

Cost-effectiveness of SHINE: A Telephone Translation of the Diabetes Prevention Program



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ABSTRACT

BACKGROUND: The Support, Health Information, Nutrition, and Exercise (SHINE) trial recently showed that a telephone adaptation of the Diabetes Prevention Program (DPP) lifestyle intervention was effective in reducing weight among patients with metabolic syndrome. The aim of this study is to determine whether a conference call (CC) adaptation was cost effective relative to an individual call (IC) adaptation of the DPP lifestyle intervention in the primary care setting.

METHODS: We performed a stochastic cost-effectiveness analysis alongside a clinical trial comparing two telephone adaptations of the DPP lifestyle intervention. The primary outcomes were incremental cost-effectiveness ratios estimated for weight loss, body mass index (BMI), waist circumference, and quality-adjusted life years (QALYs). Costs were estimated from the perspective of society and included direct medical costs, indirect costs, and intervention costs.

RESULTS: After one year, participants receiving the CC intervention accumulated fewer costs (\$2,831 vs. \$2,933) than the IC group, lost more weight (6.2 kg vs. 5.1 kg), had greater reduction in BMI (2.1 vs. 1.9), and had greater reduction in waist circumference (6.5 cm vs. 5.9 cm). However, participants in the CC group had fewer QALYs than those in the IC group (0.635 vs. 0.646). The incremental cost-effectiveness ratio for CC vs. IC was \$9,250/QALY, with a 48% probability of being cost-effective at a willingness-to-pay of \$100,000/QALY.

CONCLUSIONS: CC delivery of the DPP was cost effective relative to IC delivery in the first year in terms of cost per clinical measure (weight lost, BMI, and waist circumference) but not in terms of cost per QALY, most likely because of the short time horizon.

KEYWORDS: diabetes, diabetes prevention program, cost-effectiveness analysis

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Introduction

Metabolic syndrome, which affects approximately 34% of adult Americans, is a condition that is defined by central obesity and at least two of the following conditions: elevated blood pressure, elevated fasting glucose, and dyslipidemia.¹ Those who have metabolic syndrome are at an increased risk for serious chronic illnesses, such as type 2 diabetes and cardiovascular disease. A landmark intervention, the Diabetes Prevention Program (DPP), was designed to assess whether patients at high risk of developing type 2 diabetes, including those with metabolic syndrome, could decrease their risk by losing weight. Results showed that those who lost a significant amount of weight (the goal was 7% of their body weight) were able to decrease their risk of type 2 diabetes three years later by 58%.^{2,3}

The weight loss program developed for the DPP, known as the “Lifestyle Balance Program,” helped individuals decrease

their fat and calorie intake and increase their activity level. This program, based on key elements of successful behavioral weight-loss interventions, has been adapted and successfully translated to different settings and patient groups to increase reach and decrease cost.^{4,5}

Our research team recently reported significant weight reduction in a DPP translation conducted by telephone, called Support, Health Information, Nutrition, and Exercise (SHINE).^{6,7} DPP translations are commonly conducted in a group setting, with the assumption being that a group intervention is less costly, and potentially more cost effective, than an individual intervention. However, this assumption has not been tested. In SHINE, we compared an individual call (IC) to a conference call (CC) adaptation of the DPP. SHINE also had two key elements that could affect cost: (1) the interventionists were primary care staff who had never delivered a weight loss intervention, and were trained to do so for SHINE



and (2) the intervention was delivered over the telephone to make it convenient and accessible to individuals who are unable to attend in-person sessions, due to age, disability, geography, or personal circumstances.

Details of the SHINE trial have been reported previously.⁶ To summarize results, both intervention arms lost significant amounts of weight after 1 year (IC: -4.6 ± 17.6 kg; CC: -4.9 ± 17.7 kg). The intervention continued during a second year, and after two years, those receiving IC began to regain (IC: -2.2 ± 14.2 kg), a common result in weight loss trials, while those receiving CC continued to lose (-6.2 ± 14.3 kg). Patients were followed up for a third year with no intervention to measure maintenance of weight loss, and again, the IC group continued to regain, though their weight remained significantly lower than baseline while the CC group maintained their weight loss.⁷ The purpose of this study was to assess whether the CC intervention was cost effective relative to the IC intervention.

Methods

Study participants and procedures. Methods and procedures for the SHINE trial have been reported in detail previously.⁶ We provide an overview here. Study participants were recruited from July 2007 through November 2009 in five diverse primary care practice sites in upstate New York.⁶ Potential participants were identified from a diagnosis of metabolic syndrome in their electronic medical record and were sent a recruitment letter, with all primary care providers granting their approval to reach out to their patients. Of 938 potential participants who were sent recruitment letters, 331 were assessed for eligibility and 257 were randomized to CC ($n = 128$) or IC ($n = 129$) interventions (the CONSORT diagram has been published previously).⁶ The cost-effectiveness analysis presented here is derived from the first-year assessments. After the first year, only 53 CC patients and 54 IC patients had recorded complete costs in their diaries, which forms the sample used in the analysis. At baseline, participants did not differ on any demographic characteristics. Their mean age was 52 years, 75% were female, their mean body mass index (BMI) was 39 kg/m^2 , 85% were non-Hispanic white, and approximately 40% had incomes less than \$40,000/year. Outcomes (primary outcomes were changes in weight and waist circumference) were assessed after one, two, and three years by a research nurse blinded to group assignment. This study was approved by the Institutional Review Board (IRB) of the SUNY Upstate College of Medicine and complies with the Declaration of Helsinki. Patients gave their written, informed consent to participate in the research.

Interventions. After randomization, subjects participated in 16 sessions of the DPP lifestyle intervention core curriculum (weekly for five weeks, then monthly) during the first year. A primary care provider staff member was provided with detailed scripts and was trained to deliver the

intervention. These sessions were augmented by monthly calls with a dietitian coach for individualized problem solving. Subjects also completed a second year of monthly contact with educators. The content of both interventions was the same: a behavioral weight loss intervention that targeted decreased fat and calories, and increased activity, with goal-setting, self-monitoring, activity and dietary changes, and problem-solving. For the CC intervention, educators were trained and prompted to engage all group members in the discussions.

Costs. Costs were estimated from the perspective of society in US dollars as it prevailed in 2013 and included medical care costs, program costs, intervention costs, and indirect costs. Medical costs included physician office visits and inpatient hospital stays, which were obtained from surveys and valued at the average cost per day for the state of New York⁸ and the average reimbursement for a family practice internal medicine office visit in the United States.⁹ Program costs were costs incurred by patients for participating in the program and included costs for cooking equipment, exercise equipment, food and groceries and fitness programs, such as gym memberships. These were obtained from surveys at baseline and one year following the start of the interventions. Intervention costs were estimated from billing records and included the cost of educators and coaches, cell phone costs for the IC intervention, CC costs for the CC intervention, and shipping costs for materials. Indirect costs were assessed by assuming that each hospital day resulted in a loss of eight hours of full-time work, and each office visit resulted in a loss of two hours of work. In addition, each hour spent on the phone participating in the program or working with a coach was counted as an hour of productivity lost. These lost hours were valued at the self-reported wage for each participant. For participants who were not working or retired, the lost hours were valued at the minimum wage for the state of New York (\$8.00 per hour).¹⁰ Total costs were computed as the sum of all Medicare costs, program costs, intervention costs, and indirect costs for each patient. Univariate comparisons of costs were made using Student's *t*-tests.

Effectiveness. We studied four measures of effectiveness for the stochastic cost-effectiveness analysis: quality-adjusted life years (QALYs), weight lost (in kilogram), reduction in waist circumference (in centimeter), and reduction in BMI (per kg/m^2). QALYs were estimated from the self-administered Quality of Well-being (QWB) scale.^{11,12} The QWB is a 71-item multi-attribute utility instrument that was calibrated to community preferences and has been used previously to study utilities in diabetes.¹³ Scoring the QWB for utility involved aggregating sections summarizing acute and chronic symptoms, self care and mobility, physical activity, and self care and usual activity. These sections are weighted, yielding utility values that indicate the patient's preference for her current health state. The QWB was administered at baseline and one year following the intervention. Utilities estimated from the QWB were multiplied by the life years of each patient in the post-intervention period to



estimate QALYs. Univariate comparisons of effectiveness measures were made using Student's *t*-tests.

Cost-effectiveness analysis. Cost-effectiveness was determined by estimating the incremental cost-effectiveness ratio (ICER).¹⁴ Four ICERs were estimated: (1) incremental cost per QALYs gained, (2) incremental cost per centimeter of waist circumference reduced, (3) incremental cost per kilogram of weight lost, and (4) incremental cost per unit of BMI lost. ICERs were not computed when an intervention was both less costly and more effective, as such interventions are cost effective regardless of the ICER.

Stochastic cost-effectiveness analysis was used to characterize the uncertainty of the cost-effectiveness results and estimate a 95% confidence ellipse around the ICER.¹⁵ The bootstrap method re-sampled the data 10,000 times with replacement and computed the ICER for each replicate. From the bootstrap samples, we estimated the probability that CC intervention was cost-effective relative to the IC intervention for a given willingness-to-pay threshold. In addition, we computed cost-effectiveness acceptability curves (CEACs), which plot the probability that the CC was cost-effective relative to the IC intervention over a reasonable range of levels of willingness-to-pay.¹⁶ All stochastic cost-effectiveness analyses were performed using R statistical software (version 3.1.1, <http://www.r-project.org>).

Results

Characteristics of CC ($n = 53$) and IC ($n = 54$) patients are presented in Table 1. The characteristics of participants were well balanced, with the exception of gender; 64.2% of participants in the CC group were female, while 81.5% of participants in the IC group were female ($P = 0.04$).

Table 1. Summary of characteristics of subjects receiving CC and IC interventions.

VARIABLE	INTERVENTION GROUP		P-VALUE
	CC ($n = 53$)	IC ($n = 54$)	
Age (Mean [SD])	55.2 [11.8]	54.0 [11.1]	0.26
Gender (%)			0.044
Male	35.8%	18.5%	
Female	64.2%	81.5%	
Race/ethnicity (%)			0.89
White non-Hispanic	86.8%	90.7%	
Black	9.4%	9.3%	
Hispanic	3.8%	0.0%	
Marital status (%)			0.35
Single	24.5%	18.5%	
Married	54.7%	57.4%	
Divorced	13.2%	14.8%	
Widowed	7.5%	9.3%	

Abbreviations: IC, individual call; CC, conference call.

Table 2. Summary of costs for participants in the CC and IC interventions.

VARIABLE	INTERVENTION GROUP		P-VALUE
	CC ($n = 53$)	IC ($n = 54$)	
Medical care			
Office visits	4.98	2.87	
Hospital days	0.60	0.94	
Total medical care costs	\$1,966.79	\$2,298.96	0.85
Program costs			
Cooking equipment	\$35.04	\$30.37	
Exercise equipment	\$52.68	\$47.78	
Food/groceries	\$349.63	\$352.23	
Fitness/health programs	\$75.96	\$43.06	
Total program costs	\$513.31	\$473.44	0.55
Intervention costs			
Educators	\$97.23	\$11.86	
Coaches	\$20.37	\$20.37	
Telephone	\$96.94	\$30.44	
Shipping	\$3.78	\$3.78	
Total intervention costs	\$218.32	\$66.45	<0.0001
Indirect costs			
Time lost from work (hours)	14.79	13.30	
Total indirect costs	\$132.66	\$94.51	0.37
Total one year costs	\$2,831.08	\$2,933.35	0.95

Abbreviations: IC, individual call; CC, conference call.

A summary of costs is presented in Table 2. The majority of costs incurred during the one year following the intervention were for medical care, including office visits and inpatient hospital days. Participants in the CC group had slightly more office visits (4.98 vs. 2.87), but they also had slightly fewer hospital days (0.6 vs. 0.94). Total costs for medical care were \$1,967 (range: \$0–44,194) for those in the CC group and \$2,299 (range: \$0–79,108) for those in the IC group. Program costs, including expenditures on equipment, groceries, and health programs were slightly higher for the CC group, largely because of more spending on fitness and health programs. The intervention costs for the CC group were substantially higher (\$218.32 vs. \$66.45). Most of this difference was additional spending on educators and telephone costs. The bridging technology to host CCs was more expensive than individual cell phones for subjects. Indirect costs for time lost from work were slightly higher for CC subjects (\$132.66 vs. \$94.51, $P = 0.37$). Most of the difference in indirect costs was due to a greater number of physician office visits. Average total costs per patient were \$2,831 (range: \$308–46,306) for the CC group subjects and \$2,933 (range: \$248–79,281) for the IC group ($P = 0.95$).

Baseline cost effectiveness results are presented in Table 3. The CC approach yielded better clinical outcomes. Participants



Table 3. Summary of costs and cost-effectiveness for CC and IC interventions.

OUTCOME MEASURE	CC	IC	DIFFERENCE	ICER
Costs (2013 USD)	\$2,831.08	\$2,933.35	-\$102.27	
QALY (one-year only)	0.64	0.65	-0.011	\$9,249.68
Reduction in waist circumference (cm)	6.53	5.85	0.68	(Dominant)
Reduction in weight (kg)	6.21	5.09	1.11	(Dominant)
Reduction in BMI (kg/m ²)	2.14	1.86	0.28	(Dominant)

Abbreviations: IC, individual call; CC, conference call.

who received the CC intervention reduced their waist circumference by a mean of 6.5 cm, compared to 5.9 cm for those who received the IC intervention ($P = 0.69$). CC participants also lost a mean of 6.2 kg of weight, while IC participants lost 5.1 kg ($P = 0.48$). And those in the CC group reduced their BMI by a mean of 2.1 units, while those in the IC group reduced their BMI by 1.9 units ($P = 0.62$).

These improvements in clinical outcomes did not translate into more QALYs. Participants in the CC group achieved 0.635 QALYs and participants in the IC group achieved 0.646 QALYs. The incremental cost-effectiveness ratio was \$9,250 per additional QALY, which does not reach a threshold of cost-effectiveness. The CC intervention, however, dominated the IC approach in terms of the clinical measures, achieving better outcomes at a lower cost.

There was substantial uncertainty surrounding the ICERS. As seen in Figure 1, even if a decision maker was willing to accept \$100,000 per additional QALY lost, the CEAC suggests that the probability that the CC intervention is cost effective was only 48%. The CEAC for weight loss suggested that the probability that the CC intervention is cost

effective was over 85%, even if the decision maker was willing to pay as little as \$8,000 per additional kilogram of weight lost (Fig. 2). A similar result was achieved for waist circumference (Fig. 3). Even if a decision maker was willing to pay no more than \$14,000 per additional centimeter of waist circumference reduced the probability that the CC intervention is cost-effective is nearly 80%. Finally, if the decision maker was willing to pay \$15,000 per additional unit of BMI lost, the probability that the CC intervention is cost effective was more than 80% (Fig. 4).

Discussion

These results suggest that the CC intervention was cost effective in terms of clinical measures (weight lost, waist circumference reduced, and BMI reduced) but not in terms of QALYs; although given the relatively small sample, these results should be considered suggestive. The most obvious explanation for this finding is the short time horizon of the data analyzed. We may not expect that the mode of delivery of the DPP lifestyle intervention would impact either length of life or quality of life over a very short one-year time horizon.

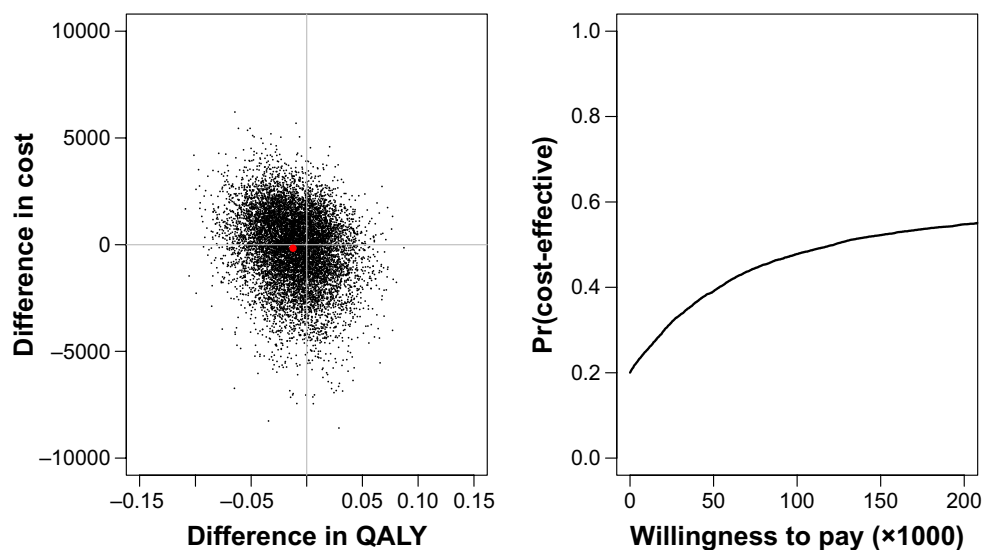


Figure 1. Plot of 10,000 bootstrap replicates of the incremental cost per QALY and cost-effectiveness acceptability curve for CC relative to IC intervention.

Abbreviations: IC, individual call; CC, conference call.

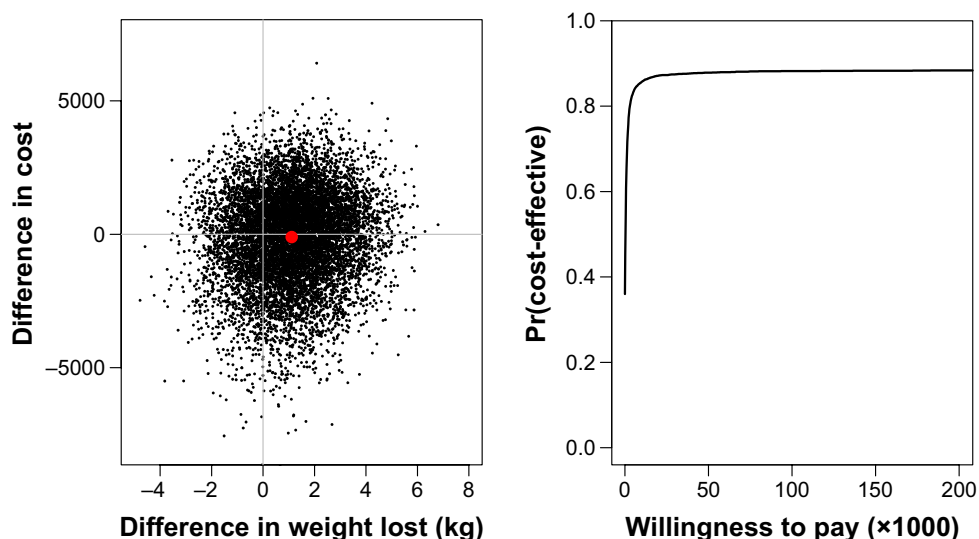


Figure 2. Plot of 10,000 bootstrap replicates of the incremental cost per kilogram of weight reduced and cost-effectiveness acceptability curve for CC relative to IC intervention.

Abbreviations: IC, individual call; CC, conference call.

Some evidence that supports this comes from Ackermann et al, who measured utilities in 3,064 patients in a clinical trial comparing outcomes for the DPP lifestyle intervention relative to a metformin strategy and placebo.¹⁷ They found that differences between patients were largely driven by weight changes independent of treatment, and that even the weight change-related effects were very small (0.007 per 5 kg of weight lost). Although they measured utilities using a different instrument than we did, this result suggests that we should not expect to see large differences in utilities or QALYs between the CC and IC interventions. We do expect, however, that if

the gains made in clinical endpoint are sustained (weight lost, waist circumference reduced, and BMI reduced), then in the future, cardiovascular events will be avoided more for the CC group than the IC group, which would be manifest in larger differences in both quantity and quality of life. And we note that weight loss was maintained at three years (even with no intervention for the third year) for the CC group, while the IC group regained.⁷

There is a substantial amount of evidence that the DPP lifestyle intervention is cost effective.¹⁸ The DPP Research group, for example, conducted a cost-effectiveness

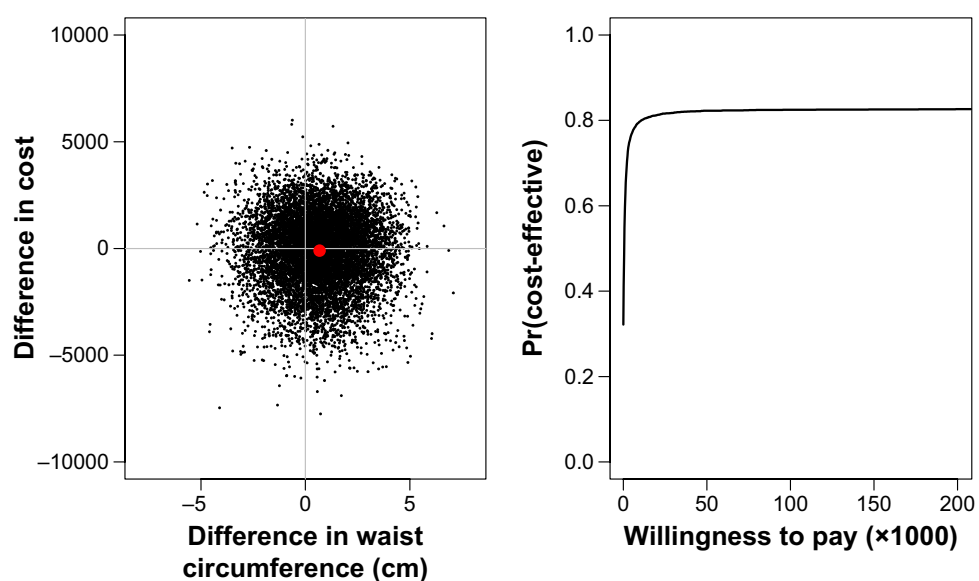


Figure 3. Plot of 10,000 bootstrap replicates of the incremental cost per centimeter of waist circumference reduced and cost-effectiveness acceptability curve for CC relative to IC intervention.

Abbreviations: IC, individual call; CC, conference call.

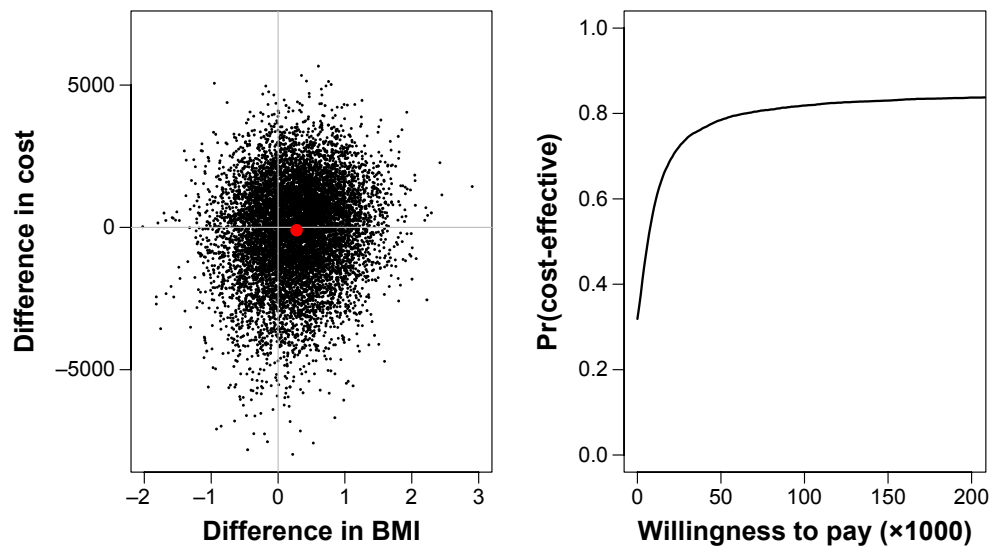


Figure 4. Plot of 10,000 bootstrap replicates of the incremental cost per unit of BMI reduced and cost-effectiveness acceptability curve for CC relative to IC intervention.

Abbreviations: IC, individual call; CC, conference call.

analysis alongside a clinical trial to compare the DPP lifestyle intervention relative to metformin and placebo.¹⁹ Over three years, they estimated an ICER from a societal perspective of \$51,600 (year 2000 US dollars) per incremental QALY for DPP relative to placebo. This study used the same instrument that we used to estimate utilities and QALYs and reported similar but slightly higher utilities (0.692–0.703) relative to ours. Interestingly, Herman et al report a 10-year follow-up cost-effectiveness analysis using adherent patients from the DPP Research Group trial.²⁰ The ICER for the DPP intensive lifestyle intervention was \$19,998 (year 2010 US dollars) per additional QALY, suggesting that the lifestyle intervention remains cost effective 10 years after the start of the intervention.

Most studies of the longer-term cost-effectiveness of the DPP are derived from Markov models of diabetes prevention. Herman et al report a cost-effectiveness analysis of the DPP lifestyle intervention relative to metformin and placebo using a Markov model.²¹ The model is an adaptation of an earlier model that was parameterized using data from the DPP trial and other sources.²² This model suggests that over a patient's lifetime, the DPP lifestyle intervention has an ICER of \$1,114 (year 2000 US dollars) per additional QALY gained, which is well below the thresholds usually cited for cost-effectiveness.²³ Eddy et al use the Archimedes model, a validated, trial-based simulation model, to estimate the cost-effectiveness of the DPP lifestyle intervention over a 30-year time horizon.^{24,25} From a societal perspective, the ICER was \$62,600 (year 2000 US dollars) per QALY gained relative to no intervention. There is also evidence from European models that suggests that the DPP lifestyle intervention is cost effective in European populations.²⁶

There have been several adaptations of the DPP lifestyle intervention. It has been adapted for group interventions, for sustainability in communities, for minority populations, and for telephone delivery.^{6,27,28} The DPP Research Group combined data from the DPP study and the DPP Outcomes Study to extrapolate cost-effectiveness of an adaptation to group delivery of the DPP lifestyle intervention.²⁹ From a societal perspective, the DPP was cost effective, with a (discounted) ICER of \$14,365 per additional QALY gained relative to placebo. Smith et al also report the cost-effectiveness of a Markov model group delivery adaptation of the DPP lifestyle intervention.³⁰ They report an ICER of \$3,420 (year 2000 US dollars) per additional QALY gained over a three-year horizon.

There are a few important limitations to this study. The most important limitation is the small sample size. Cost and resource utilization data, which were self reported, were missing for more than half of patients at the end of year one. Clinical endpoints appeared similar for the subset of patients with cost and resource utilization data, but power was substantially reduced. We therefore interpret our results with caution. While at mean values the ICERs suggest that CC is cost effective, the small sample and relatively low power make these result suggestive at best. The second important limitation was the short time horizon, which in part stems from the missing cost data. This limitation could be overcome in one of two ways: (1) with additional follow-up beyond one year and (2) with a model that extrapolates findings beyond one year. In fact, the trial did collect data on biological endpoints over three years. However, response rates for resource utilization dropped steadily over the follow-up period. A future study will use the clinical results observed in our analysis to parameterize a Markov model and extend our results beyond one year. Another limitation is the



fact that in spite of randomization, there remained significant differences in the distribution of sex between the two groups. In fact, Weinstock et al reported that there was no significant difference in the sex distribution for the full sample. However, men were less likely to complete the cost surveys, and were therefore less likely to be included in this study.

In conclusion, these results suggest that CC delivery of the DPP lifestyle intervention is cost effective in terms of cost per additional gains in clinical endpoints (waist circumference, weight lost, and BMI reduced), but it is not cost effective in terms of cost per QALY gained, most likely because of the relatively short one-year time horizon of the study. However, it should be recognized that there remains substantial uncertainty about these results. Given the need to identify effective weight loss interventions for patients at risk for diabetes that are sustainable, these findings may hold promise since they suggest that waist circumference, weight loss, and BMI reductions can be achieved at a marginally lower cost by delivering the DPP with group CCs and trained primary care staff rather than more costly health care providers.

Novelty Statement

- This study estimated the cost-effectiveness of a conference call adaptation of the Diabetes Prevention Program (DPP) lifestyle intervention to an individual call adaptation.
- Conference call delivery of the DPP was cost effective relative to individual call delivery in the first year in terms of cost per clinical measure (weight lost, BMI, and waist circumference).
- Conference call delivery was not cost effective in terms of cost per QALY, most likely because of the short time horizon.

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Trial Registration

ClinicalTrials.gov number NCT00749606.

Author Contributions

Conceived and designed the experiments: CSH, PMT, and RSW. Analyzed the data: CSH and DC. Wrote the first draft of the manuscript: CSH, PMT, and RSW. Contributed to the writing of the manuscript: CSH, PMT, RSW, DC, and LMD. Agree with manuscript results and conclusions: CSH, PMT, RSW, DC, and LMD. Jointly developed the structure and arguments for the paper: CSH, PMT, and RSW. Made

critical revisions and approved final version: CSH, PMT, RSW, DC, and LMD. All authors reviewed and approved of the final manuscript

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