



A NONPROFIT, NONPARTISAN ORGANIZATION

Top Tier Evidence Initiative:

Evidence Summary for Healthy Living Partnerships to Prevent Diabetes

HIGHLIGHTS:

- **Intervention:** A community-based lifestyle weight-loss program for overweight or obese adults with prediabetes.
- **Evaluation Methods:** A well-conducted randomized controlled trial.
- **Key Findings:** Two years after random assignment, a 7.5-pound reduction in body weight, a 4% decrease in fasting blood glucose (a test used to diagnose prediabetes and diabetes), and a promising but not yet definitive reduction in incidence of diabetes – from 8% to 3%.
- **Other:** A study limitation is that its sample was relatively small and geographically concentrated in the Winston-Salem, North Carolina area. Replication of these findings in a second trial, in another setting, would be desirable to confirm the initial results and establish that they generalize to other settings where the intervention might be implemented.

I. The Top Tier initiative's Expert Panel has identified this intervention as **Near Top Tier**.

The Panel finds that this intervention meets the “Near Top Tier” evidence standard, defined as:

Interventions shown to meet almost all elements of the Top Tier standard (i.e., well-conducted randomized controlled trials... showing sizable, sustained effects), and which only need one additional step to qualify. This category includes, for example, interventions that meet all elements of the standard in a single site, and just need a replication trial to confirm the initial findings and establish that they generalize to other sites.

II. Description of the Intervention:

Healthy Living Partnerships to Prevent Diabetes (HELP PD) is a community-based lifestyle weight-loss program designed for overweight or obese adults with prediabetes.¹ The goal is for participants to lose 5-7% of their body weight over six months – through increased physical activity (at least 180 minutes/week) and limited caloric intake (approximately 1,500 calories/day) – and to maintain the weight loss for an additional 18 months.

The program is delivered over 24 months. For the first six months (the intensive phase), participants attend 24 weekly group sessions (8-12 participants per group), each of which is led by a trained community health worker. The sessions take place at community sites, such as recreation centers or parks. The sessions focus on reducing caloric intake (e.g., reducing portion sizes), increasing aerobic physical activity (e.g., brisk walking), and adopting behavioral self-management strategies (e.g., controlling negative emotions). Participants also receive three personalized consultations with a registered dietitian. During the next 18 months (the maintenance phase), participants have two contacts each month with the community health worker – one group session and one telephone call – to reinforce the strategies described above and help participants address barriers to weight loss.

¹ HELP PD is designed as a low-cost, group-based adaptation of the Diabetes Prevention Program (DPP) – a more expensive, individualized lifestyle program delivered by specialized personnel. DPP has previously been found in a [large, well-conducted RCT](#) to produce sizable and sustained effects on weight loss and incidence of diabetes.

The community health workers were recruited specifically for the study described below, and all have well-controlled type 2 diabetes and a history of healthy eating and physical activity. They each received brief training (36 hours) from registered dietitians, who also monitored their delivery of the program. The program’s cost is \$911 per participant (in 2013 dollars).² The program website is www.healthylivingpartnership.org.

III. Evidence of Effectiveness:

This summary of the evidence is based on a systematic search of the literature, and correspondence with leading researchers, to identify all well-conducted randomized controlled trials of HELP PD. Our search identified one such trial. What follows is a summary of the study design and the program’s effects on the main outcomes measured in the study, including any such outcomes for which no or adverse effects were found. All effects shown are statistically significant at the 0.05 level unless stated otherwise.

Overview of the Study Design: Randomized controlled trial of HELP PD in a sample of 301 adults with prediabetes in the Winston-Salem, North Carolina area, conducted 2007-2011.

This trial was conducted in a sample of 301 overweight or obese adults with prediabetes who lived in the Winston-Salem, North Carolina area, had agreed to participate in the study, and had no health conditions that could interfere with participation in a weight-loss program or independent physical activity (e.g., cardiovascular disease, uncontrolled hypertension, pregnancy, chronic disease likely to limit lifespan to less than 2-3 years, or major psychiatric or cognitive problems). These individuals were randomly assigned to (i) a group that received the HELP PD program, or (ii) a control group that received enhanced usual care, consisting of two individual sessions with a nutritionist during the first three months after randomization and a monthly newsletter about healthy lifestyles.

74% of the sample members were white, 58% were female, and 48% had a bachelor’s degree or higher. Their average age was 58 and weight was 206 pounds. They averaged 105.5 mg/dL in fasting blood glucose, which is in the prediabetic range as defined by the American Diabetes Association [ADA, 2013]:

Condition	Fasting Blood Glucose
Diabetes	Greater than 125 mg/dL
Prediabetes	100 – 125 mg/dL
Normal	Less than 100 mg/dL

Effects of HELP PD two years after random assignment:

Compared to the control group, members of the HELP PD group –

- Weighed an average of 7.5 pounds less (195.8 pounds for the HELP PD group versus 203.3 pounds for the control group);
- Were much more likely to lose at least 10% of their body weight – i.e., approximately 20 pounds (21.3% versus 5.3%);

² This amount includes all costs of delivering the program except for training of the community health workers and dietitians (which is likely to be modest when spread over the many participants they work with).

- Had 4% lower fasting blood glucose levels (103.3 mg/dL versus 107.6 mg/dL); and
- Were less likely to develop diabetes (3.1% versus 8.3%). This effect was statistically significant at the 0.10 level but not the 0.05 level.

The study did not find statistically-significant effects on measures of health care utilization or expenditures (e.g., number of days hospitalized, and cost of hospital care).

Discussion of study quality:

- The study had low sample attrition: Outcome data were obtained for 84% of the HELP PD group and 89% of the control group at the two-year follow-up.
- At the start of the study, the HELP PD and control group members were highly similar in their observable characteristics (e.g., demographics, weight, fasting blood glucose).
- The study appropriately sought outcome data for all individuals assigned to the HELP PD group, regardless of whether or how long they participated in the program (i.e., the study used an “intention-to-treat” analysis).
- The study measured biochemical outcomes (e.g., fasting blood glucose) using blood tests performed by research assistants who were unaware (“blind”) as to which sample members were in the HELP PD group versus control group. Physical measurements (e.g., weight, waist circumference) were assessed using objective measures (e.g., digital scale).
- The study evaluated HELP PD as delivered by community health workers in a typical community setting, thus providing evidence of the program’s effectiveness under real-world implementation conditions.
- Study limitations:
 - The study sample was relatively small, and geographically concentrated in Winston-Salem, North Carolina. The Top Tier initiative’s Expert Panel believes that replication of the above findings in a second trial, conducted in another setting, would be desirable to confirm the initial findings and establish that they generalize to other settings where the intervention might normally be implemented. Preferably, the replication trial would have a sample large enough to confirm whether this study’s promising finding of an effect on incidence of diabetes (statistically significant at the 0.10 level) is valid.
 - The study’s follow-up period was only two years. Longer-term follow-up would be desirable to determine if the effects at two years persist.

IV. Summary of the Intervention's Benefits and Costs:

If taxpayers fund implementation, what benefits to society can they expect to result, and what would be their net cost? The following table provides a summary. This is intended to be a general overview of social benefits in relation to taxpayer cost, rather than a comprehensive benefit-cost analysis. It assigns monetary value to particular benefits and costs only when doing so requires minimal assumptions.

<u>Benefits To Society</u>
Two years after random assignment:
<ul style="list-style-type: none">▪ A 7.5-pound reduction in body weight.▪ A 4% reduction in fasting blood glucose (a test used to diagnose prediabetes and diabetes).▪ A promising but not yet definitive reduction in incidence of diabetes – from 8% to 3%.
<u>Net Cost To Taxpayers</u>
<ul style="list-style-type: none">▪ Approximately \$911 per participant in 2013 dollars, to deliver program services.*

* This amount includes all costs of delivering the program except for training of the community health workers and dietitians (which is likely to be modest when spread over the many participants they work with).

V. References:

Main study

- [Katula, Jeffrey A.](#), Mara Z. Vitolins, Timothy M. Morgan, Michael S. Lawlor, Caroline S. Blackwell, Scott P. Isom, Carolyn F. Pedley, and David C. Goff, Jr. “The Healthy Living Partnerships to Prevent Diabetes Study: 2-Year Outcomes of a Randomized Controlled Trial.” *American Journal of Preventive Medicine*, 2013, vol. 44, no. 4S4, pp. S324-S332.
- [Lawlor, Michael S.](#), Caroline S. Blackwell, Scott P. Isom, Jeffrey A. Katula, Mara Z. Vitolins, Timothy M. Morgan, and David C. Goff Jr. “Cost of a Group Translation of the Diabetes Prevention Program: Healthy Living Partnerships to Prevent Diabetes.” *American Journal of Preventive Medicine*, 2013, vol. 44, no. 4S4, pp. S381–S389.
- [Katula, Jeffrey A.](#), Mara Z. Vitolins, Erica L. Rosenberger, Caroline S. Blackwell, Timothy M. Morgan, Michael S. Lawlor, and David C. Goff, Jr. “One-Year Results of a Community-Based Translation of the Diabetes Prevention Program.” *Diabetes Care*, 2011, vol. 34, no. 7 pp. 1451-1457.

Other reference

- American Diabetes Association. “Standards of Medical Care in Diabetes – 2013.” *Diabetes Care*, 2013, vol. 36, supplement 1, pp. S11-S66.