

A Randomized Trial of Weight Change in a National Home Visiting Program



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Introduction: Clinical trials have demonstrated significant impact in reducing weight and incidence of type 2 diabetes mellitus. However, the intensity of these trials limits their scalability to real world settings. The purpose of this study was to embed a lifestyle intervention for overweight and obese mothers within the routine practice of a parent education, home visiting organization.

Design: Pragmatic trial that used a stratified random design.

Setting/participants: Overweight or obese mothers of preschool children located across St. Louis, Missouri, enrolled in Parents As Teachers, a home visiting organization reaching women and children nationwide.

Intervention: A lifestyle intervention derived from the Diabetes Prevention Program was embedded within Parents As Teachers entitled Healthy Eating and Active Living Taught at Home (HEALTH).

Main outcome measures: Outcomes included the proportion of women that achieved 5% weight loss at 24 months and improvements in clinical and behavioral outcomes at 12 and 24 months. Participants were enrolled from 2012 to 2014 and data analysis began in 2016.

Results: Women in the usual care versus intervention group were significantly less likely to achieve 5% weight loss at 24 months (11% vs 26%, $p=0.01$). At 12 months, there was a 2.8-kg difference in weight between groups ($p=0.0006$), and by 24 months a 4.7-kg difference in weight (3.2 [SD=7.6] kg vs -1.5 [SD=8.3] kg, $p=0.002$); group differences in waist circumference were also evident by 12 months (2.1 [SD=8.4] cm vs -0.7 [SD=9.8] cm, $p=0.04$) and 24 months (3.8 [SD=10.6] cm vs -2.5 [SD=9.1] cm, $p=0.005$), as were improvements in behavioral outcomes. There was no difference in blood pressure between groups.

Conclusions: HEALTH achieved modest but clinically significant weight loss outcomes, and reduced weight gain in mothers of young children. The scalability of this embedded intervention offers the potential to reach mothers in Parents As Teachers programs nationally.

Trial registration: This study is registered at www.clinicaltrials.gov NCT01567033.

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INTRODUCTION

Diabetes is a major public health problem of the 21st century.¹ Several successful large-scale clinical trials have clearly demonstrated the significant impact of intensive lifestyle interventions in reducing weight and incidence of type 2 diabetes mellitus from 29% to 58%.^{2–4} However, the intensity and expense of these clinical trials limits applicability in real world settings. Lifestyle interventions have been translated across a variety of primary care and community health settings, such as the YMCA,⁵ as well as non-health focused settings including churches and worksites.^{6,7} Public health priorities continue to call for transfer and scale-up of efficacious lifestyle interventions that are sustainable to reach populations at risk.⁸

Higher rates of obesity are reported for women than men.^{9,10} Maternal weight gain, initiated and repeated across pregnancies and maintained after childbirth, impacts lifelong risk for obesity and development of type 2 diabetes in reproductive age and postmenopausal women.^{11,12} Mothers of young children face multiple competing demands that limit their ability to participate or benefit from lifestyle interventions, further increasing risk for weight-related comorbid conditions. Sleep deprivation and fatigue, lack of child care, and competing roles and responsibilities are major deterrents to women engaging in healthy lifestyle behaviors necessary to achieve ideal body weight.¹³ These same barriers are associated with decreased activity and increased intake of convenience or away foods, resulting in additional caloric intake and weight gain.^{14,15} Women also serve as role models and important influencers on the learned lifestyle behaviors of their children and families.^{16,17}

One approach for addressing barriers to obesity prevention and treatment lies in partnerships with home visiting organizations that already reach women at home as part of their mission. Pragmatic interventions embedded in home visiting organizations can enhance accessibility to lifestyle interventions and allow for ongoing contact and support for behavior change. This also offers the opportunity to scale up effective interventions to maximize public health impact in preventing type 2 diabetes.¹⁸ The translational challenge lies in integrating lifestyle interventions within the mission, standards, and funding requirements of home visiting organizations that may not prioritize health-related content.

Parents As Teachers (PAT) is a national home visiting organization whose mission is to empower parents as their child's most influential teacher, promoting positive child development and school readiness.¹⁹ PAT offers an evidence-based curriculum delivered by parent educators

free of charge to families until the youngest child enters school, allowing for ongoing support and contact.¹⁹ The program is supported through federal and state funds. As of 2016, PAT was located in all 50 states reaching 123,468 parents and 148,659 children nationally.¹⁹ PAT offers an excellent organizational system for delivering, sustaining, and scaling-up interventions derived from the Diabetes Prevention Program (DPP) for obese or overweight mothers of young children.

Prior work with PAT effectively tested dietary interventions targeted to African American parents of infants,²⁰ rural parents of young children,²¹ and teen mothers.²² This study tests the impact of Healthy Eating & Active Living Taught at Home (HEALTH),²³ a lifestyle intervention derived from DPP, embedded within the usual PAT curriculum, and targeting overweight and obese mothers of preschool children at risk for excess weight. It is hypothesized that when compared with usual care, participants in the HEALTH intervention group are significantly more likely to achieve and maintain a 5% weight loss at 24 months and show improvements at 12 and 24 months in waist circumference, blood pressure, and behavioral outcomes defined by eating patterns and physical activity.

METHODS

Study Sample

This pragmatic trial used a stratified random design implemented with PAT affiliated programs located across eight St. Louis, Missouri regions. Inclusion criteria included female participants, aged between 18 and 45 years, overweight or obese (BMI 25–45), having at least one preschool-aged child at risk for overweight (BMI percentile $\geq 60\%$)²⁴ living in the home, plans to continue in the PAT program for > 2 years, and able to give informed consent. Exclusion criteria included women who were currently pregnant or planned to become pregnant in the next 24 months, unable to speak English, current enrollment in a weight-loss program, undergoing treatment for diabetes or eating disorders, or inability to engage in a walking program. PAT rolling recruitment of parents was conducted through informational events, provider referrals, and child care organizations. Participants were enrolled from 2012 to 2014, the intervention concluded in 2016, and data analysis began. Study staff called interested mothers to establish eligibility; baseline assessments were completed in a clinical setting where consent was also obtained. Participants were randomized to treatment condition by study staff using randomization sequences generated a priori by the study statistician using a formal probability model with a 1:1 allocation ratio and random block size. Randomization sequences were stratified by region. Sample size was calculated from pilot data assuming a 5% weight loss from baseline, using a two-sided test ($\alpha=0.05$) with a power of 0.9. Data were collected at baseline, 12 months, and 24 months at the study clinic site. Participants received \$50 gift cards for completing data collection at each time frame. The IRB of Washington University in St. Louis approved this study.

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