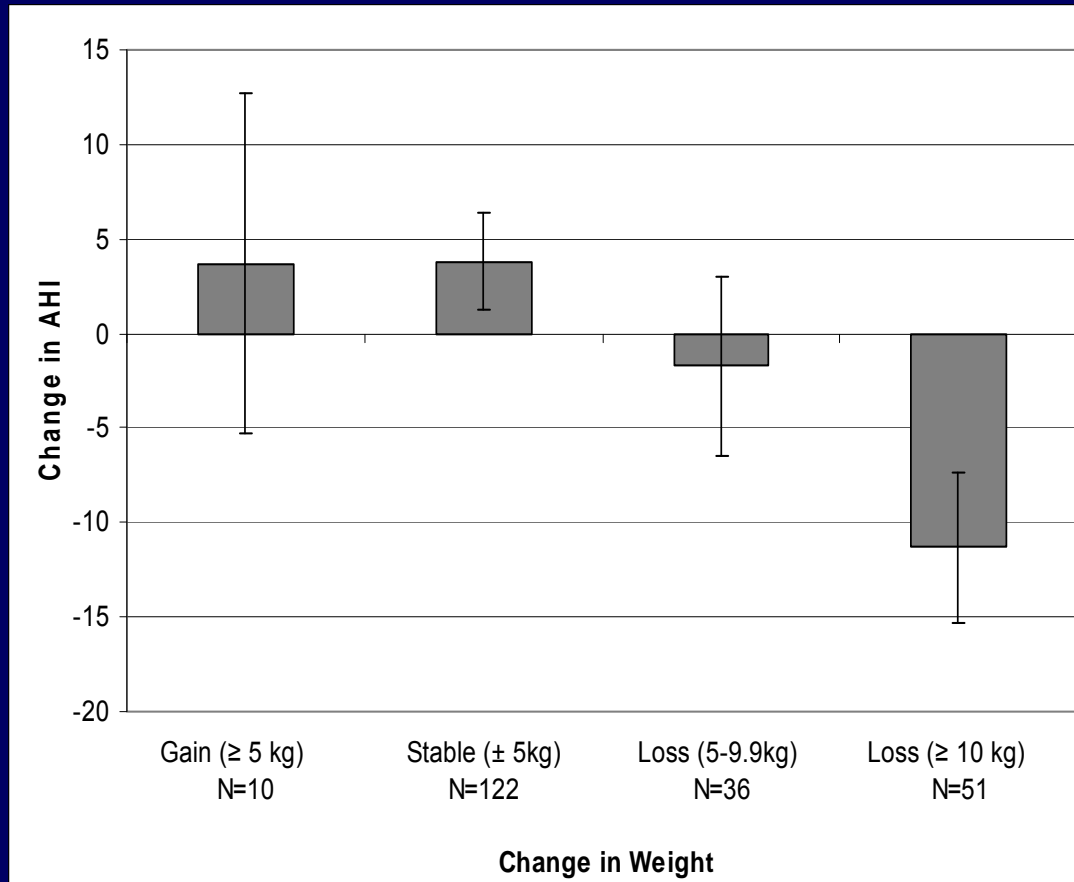


Changes in Weight and AHI

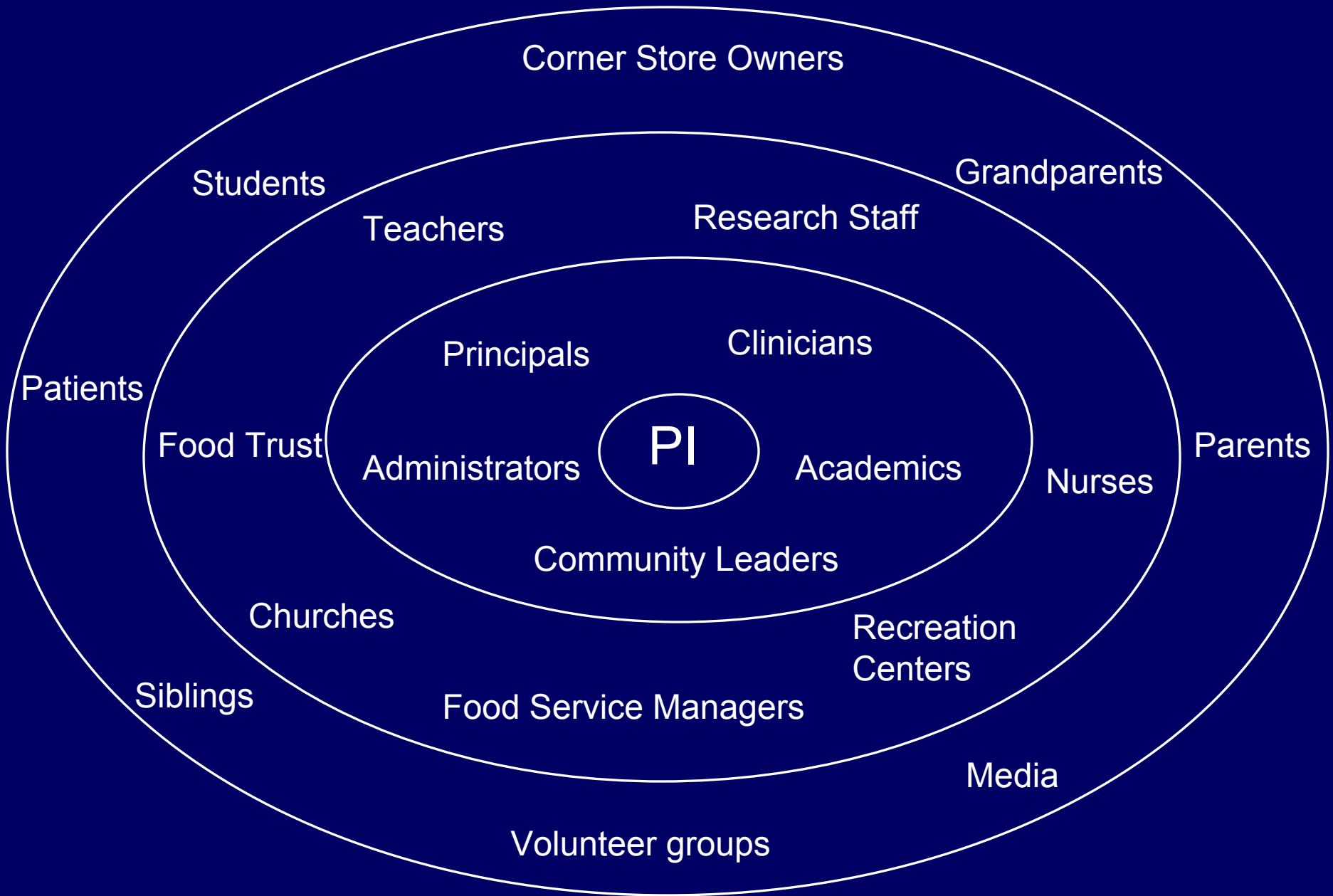


The between-group differences were significant for changes in weight ($p < .0001$) and AHI ($p < .0001$).

Changes in Weight and AHI

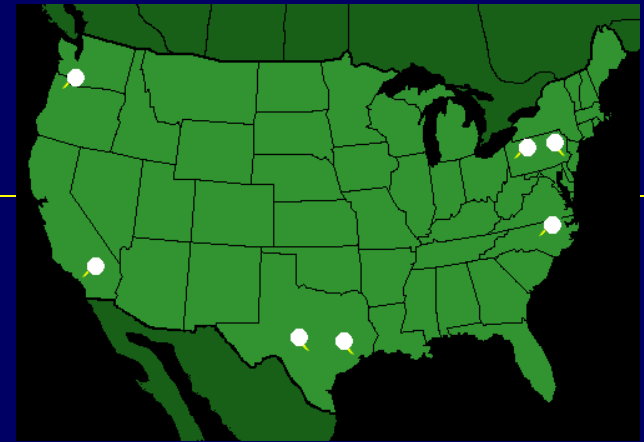


After controlling for multiple comparisons, participants who lost ≥ 10 kg had significantly greater reductions in AHI than all other groups ($p < .01$ for all).



HEALTHY Sample

- 42 middle schools
 - Randomized to intervention or control
- Intervention:
 - Environmental changes to school food service and physical education class activities
 - Communications and promotional campaign
 - Behavior change activities, messages, and goal setting
- Intervention goal: ↓ risk factors for T2D
- 3 primary outcomes indicating risk
 - BMI ≥ 85th percentile
 - Fasting glucose ≥ 100 mg/dL
 - Fasting insulin ≥ 30 μU/mL



Distribution of BMI Percentile Categories

	Control	Intervention	Overall
	n(%ile)	n (%ile)	n (%ile)
Underweight (< 5 %ile)	63 (2.0)	38 (1.2)	101 (1.6)
Normal Weight (5-84%ile)	1,536 (48.4)	1,576 (49.3)	3,112 (48.9)
Overweight (85-94 %ile)	630 (19.9)	631 (19.8)	1,261 (19.8)
Obese (\geq 95 %ile)	944 (29.8)	949 (29.7)	1,893 (29.7)

ORIGINAL ARTICLE

A School-Based Intervention for Diabetes Risk Reduction

The HEALTHY Study Group*

ABSTRACT

BACKGROUND

We examined the effects of a multicomponent, school-based program addressing risk factors for diabetes among children whose race or ethnic group and socioeconomic status placed them at high risk for obesity and type 2 diabetes.

METHODS

Using a cluster design, we randomly assigned 42 schools to either a multicomponent school-based intervention (21 schools) or assessment only (control, 21 schools). A total of 4603 students participated (mean \pm SD age, 11.3 \pm 0.6 years; 54.2% Hispanic and 18.0% black; 52.7% girls). At the beginning of 6th grade and the end of 8th grade, students underwent measurements of body-mass index (BMI), waist circumference, and fasting glucose and insulin levels.

RESULTS

There was a decrease in the primary outcome — the combined prevalence of overweight and obesity — in both the intervention and control schools, with no significant difference between the school groups. The intervention schools had greater reductions in the secondary outcomes of BMI z score, percentage of students with waist circumference at or above the 90th percentile, fasting insulin levels ($P=0.04$ for all comparisons), and prevalence of obesity ($P=0.05$). Similar findings were observed among students who were at or above the 85th percentile for BMI at baseline. Less than 3% of the students who were screened had an adverse event; the proportions were nearly equivalent in the intervention and control schools.

CONCLUSIONS

Our comprehensive school-based program did not result in greater decreases in the combined prevalence of overweight and obesity than those that occurred in control schools. However, the intervention did result in significantly greater reductions in various indexes of adiposity. These changes may reduce the risk of childhood-onset type 2 diabetes. (Funded by the National Institutes of Health and the American Diabetes Association; ClinicalTrials.gov number, NCT00458029.)

The members of the writing group (Gary D. Foster, Ph.D., Temple University, Philadelphia; Barbara Linder, M.D., Ph.D., National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD; Tom Baranowski, Ph.D., Baylor College of Medicine, Houston; Dan M. Cooper, M.D., University of California at Irvine, Irvine; Linn Goldberg, M.D., Oregon Health and Science University, Portland; Joanne S. Harrell, Ph.D., University of North Carolina at Chapel Hill, Chapel Hill; Francine Kaufman, M.D., Children's Hospital Los Angeles, Los Angeles; Marsha D. Marcus, Ph.D., University of Pittsburgh, Pittsburgh; Roberto P. Treviño, M.D., University of Texas Health Science Center at San Antonio, San Antonio; and Kathryn Hirst, Ph.D., George Washington University, Washington, DC) assume responsibility for the integrity of the article. Address reprint requests to Dr. Foster at the Center for Obesity Research and Education, Temple University, 3223 N. Broad St., Suite 175, Philadelphia, PA 19140, or at gfooster@temple.edu.

*The members of the HEALTHY Study Group are listed in the Appendix.

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Summary

- Overall Sample
 - No difference Intervention or Control schools in prevalence of combined overweight and obesity (45.8% vs. 45.2%)
 - Intervention schools had significantly greater decreases than control schools in:
 - BMI z-score (-0.05 vs. -0.01, $p = .04$)
 - Insulin (3.8 vs. 4.0, $p = .04$)
 - Waist circumference $\geq 90^{\text{th}}$ percentile (-8.1 vs. -5.9, $p = .04$)
 - With a strong trend (-5.5 vs. -3.8, $p = .05$) for a greater reduction in obesity (BMI $\geq 95^{\text{th}}$ percentile)

Summary

- Overweight/Obese Subgroup
 - Intervention schools had significantly greater decreases than control schools in:
 - Prevalence of obesity (-11.5 vs. -8.5, $p = .04$)
 - Insulin (3.6 vs. 4.1, $p = .04$)
 - Waist circumference $>90^{\text{th}}$ percentile (-17.0 vs. -12.6, $p = .03$)

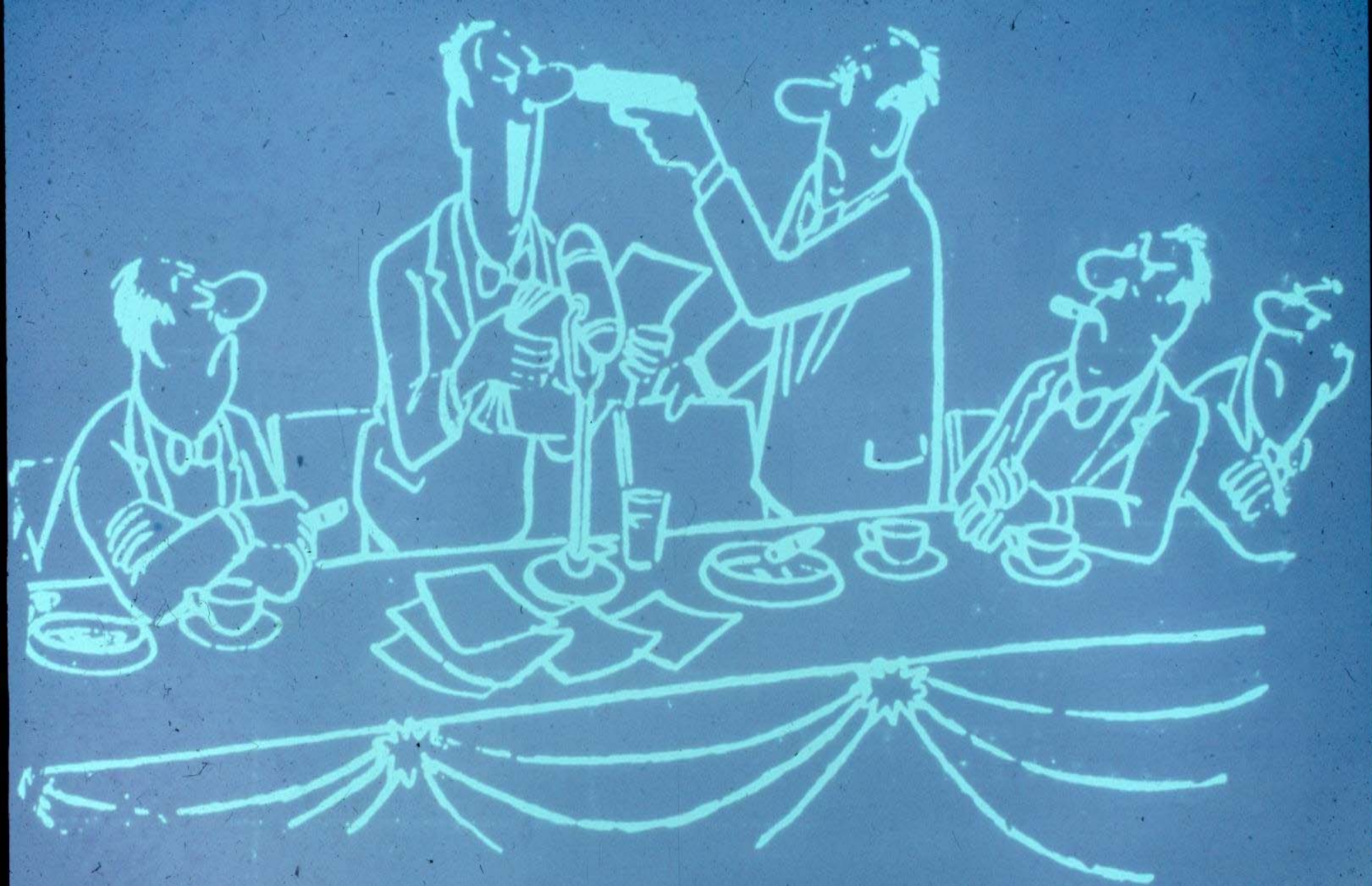
Diabetes Risk Factors by BMI Percentile Category in 8th Grade

BMI Percentile

Variable	<85 th	85-94 th	≥ 95 th
Insulin ≥ 30 μU/dL	2%	6%	35%
Glucose ≥ 100mg/dL	19%	21%	30%

Summary

- Collaboration improves the quality of the research.
- It takes patience and compromise.
- It's worth it!



THE SATURDAY EVENING POST

"Well, I see my time is up . . ."