Weight Loss Success in Metabolic Syndrome by Telephone Interventions: Results from the SHINE Study

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BACKGROUND: The Diabetes Prevention Program (DPP) intensive lifestyle intervention resulted in significant weight loss, reducing the development of diabetes, but needs to be adapted to primary care provider (PCP) practices.

OBJECTIVES: To compare a DPP-translation using individual (IC) vs. conference (CC) calls delivered by PCP staff for the outcome of percent weight loss over 2 years.

DESIGN: Randomized clinical trial.

SETTING: Five PCP sites.

PARTICIPANTS: Obese patients with metabolic syndrome, without diabetes (IC, $n=129$; CC, $n=128$).

INTERVENTION: Telephone delivery of the DPP Lifestyle Balance intervention [16-session core curriculum in year 1, 12-session continued telephone contact in year 2 plus telephone coaching sessions (dietitians)].

MAIN MEASURES: Weight (kg), body mass index (BMI), and waist circumference.

KEY RESULTS: Baseline data: age=52 years, BMI=39 kg/m², 75 % female, 85 % non-Hispanic White, 13 % non-Hispanic Black, and 48 % annual incomes <\$40,000/year. In the intention-to-treat analyses at year 2, mean percent weight loss was -5.6 % (CC, $p<0.001$) and -1.8 % (IC, $p=0.046$) and was greater for CC than for IC ($p=0.016$). At year 2, mean weight loss was 6.2 kg (CC) and 2.2 kg (IC) ($p<0.001$). There was similar weight loss at year 1, but between year 1 and year 2 CC participants continued to lose while IC participants regained. At year 2, 52 % and 43 % (CC) and 29 % and 22 % (IC) of participants lost at least 5 % and 7 % of initial weight. BMI also decreased more for CC than IC (-2.1 kg/m² vs. -0.8 kg/m² $p<0.001$). Waist circumference decreased by 3.1 cm (CC) and 2.4 cm (IC) at year 2. Completers (≥ 9 of 16 sessions; mean 13.3 sessions) lost significantly more weight than non-completers (mean 4.3 sessions).

CONCLUSIONS: PCP staff delivery of the DPP lifestyle intervention by telephone can be effective in achieving weight loss in obese people with metabolic syndrome. Greater weight loss may be attained with a group telephone intervention.

KEY WORDS: obesity; health behavior; prevention.

J Gen Intern Med 28(12):1620-8

DOI: 10.1007/s11606-013-2529-7

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INTRODUCTION

Metabolic syndrome (34 % of US adults) is associated with increased morbidity and mortality related to development of serious illnesses, especially cardiovascular disease.¹ People with metabolic syndrome have central obesity and dyslipidemia, elevated blood pressure and/or abnormal fasting glucose (2 of 3 required for diagnosis). Lifestyle change resulting in weight loss can prevent or forestall the development of diabetes.²⁻⁴ In the Diabetes Prevention Program (DPP), participants in the lifestyle arm lost on average 5.6 kg over 2.8 years.² Of those with metabolic syndrome at baseline (53 %), there was significant resolution (38 % no longer met criteria for metabolic syndrome) in the lifestyle arm compared to placebo at 3 years.⁵

To improve public health we must translate the expensive and limited reach DPP to an effective, accessible intervention. Studies have tested DPP adaptations delivered in different real-world settings, e.g., YMCAs.⁶⁻⁹ However, in-person programs have limited reach when distance, transportation and time constraints exist.

Primary care provider (PCP) practices are ideal settings in which to intervene for weight loss. The US Preventive Services Task Force recommends that PCPs offer, or refer to, multi-component behavioral interventions.¹⁰ Yet, PCPs commonly do not address weight reduction,¹¹ and when they do, success has been limited.¹²⁻¹⁴ Effective programs that can be easily administered through PCP practices are needed.¹⁵ Program delivery by telephone has the advantage of unlimited reach, through flexible scheduling and access for those with time and other barriers.¹⁶ Group weight loss programs have demonstrated superiority over individual counseling in some studies.¹⁷⁻¹⁹ However, there are no randomized clinical trials of group phone lifestyle change interventions.

The purpose of this study, SHINE (Support, Health Information, Nutrition and Exercise), was to compare the

Trial Registration: clinicaltrials.gov Identifier: NCT00749606

Received November 28, 2012

Revised April 4, 2013

Accepted May 31, 2013

Published online July 11, 2013

effectiveness of two PCP staff telephone-delivered DPP translation interventions. We hypothesized that both would be effective and that group support would promote greater weight loss. Participants were obese with metabolic syndrome but not diabetes from diverse PCP practices. Weight loss was the primary outcome; SHINE was not powered to study the prevention of diabetes, previously shown in the DPP.²⁻⁵ We chose not to include a usual care control group as it is well documented that usual care participants do not achieve significant weight loss.

METHODS

Overview

Participants were randomized to receive the DPP lifestyle intervention by telephone either individually (IC) or in conference calls (CC), up to eight participants/call. Year 1 included the 16 DPP Lifestyle Balance Core Curriculum sessions²⁰ with a PCP educator, augmented by monthly coach (dietitian) sessions. A modified 12-session curriculum (monthly calls) was used by educators during year 2, per DPP materials, with optional coach contact. The primary outcome was change in weight/BMI after 6, 12 and 24 months of intervention.

Setting and Participants

Five diverse PCP sites in upstate NY participated: Oneida Healthcare Center (small city), Pulaski Health Center (rural), Syracuse Community Healthcare Center and University Health Care Center (urban, poor, medium city), and University Internists (higher income, medium city). Inclusion criteria were: >18 years old, presence of metabolic syndrome (IDF criteria²¹) and BMI ≥ 30 kg/m². The International Diabetes Federation definition requires central obesity, measured by waist circumference (WC) with ethnicity-based cutoffs, plus two of four other criteria: triglyceride level ≥ 150 mg/dl or triglyceride treatment, HDL-cholesterol <40 mg/dl (males) and <50 mg/dl (females) or HDL treatment, elevated blood pressure (systolic ≥ 130 or diastolic ≥ 85 mmHg) or treatment of diagnosed hypertension, and high fasting plasma glucose (≥ 100 mg/dl). Exclusion criteria were: diagnosed diabetes and presence of severe medical problems that could interfere with participation (e.g., severe current psychiatric illness). Potential volunteers were offered study involvement by their PCP at office visits or were identified (chart review) and contacted (letter/phone). Participants provided informed consent. Enrollment began on June 22 2009 and ended on November 2 2010. This project was approved by the

Institutional Review Board for the Protection of Human Subjects at Upstate Medical University, Syracuse, NY.

Randomization

Participants were randomized to treatment arms using a balanced block randomization schedule stratified by site and gender. Block sizes varied randomly from 6 to 12 participants. The gender stratum ensured balanced randomization of males and females to both arms. Randomization occurred within each practice site to control for subject and practice differences that might obscure significant findings.

Intervention

DPP materials were adapted for delivery by telephone. Written materials were provided to participants at baseline visits. For both interventions, educators followed scripts per DPP materials for the 16-session core curriculum, which includes goal-setting, self-monitoring, diet/activity modification and problem-solving. Topics were presented weekly for the first 5 weeks, then monthly for 1 year. A modified 12-session curriculum was used by educators during year 2, per DPP materials for additional topics. For the CC intervention, scripts included prompts for educators to engage all group members in the discussion. For example, where the script says "What did you learn by keeping track of your eating?" the group educator asked each member to respond and promoted intra-group discussion. Educators, in general, were chosen by the PCP practices. Educators were LPNs ($n=4$), RNs ($n=5$), FNP's ($n=2$) and a medical office assistant ($n=1$).

In the DPP, the core curriculum was augmented with other components (e.g., group diet and fitness classes). We included a "coach" to provide similar session enhancement. Coaches were registered dietitians, were hired centrally, and had no specific script. They answered questions, provided individualized goal setting and feedback, and problem solved behavior change barriers. Coaches made monthly calls (after first 5 weeks) alternating with educators. During year 2, each participant could request up to six coach contacts, but very few did so.

Participants used "keeping track logs" to quantify diet and activity behaviors and review progress. They mailed these monthly for dissemination to their educator and coach. Participants were given scales to self-weigh. In year 1, they recorded weight weekly, in year 2 monthly. Self-weights were discussed during calls but all outcome measures were obtained by a trained research nurse using standardized protocols.

Educators and coaches participated in a 2-day training course and supervision to competence. For quality assur-

ance, educators audiotaped a random sample of sessions during the first 6 months of year 1 and year 2 interventions. The second author reviewed audiotapes and provided supervision (face-to-face or phone) to ensure adherence to the script and the active engagement of participants. Interventionists were supervised at least six times for competence and consistency. They contacted the second author with questions, who consulted with the fifth author (consultant, a developer of the DPP curriculum) as needed.

Interventionists initiated individual calls at mutually agreed times. Conference calls were also at mutually convenient times, mediated by a telephone conferencing service (Syntela, Syracuse, NY). Educators served as liaisons to the PCPs and were asked to provide quarterly feedback to them about patient progress. These interactions were not monitored. Written assessment results (weight, blood pressure, fasting glucose, lipids) were given to PCPs.

Outcomes and Follow-Up

At baseline, 6 months, 1 and 2 years, a research nurse performed standardized assessments at the practice sites and measured height, weight, waist circumference, blood pressure, fasting glucose and lipids (Alere Cholestech LDX System, San Diego, CA). Demographic data were collected from participants, session attendance data from interventionists.

Statistical Analyses

Mixed linear model procedures (SPSS Ver. 20) were used to analyze within-subject variation in repeated outcome measures over time. Predictors included assessment period, treatment group and their interaction. All significance testing procedures were two-tailed and performed at the 5 % significance level. The intention-to-treat analysis was performed using a data set with multiple (5) imputations for missing outcome measurements. The imputed data were produced with the SPSS Ver. 20 imputation module using linear regression and the following predictors: baseline measurement, treatment arm, gender, age and site.

RESULTS

Interested individuals ($n=331$) identified by providers as obese were assessed for eligibility; 257 were randomized to the CC ($n=128$) or IC ($n=129$) interventions (Fig. 1). Of the 74 excluded, 63 did not meet eligibility criteria. At baseline, participants in the two arms did not differ on any demographic characteristics (Table 1). Mean age was 52 years, mean BMI was 39 kg/m², 75 % were female,

85 % were non-Hispanic White and 13 % non-Hispanic Black. Approximately half had annual incomes <\$40,000/year. Follow-up assessments were performed at 6 months for 71 % (CC) and 65 % (IC) of participants, at 1 year for 63 % (CC) and 57 % (IC) of participants, and at 2 years for 56 % (CC) and 49 % (IC) of participants (Fig. 1).

We present weight loss data as mean percent reduction in weight from baseline and as actual weight loss (kg) from baseline (Fig. 2). Mean percentage weight loss ($\pm$ SD, p -value) from baseline for IC at 6, 12 and 24 months was -3.9 % (15.2 %, $p<0.001$), -4.2 % (16.9 %, $p<0.001$) and -1.8 % (18.6 %, $p=0.046$), respectively. Comparable rates for CC were -4.0 % (14.8 %, $p<0.001$), -4.5 % (20.3 %, $p<0.001$) and -5.6 % (26.8 %, $p<0.001$). Mean percentage weight loss was greater for CC than IC at year 2 ($p=0.016$) but did not differ significantly at the 6- and 12-month assessments. Participants in the CC intervention lost a mean ($\pm$ SD, p -value) of 4.5 kg (15.7, $p<0.001$) at 6 months, 4.9 kg (17.7, $p<0.001$) at 1 year and 6.2 kg (14.3, $p<0.001$) at 2 years. Participants in the IC intervention lost 4.3 kg (15.6, $p<0.001$) at 6 months, 4.6 kg (17.6, $p<0.001$) at 1 year and 2.2 kg (14.2, $p<0.001$) at 2 years. At 2 years, mean weight loss from baseline was greater for CC than for IC participants ($p<0.001$). Sensitivity analysis for weight loss over time was also performed. Mixed linear model analysis on the original (missing-values) data and on baseline carried forward data showed significant weight loss from baseline for all subsequent assessments for both CC and IC participants (all $p<0.001$).

For CC participants, BMI decreased by 1.7 kg/m² and 2.1 kg/m² at years 1 and 2; for IC intervention decreases were 1.7 kg/m² and 0.8 kg/m². At 2 years, mean BMI reduction from baseline was greater for CC than for IC intervention ($p<0.001$). Waist circumference decreased by 4.5 cm (19.5) in CC participants and 5.0 cm (19.4) in IC participants at 1 year and by 3.1 cm (15.5) and 2.4 cm (15.5) at 2 years (Fig. 2d). Mean decrease in waist circumference did not differ significantly between the two arms.

Completers ($N=117$) were defined as participants who attended ≥ 9 of the 16 core sessions (9 was the mean and median of sessions attended), as this threshold is consistent with the Centers for Disease Control and Prevention's attendance criteria for diabetes prevention recognition programs.²² Completers attended, on average, 13.3 (SD 5.9) sessions; non-completers ($N=114$, includes those lost to follow-up) attended on average 4.3 (SD 2.3) sessions. There were no significant differences between the number or percent of participants who were completers in each arm. There was significantly greater decrease in mean percent weight change, mean weight, BMI and WC of completers compared to non-completers at year 2 [mean, (SD): 5.7 % (11.8 %) vs. 1.3 % (20.9 %), 6.2 kg (11.8) vs. 1.2 kg (20.5), 2.0 kg/m² (5.1) vs. 0.4 kg/m² (8.8) and 4.3 cm (12.3) vs. 0.6 cm (21.6), all $p\leq 0.003$] (Fig. 3).

Figure 1. CONSORT flow diagram.

The weight loss goal was defined as a loss of at least 5 % of initial body weight (7 % was the goal in the DPP). Achievement of these goals was similar for CC and IC participants at 1 year, but at 2 years there was greater attainment of weight loss goals in CC. At year 2, 52 % and 43 % (CC) and 29 % and 22 % (IC) of participants lost at least 5 % and 7 % of initial weight (all $p \leq 0.01$) (Table 2). In intention-to treat analyses, overall, 41 % and 32 % of participants lost ≥ 5 % and ≥ 7 % body weight at 1 year, and 87 % of those who lost ≥ 5 % were completers. At 2 years, 41 % and 33 % of participants lost ≥ 5 % and ≥ 7 % of initial weight, and 83 % of those who lost ≥ 5 % were completers

($p < 0.002$). There were also significant differences in weight loss between sites. At 2 years, percent weight loss (mean, SD) at site 3 (10.2 %, 25.0 %) was significantly greater than at site 2 (1.5 %, 23.2 %), site 5 (2.0 %, 30.4 %), site 1 (3.8 %, 21.5 %) and site 4 (3.9 %, 18.8 %), with all Sidak-adjusted p -values ≤ 0.002 . No other differences between sites were significant. The educator at the site with the greatest weight loss was a medical office assistant. Participants who did not lose ≥ 5 % body weight were also more likely to have higher non-HDL cholesterol levels ($p = 0.025$). Other baseline characteristics (age, race, gender, education, income, employment status, marital status, fasting glucose, blood pressure,

Table 1. Baseline Measures and Characteristics of Participants (n=257)

		Mean (SD)		
Clinical measures		IC (n=129)	CC (n=128)	p
Age (years)		50.7 (13.1)	52.7 (12.8)	0.22
Weight (kg)		105.8 (23.6)	109.4 (26.1)	0.25
Height (cm)		164.7 (9.3)	165.9 (9.2)	0.32
Body mass index (kg/m ²)		38.9 (7.6)	39.7 (8.3)	0.44
Waist circumference (cm)		118.3 (15.9)	118.8 (17.6)	0.81
Systolic BP (mmHg)		127.7 (15.4)	130.4 (19.8)	0.22
Diastolic BP (mmHg)		75.1 (9.3)	76.4 (11.3)	0.30
Heart rate (bpm)		73.8 (10.1)	72.3 (10.5)	0.23
Fasting glucose (mg/dl)		100.3 (11.8)	98.9 (12.2)	0.36
Total cholesterol (mg/dl)		178.2 (38.3)	182.4 (36.6)	0.37
HDL cholesterol (mg/dl)		43.7 (14.2) ^a	41.1 (12.5) ^a	0.12
LDL cholesterol (mg/dl)		106.7 (29.3) ^b	109.8 (27.2) ^c	0.39
Non-HDL cholesterol (mg/dl)		135.2 (37.7)	141.6 (38.0)	0.17
Triglycerides (mg/dl)		141.0 (72.1) ^a	150.4 (91.7)	0.37
Characteristics		n (%)		
Sex	Female	101 (78.3)	92 (71.9)	0.23
Race	White	109 (84.5)	110 (85.9)	0.80
	African American/other races	18 (13.9)	16 (12.5)	
	Hispanic	1 (0.8)	2 (1.6)	
	Missing	1 (0.8)	0 (0.0)	
Marital status	Married	68 (52.7)	67 (52.3)	0.80
	Single	38 (29.5)	33 (25.8)	
	Divorced/separated	16 (12.4)	18 (14.1)	
	Widowed	7 (5.4)	10 (7.8)	
Employment	Employed	63 (48.8)	56 (43.8)	0.41
Education	No high school diploma	15 (11.6)	11 (8.6)	0.36
	High school/technical diploma	70 (54.3)	64 (50.0)	
	Associates degree	18 (14.0)	22 (17.2)	
	Bachelor's degree	13 (10.1)	22 (17.2)	
	Post-bachelor's degree	13 (10.1)	9 (7.0)	
Retired	Not retired	103 (79.8)	96 (75.0)	0.29
	Retired	25 (19.4)	32 (25.0)	
	Missing	1 (0.8)	0 (0.0)	
Household income (\$)	≤20,000	28 (21.7)	21 (16.4)	0.71
	20,001 –40,000	37 (28.7)	38 (29.7)	
	≥40,001	51 (39.5)	53 (41.4)	
	Missing	13 (10.1)	16 (12.5)	

^an= 127^bn= 116^cn= 122

LDL-cholesterol, HDL-cholesterol and triglyceride levels) were not predictors of weight loss.

Though no participant had diabetes at baseline, six participants were diagnosed with diabetes during participation (3 non-completers, 3 completers). Between baseline and 2 years, there were no significant changes in fasting glucose, lipid or blood pressure levels within either arm. Metformin was taken by 4 participants at baseline, 6 participants at 1 year and 11 participants at 2 years. Lipid-lowering medications were used by 45 % of the sample at baseline, 47 % at 1 year and 44 % at 2 years; blood pressure-lowering medications were used by 66 % at baseline, 62 % at 1 year and 63 % at 2 years (not significant).

DISCUSSION

SHINE, a real-world, widely deployable, telephone adaptation of the DPP intensive lifestyle program, delivered by PCP staff, was effective in achieving significant weight loss at 1 and 2 years in obese people with metabolic syndrome.

These individuals are at high risk for type 2 diabetes and cardiovascular disease, and are important to target for weight loss. Using the telephone can overcome transportation, distance, financial and time barriers.

The CC intervention resulted in greater weight loss at 2 years than the IC intervention. CC educators were trained to promote intra-group discussion, and group members shared weight loss strategies within a supportive environment. The continued weight loss of CC participants compared to weight regain (common in weight loss trials) of IC participants may be due to this dynamic, i.e., group members benefitted from interaction and support. Also, there may have been undetected differences in session completion. In the IC arm, if participants missed sessions, educators resumed the curriculum where they left off and completed sessions feasible in the time allotted. If CC participants missed sessions, they would resume the curriculum at the topic that the group was discussing. This may have led them to “cover” the missed content independently.

There are differences between the participants in SHINE and the DPP. SHINE was neither designed nor powered to

*p<0.05 for within-arm comparison to baseline mean

Figure 2. Mean percent weight change (a), weight (b), body mass index (c) and waist circumference (d) at baseline, 6, 12 and 24 months for participants in the Individual Call (IC) and Conference Call (CC) interventions. Vertical lines indicate 95 % confidence intervals.

show reduction in glucose levels like the DPP was. All DPP participants had impaired glucose tolerance or pre-diabetes, whereas SHINE enrolled people with metabolic syndrome, but not necessarily pre-diabetes. Our participants, compared to those in the DPP, had greater weight, BMI and percent with annual income <\$20,000, and lower education and employment.²³

Appel and coworkers²⁴ reported the effectiveness of two weight loss interventions in primary care: an in-person intervention with motivational interviewing and case management support, and one using a study-specific web site, telephone and e-mail. Results of both are similar to those reported here. At 2 years, their remote support group lost 4.6 kg and in-person support group lost 5.1 kg, compared to 6.2 kg (CC) and 2.2 kg (IC) in SHINE. Similarly, 38.2 % (remote support) and 41.4 % (in-person support) lost ≥ 5 % of initial weight vs. 52.2 % (CC) and 28.6 % (IC) in SHINE. There were key participant differences. Appel's participants lived in an urban environment, with greater incomes, education and employment than SHINE participants. They also included individuals with diabetes and were provided assistance with blood glucose self-monitoring and medication adjustment. Our results, achieved in the setting of community PCPs serving individuals with lower socioeconomic status, surpass those observed in many other in-person studies, including one led by primary care nurses, and a community health center-based program using the web, interactive voice response, monthly counseling calls and optional group support sessions.^{6,25,26} Thus, SHINE is important as a relatively simple, telephone translation of the DPP weight loss intervention in primary care, with 1- and 2-year results that are similar to or surpass those observed with other interventions.

A recent systematic review and meta-analysis of 28 DPP translation lifestyle programs (2003–2011) delivered in-person through community and health care facilities, and delivered using electronic media, showed mean weight loss of 4 % at 1 year.⁶ One factor associated with successful weight loss was attending more sessions. This was also demonstrated in SHINE, with 41.9 % of completers achieving ≥ 5 % loss of baseline weight at 1 year. It was also reported that non-medical interventionists were as successful as medical personnel, a finding also observed in SHINE. Even a medical office assistant was effective and likely helped curtail practice costs.

The strengths of SHINE are delivery of the intervention by telephone, which is widely available with excellent usability; the enrollment of obese patients with metabolic syndrome from diverse PCP practice sites and socioeconomic groups; and use of non-physician staff as interventionists with

Figure 3. Mean weight (a), body mass index (b) and waist circumference (c) at baseline, 6, 12 and 24 months for Completers and Non-completers. Vertical lines indicate 95 % confidence intervals.

Table 2. Percentage of Participants Who Achieved Weight Loss Goals in the Individual (IC) and Conference Call (CC) Interventions

	IC			CC		
	Completers	Non-completers	Total	Completers	Non-completers	Total
6 Months						
≥5 %	52.8*	10.0	37.3 (NS)	50.0*	25.0	41.3
≥7 %	35.8*	10.0	26.5 (NS)	43.3*	18.8	34.8
≥10 %	20.8*	3.3	14.5 (NS)	18.3 (NS)	9.4	15.2
12 Months						
≥5 %	41.9*	14.3	39.2 (NS)	50.9*	21.7	42.5
≥7 %	35.8*	9.5	28.4 (NS)	45.6*	13.0	36.2
≥10 %	24.5 (NS)	4.8	18.9 (NS)	31.6*	8.7	25.0
24 Months						
≥5 %	29.8 (NS)	25.0	28.6**	60.8*	27.8	52.2
≥7 %	25.5 (NS)	12.5	22.2**	51.0*	22.2	43.5
≥10 %	17 (NS)	0.0	12.7 (NS)	31.4 (NS)	11.1	26.1

*Completer vs. non-completer within each arm: $p \leq 0.05$. NS: $p > 0.05$

**IC vs. CC: $p \leq 0.05$. NS: $p > 0.05$

minimal physician involvement. Limitations include the limited race/ethnicity of participants, which reflect the demographics of upstate NY (few Hispanics) and significant attrition. Attrition is common in obesity studies, particularly in low-income populations and community settings. In addition, in SHINE, PCPs assigned staff to serve as educators. The staff had varying levels of enthusiasm. It is possible that retention, and even weight loss success, would have been better if staff chosen as educators had volunteered, were highly interested in the program and/or were provided additional incentives for participation.

In conclusion, the SHINE translation of the DPP intensive lifestyle intervention for obese people with metabolic syndrome is novel and was shown to be equally effective at 1 year when delivered by conference call or individually. At 2 years CC participants had greater relative weight loss and, as compared to the slight regain for IC participants, continued additional weight loss. The interventions were delivered using the telephone as a way to increase reach through flexible scheduling and access for those less likely to enroll if travel was required (e.g., rural, disabled, poor, elderly, those with time limitations). This model holds promise for use to effect lifestyle change and weight loss in primary care settings.

Acknowledgments:

Contributors: We thank our participants, their primary care providers, the health care professionals who served as educators and our dietitian coaches. We also thank Julie J. Stone, RN, for performing the participant assessments and Jane D. Bulger, MS, CCRC, and Michael J. Wade, MS, for facilitating data collection and data entry.

Funders: This study was supported by grant R18-DK078553 from the National Institutes of Health (NIDDK; Trief and Weinstock PIs).

Prior presentations: Some of these findings were published in abstract form and presented in oral sessions at the annual meeting of the American Diabetes Association meeting in June 2012 and June 2013.

Conflict of Interest: The authors declare that they do not have any conflicts of interest.

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