

## Found in Translation: The Diabetes Prevention Program Approach in a Community Setting

Interim results have been reported for the Healthy Living Partnership to Prevent Diabetes (HELP PD) study (NCT00631345), a community-based interpretation of the clinical methods that are described in the landmark Diabetes Prevention Program (DPP; Diabetes Prevention Program Research Group. *N Engl J Med* 2002). These 6- and 12-month data points for the planned 2-year investigation suggest that onset of diabetes may be delayed or prevented by modest weight loss that is achieved through proper diet and exercise—without the use of pharmacotherapy.

As reported by Jeffrey Katula, PhD, MA, Wake Forest University School of Medicine, Winston-Salem, NC, HELP PD is a two-arm, randomized trial that compares:

- Lifestyle Weight loss (LW): Three sessions with a registered dietitian (RD) in the first 6 months and group meetings with community health workers (CHW), focused on weight loss, increased physical activity, and nutrition; weekly for the first 6 months, then monthly for the remaining 18 months (unlike DPP, the use of pharmacotherapy was not compared)
- Usual Care (UC): Two sessions with an RD during the first 3 months; monthly newsletters about community resources for weight loss thereafter

Eligibility for HELP PD included age  $\geq 21$  years, body mass index (BMI) 25 to 40 kg/m<sup>2</sup>, fasting blood glucose (FBG) 95 to 125 mg/dL, no previous diabetes diagnosis, no recent history of cardiovascular disease, and no uncontrolled high blood pressure  $\geq 160/100$  mm Hg. Enrolled subjects were randomized in a 1:1 fashion and were to be evaluated every 6 months for adiposity, fasting glucose, and HOMA-IR (n=301).

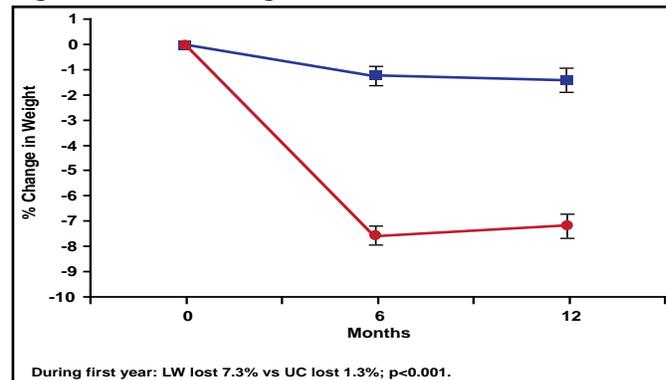
As previously described, therapeutic goals for the first 6 months—“intensive phase”—consisted of a dietary reduction of 500 to 1000 calories/day, an increase to 180 minutes/week of physical activity (most typically, walking), weight loss of 1 to 2 pounds/week, and 7% weight loss overall. Following this, the remaining 18-month period consisted of two contacts with CHWs—one contact by telephone and one group meeting—and maintenance of 180 minutes/week increase in activity over baseline (Katula et al. *Contemp Clin Trials* 2009).

At baseline, HELP PD subjects were 57.5% female and 74% Caucasian. Median age was 57.8 years, weight 94.1 kg, BMI 32.8 kg/m<sup>2</sup>, FBG 105 mg/dL, and HOMA-IR 4.4.

Reporting interim results, Dr. Katula highlighted continued participation, defined as attendance at scheduled HELP PD intervention appointments, the treatment parameter that is most critical for a successful weight loss program. The LW cohort had an adherence rate of 83.8% during the 1-to-6-month time period and 64.1% during the 7-to-12-month time period. Eight percent LW versus 11% UC were lost to follow-up.

As expected, reductions in weight (kg), percentage of total weight, and BMI at 6 and 12 months for LW were superior to UC (7.1 kg vs 1.5; 7.3% vs 1.3%; 2.2 kg/m<sup>2</sup> vs 0.3 kg/m<sup>2</sup>; all p<0.001). Of note, the statistically significant reductions that were observed in all three parameters occurred within the first 6 months of the study, and were thereafter maintained or incurred slight increases (Figure 1).

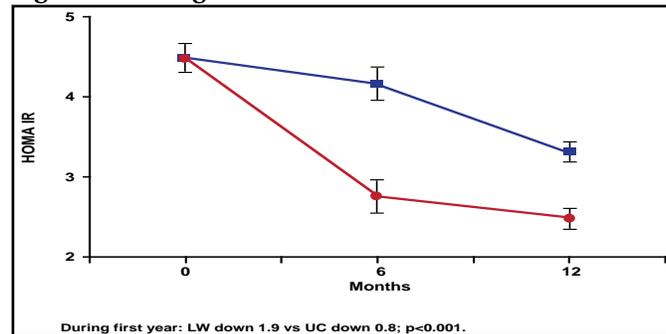
**Figure 1. Percent Weight Loss at 6 and 12 Months.**



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Laboratory values also reflected benefit from the HELP PD intervention. Both FBG and insulin levels were significantly reduced for LW versus UC, resulting in HOMA IR decreases of 1.9 versus 0.8, respectively (p<0.001; Figure 2).

**Figure 2. Fasting HOMA IR at 6 and 12 Months.**



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