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By Mohammed K. Ali, Justin B. Echouffo-Tcheugui, and David F. Williamson

How Effective Were Lifestyle Interventions In Real-World Settings That Were Modeled On The Diabetes Prevention Program?

ABSTRACT We conducted a systematic review and meta-analysis of twenty-eight US-based studies applying the findings of the Diabetes Prevention Program, a clinical trial that tested the effects of a lifestyle intervention for people at high risk for diabetes, in real-world settings. The average weight change at twelve months after the intervention was a loss of about 4 percent from participants' baseline weight. Change in weight was similar regardless of whether the intervention was delivered by clinically trained professionals or lay educators. Additional analyses limited to seventeen studies with a nine-month or greater follow-up assessment showed similar weight change. With every additional lifestyle session attended, weight loss increased by 0.26 percentage point. We conclude that costs associated with diabetes prevention can be lowered without sacrificing effectiveness, using nonmedical personnel and motivating higher attendance at program sessions.

Mohammed K. Ali (mkali@emory.edu) is an assistant professor of global health at the Rollins School of Public Health, Emory University, in Atlanta, Georgia.

Justin B. Echouffo-Tcheugui is a postdoctoral research fellow at the Rollins School of Public Health, Emory University.

David F. Williamson is a visiting professor at the Rollins School of Public Health, Emory University.

Diabetes causes disabling complications, high health costs, and reduced life expectancy.[1,2] In the United States, twenty-six million adults have the disease. A further seventy-nine million people have prediabetes, where elevated blood glucose is not yet in the diagnostic range for diabetes,[3] but the risk of developing type 2 diabetes is four to twelve times higher than in people with normal glucose tolerance.[4] Effective, affordable, acceptable, and sustainable prevention efforts are essential to curbing the diabetes epidemic.

The US Diabetes Prevention Program clinical trial demonstrated that structured lifestyle interventions—such as training people with prediabetes to achieve modest weight loss through diet and physical activity—reduced three-year diabetes incidence by 58 percent.[5] Evidence from this trial and others has existed for a decade.[5–8] Yet these results have not been "translated" into routine clinical practice and public health policy.[9]

Two realities stand in the way of progress in reducing the incidence of diabetes in the United States. The first is a fragmented health care system with complex financing; the second involves challenges inherent in implementing and maintaining behavioral interventions.

Another factor is cost. The Diabetes Prevention Program trial was resource intensive. The lifestyle intervention involved in the trial contained sixteen "core" one-to-one sessions delivered by specialist case managers who were trained nutritionists, exercise physiologists, or behavioral psychologists. These sessions were followed by twice-monthly in-person "maintenance" sessions with telephone contact between sessions.[10,11]

Participants were also given lifestyle modification aids, such as meal replacements or access to exercise facilities, at no cost to them. Altogether, the cost to deliver the intervention in its first year was $1,399 per participant. This cost poses a major challenge for scaling such a program to a broader population and for its economic sus-

tainability.[12]

The Diabetes Prevention Program trial established that weight loss was the single most important factor in reducing diabetes incidence—for every kilogram of weight loss, diabetes incidence was reduced by 16 percent.[13] Several lower-cost interventions based on the trial's principles have been tested in real-world settings.

To estimate the magnitude of weight loss achieved in these translation studies, we performed a meta-analysis of published US-based studies that adapted the Diabetes Prevention Program trial's lifestyle intervention. We also examined which program features—such as the number of core sessions, type of intervention staff, and inclusion of the maintenance component—influenced weight loss.

Study Data And Methods

STUDY SELECTION We systematically searched the MEDLINE, EMBASE, Cochrane Library, and ClinicalTrials.gov electronic databases for US studies that were published between January 1, 2003, and April 30, 2011, and that translated the Diabetes Prevention Program trial lifestyle intervention to real-world settings. We used medical subject heading and free-text terms related to diabetes (available online in Appendix A).[14] We manually searched reference lists of review articles[11,15] and sought published data from the 2010 American Diabetes Association scientific sessions.

Two investigators independently determined the relevance of articles and extracted data using a standardized form. Discrepancies were resolved by consensus. Where data were not fully reported, individual study authors were contacted.

Studies considered for inclusion had to satisfy three criteria. First, the studies had to be original intervention studies, not review articles or editorials. Second, the studies had to have included adults age eighteen or older at high risk for diabetes. *High risk* was defined as patients with biochemically confirmed prediabetes that included impaired fasting glucose, impaired glucose tolerance, or both; or patients who were overweight with a body mass index greater than or equal to 25 kg/m^2, and with one or more metabolic risks, such as family or gestational diabetes history. The third and final inclusion criterion was that the studies must also have reported starting weight and weight loss achieved.

We included studies that had participants with preexisting diabetes as long as the proportion of those participants was less than 50 percent. We excluded studies conducted before 2003 because

the Diabetes Prevention Program trial findings were not published until February 2002, leaving insufficient time for translation studies to be completed and published. Studies were also excluded if they applied other weight-loss principles or commercial programs that differed from those tested in the trial. The trial specifically emphasized calorie restriction and 150 minutes per week of physical activity, with the target of 7 percent weight loss (a detailed diagrammatic representation of literature searches and study selection is shown in Appendix B).[14]

OUTCOMES AND COVARIATES The main outcome was percentage change from participants' starting weight. Although levels of glycemia and diabetes incidence are important outcomes, few studies measured these. This was because proof that weight loss is a key driver of preventing diabetes in high-risk individuals was already demonstrated in the Diabetes Prevention Program trial.[5,13]

We examined the influence of program characteristics, such as number of core sessions, provision of maintenance sessions, and the type of personnel delivering the intervention, as classified and defined in Appendix C,[14] and participants' characteristics, such as sex and race or ethnicity, in relation to weight loss achieved.

QUALITY ASSESSMENT Many translation studies used pre-post study designs without control groups because the Diabetes Prevention Program trial had already established that control participants lose very little weight without support. Therefore, we included both controlled and uncontrolled studies, but we limited our analyses to studies in which participants received structured lifestyle interventions.

Selection bias is inherent in uncontrolled, nonrandomized, and unblinded studies, so critical assessments of allocation and blinding are irrelevant. We therefore modified Peter Jüni and colleagues' quality assessment framework[16] to classify studies using the following quality assessment criteria.

The first criterion was that the study defined the target population as being at high risk for diabetes (using at least two of the following: self-reported risk factors, anthropometric measurements, and blood glucose testing). The second was that the study included steps to minimize attrition (used intention-to-treat analysis); reported low attrition, meaning 20 percent or less loss to follow-up at twelve months or the closest time point; or compared the characteristics of program completers and noncompleters.

The third criterion was that the study clearly reported data limitations, such as uncertainties or distribution of estimates; investigated sample sizes of 100 or more; or was nonselective in re-

porting). Fourth, the study must have contained reporting to inform practical translatability of interventions through four or more of the following: describing the process of designing the program; describing the enrollment process; documenting the session attendance; reporting costs/resource inputs; documenting the training and qualifications of personnel; and describing qualitative feedback from participants or providers.

We documented whether studies met each criterion; the results are in Appendix Exhibit 1.[14]

DATA ANALYSIS Analyses were carried out using the statistical analysis software Stata, version 11.0. Pooled mean sociodemographic characteristics were sample weighted. We estimated the pooled percentage weight change (from baseline) by fitting a random-effects meta-analysis model that allows for heterogeneity between studies. We stratified our meta-analysis by the type of personnel delivering the intervention, because salaries represent a sizable portion of program costs. We quantified heterogeneity between studies with the I^2 statistic.[17]

The number of core intervention sessions— that is, those taking place in the first three to six months—is critical,[18] because maximum weight loss occurs during this period[19,20] and because initial weight loss predicts longer-term weight maintenance.[21] We assessed whether the number of core sessions offered was related to session attendance, using the Spearman Rank Correlation Test.[22]

In studies with complete data ($n = 26$), we used meta-regression[23] to explore whether program factors—core sessions attended, type of personnel delivering the intervention, and presence of a maintenance phase—influenced the summary weight-loss estimates, adjusted for participants' characteristics (proportion male and proportion non-Hispanic white).

To assess the effects of study duration on weight loss, we conducted a sensitivity analysis, isolating studies with total follow-up of nine months or more. We also assessed publication and small study biases using Begg's and Eggers's tests, respectively.[23]

LIMITATIONS Our study shares some limitations with other reviews on diabetes prevention.[11,15,24] The precision of estimates was limited by the small number of participants included in published studies and by heterogeneity in study designs, interventions, analyses, outcomes, and reporting across studies.

In contrast to the Diabetes Prevention Program trial, in which participants all had clinically established prediabetes, a number of translation studies included people at "high risk" but lacking glucose measures to confirm prediabetes status. It remains unclear how weight reduction in these lower-risk individuals translates into changes in diabetes incidence and related health costs.

Studies predominantly included female, non-Hispanic white participants. Also, our analyses summarized effects only in participants receiving the intervention. However, we acknowledge that translation studies resemble the real world, where the uptake of an intervention depends on motivation or incentives, and the effects of interventions may be diluted by factors that are otherwise controlled for in efficacy trials.[10]

A lack of descriptive details in some published studies may have resulted in minor misclassification of some program features, although we made efforts to retrieve additional data from studies' authors. Also, lifestyle programs provide collateral benefits on other cardiovascular risk factors. However, reporting of these outcomes was inconsistent across studies. This precluded a summary analysis.

Study Results

Twenty-eight distinct studies (derived from twenty-six publications) met our eligibility criteria (Appendix B).[14] Among the studies were four randomized controlled trials, two cluster-randomized controlled trials, twenty single-group pre-post studies, and two nonrandomized controlled studies.
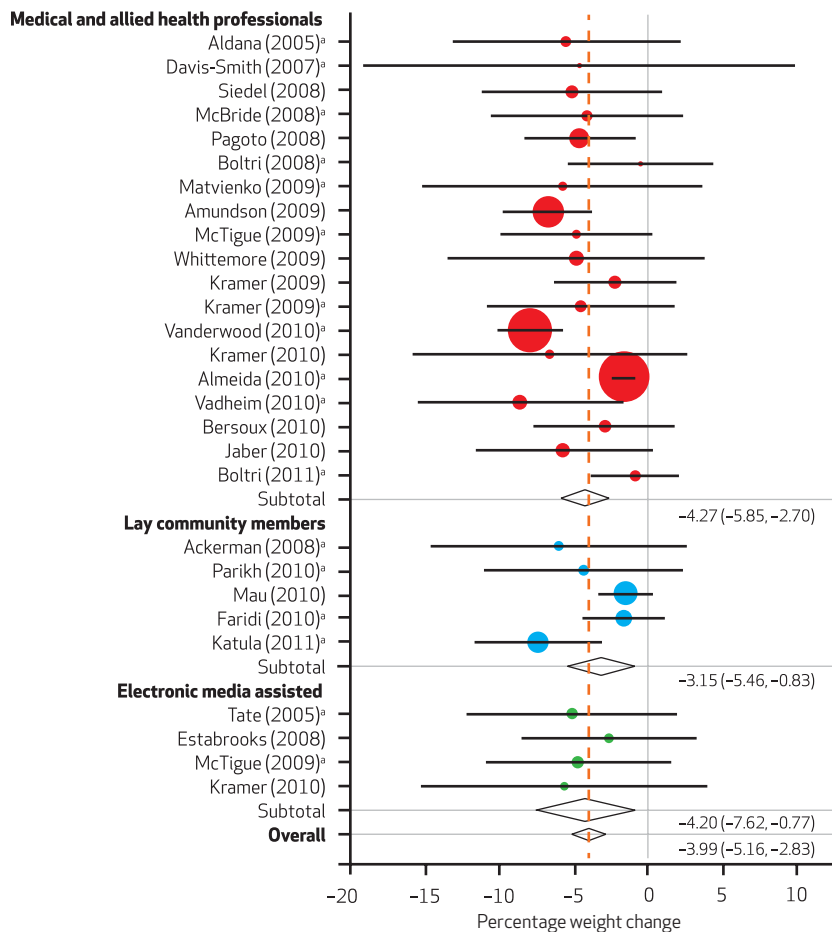
Most studies were conducted in urban areas— twelve were based primarily in community environments, such as community centers, recreation centers, and faith-based organizations, and eleven were conducted in health care facilities—while four studies used electronic media to engage participants. There was variability in study attrition (range: 0–49 percent) and analytical approaches used (seventeen studies reported intention-to-treat or last-observation-carried-forward; eleven analyzed completers). Low attrition (10–16 percent) was observed in online- and DVD-format interventions, but not in studies using interactive voice response.[25–28]

In total, 3,797 participants were enrolled in interventions, from which 2,916 participants with complete follow-up data were included in the analysis. On average, enrolled participants were 55.1 years old, with body mass index of 34.0 kg/m^2; 69.9 percent were female, and 70.9 percent were non-Hispanic white. Median study duration was twelve months (range: 3–12 months; mean±standard deviation: 8.8±3.9 months).

Across all studies, mean weight change was −3.99 percent (95% confidence interval: −5.16, −2.83; $I^2 = 52.4$ percent) at twelve-month fol-

EXHIBIT 1

Mean Weight Loss Among Study Participants, By Type Of Personnel Delivering The Interventions, In US-Based Diabetes Prevention Program Translation Studies

Medical and allied health professionals
Aldana (2005)[a]
Davis-Smith (2007)[a]
Siedel (2008)
McBride (2008)[a]
Pagoto (2008)[a]
Boltri (2008)[a]
Matvienko (2009)[a]
Amundson (2009)
McTigue (2009)[a]
Whittemore (2009)
Kramer (2009)
Kramer (2009)[a]
Vanderwood (2010)[a]
Kramer (2010)
Almeida (2010)[a]
Vadheim (2010)[a]
Bersoux (2010)
Jaber (2010)
Boltri (2011)[a]
Subtotal −4.27 (−5.85, −2.70)
Lay community members
Ackerman (2008)[a]
Parikh (2010)[a]
Mau (2010)
Faridi (2010)[a]
Katula (2011)[a]
Subtotal −3.15 (−5.46, −0.83)
Electronic media assisted
Tate (2005)[a]
Estabrooks (2008)
McTigue (2009)[a]
Kramer (2010)
Subtotal −4.20 (−7.62, −0.77)
Overall −3.99 (−5.16, −2.83)

Percentage weight change
−20 −15 −10 −5 0 5 10

SOURCE Authors' analysis of studies examined. Complete sources are in the article's endnotes. **NOTES** Red, blue, and green circles indicate percentage weight change achieved for each study; sizes of circles indicate the weight of each study in random-effects analysis based on sample size, and colors correspond to the three intervention categories. Horizontal lines indicate 95% confidence intervals. Unfilled diamond shapes indicate the subtotal and overall pooled estimates of percentage weight change for each category of delivery personnel and overall, respectively. The orange dashed vertical line indicates the overall percentage weight change estimate. [a]Denotes studies with nine months of follow-up or more.

low-up (Exhibit 1; a detailed plot is in online Appendix D).[14] Weight change was comparable in studies using medical and allied health professionals (−4.27 percent; 95% confidence interval: −5.85, −2.70), those using lay community educators (−3.15 percent; 95% confidence interval: −5.46, −0.83), and those using electronic media–assisted interventions (−4.20 percent; 95% confidence interval: −7.62, −0.77). Limiting the meta-analysis to studies with nine months or more of follow-up ($n = 17$) resulted in a small increase in estimated weight change (−4.14 percent; 95% confidence interval: −5.85, −2.44; $I^2 = 63.6$; see Appendix E).[14]

The number of core sessions attended was strongly correlated with the number of core sessions offered ($r = 0.90$; $p < 0.01$; see Exhibit 2). When the data were adjusted for sex and race or ethnicity, meta-regression analysis (Exhibit 3) showed that every additional core session attended was associated with additional weight change of −0.26 percentage point (95% confidence interval: −0.54, 0.01).

Point estimates from our overall and sensitivity analyses suggest that programs with lay community intervention staff may have been associated with better weight loss (estimates ranged from −1.84 to −0.36 percentage points) than that achieved by medical and allied health professionals. Studies using electronic media to deliver interventions showed poorer weight loss (estimates ranged from +1.11 to +1.93 percentage points). Because of the small number of studies, these estimates had wide confidence intervals. Presence of a maintenance phase was not clearly beneficial for weight loss (estimates ranged from −0.46 to +0.36 percentage point), and confidence intervals were wide.

Begg's test showed no publication bias ($p = 0.23$)—that is, the possibility that studies with positive and statistically significant findings are preferentially published. Eggers's test indicated a tendency for smaller studies to show larger effects ($p = 0.02$).

OTHER OBSERVATIONS Randomized controlled trials testing lay staff–led lifestyle interventions reported highly statistically significantly greater weight loss—6.1 percentage points and 2.9 percentage points—compared to lower-intensity interventions (three in-person sessions plus newsletter lifestyle recommendations)[29] or delayed intervention,[30] respectively. Two other randomized clinical trials, one comparing behavior e-counseling with a more basic online program[27] and another evaluating interactive voice response compared to no program,[28] observed 2.7-percentage-point and 1.0-percentage-point greater weight loss in the more intensive programs.

Six studies reported intervention costs. Different cost-reporting approaches were used, which precluded formal analysis. Aggregate material costs (such as for glucose testing, educational materials, and weighing scales) were comparable for six-session ($934) and sixteen-session programs ($1,075).[31,32] Intervention staff salaries varied by level of formal training—from $10–$15 per participant per session by lay personnel in communities[29] to $25 per participant per session by clinically trained staff.[33,34] Capillary glucose measurement—the use of a much smaller amount of blood to measure glucose levels[30–32] —and use of databases to identify eligible subjects also helped reduce costs.[35–38]

Focus groups from three studies[30,32,39] suggested that intervention uptake and attendance were influenced by participants' concern for personal health; the influence of a trusted person or persons; receipt of elevated glucose test results; receipt of free checkups; commitment contracts involving fees or deposits; group support; and participants' sense of increased empowerment.

STUDY STRENGTHS To our knowledge, this is the first meta-analysis of US diabetes prevention translation studies. Studies were systematically compiled from four leading medical literature databases and were analyzed using well-accepted meta-analytic methods.

Our analysis focused on key technical issues related to the effectiveness and economic sustainability of diabetes prevention in the United States. We included only studies adapting the Diabetes Prevention Program trial (the largest, most ethnically diverse intervention study for diabetes prevention) lifestyle curriculum because it offered robust proof of principle, is applicable to diverse subpopulations, and is the most widely replicated model in the United States.

Our focus on one-year weight loss is justified because none of the translation studies was designed to assess changes in diabetes incidence. Weight loss was also the single most important predictor of diabetes incidence in the Diabetes Prevention Program trial,[13] and the one-year duration criterion for weight loss is consistent with recommendations by the Institute of Medicine.[40]

We improved comparability across studies by standardizing the outcome (percentage change from baseline weight). We used a random-effects meta-analysis model that assumed between-study variability. We investigated sources of heterogeneity using meta-regression. Finally, we conducted sensitivity analyses.

We also formally examined sources of bias. Statistical testing for publication bias suggested that this was not a factor affecting overall estimates. Furthermore, we included small studies reporting null or low effect sizes in our meta-analysis. Not surprisingly, smaller studies had less precise estimates (wider confidence intervals) than larger studies had.

Discussion

Across diverse settings and populations, lifestyle intervention programs that adapted the Diabetes Prevention Program curriculum achieved clinically significant (4–5 percent) weight loss and maintained this over nine months of follow-up. Interventions offering more core sessions achieved greater attendance, which was associated with greater weight loss. Lay educators ap-

Relationship Between The Number Of Core Sessions Offered And Attended In Diabetes Prevention Program Translation Programs
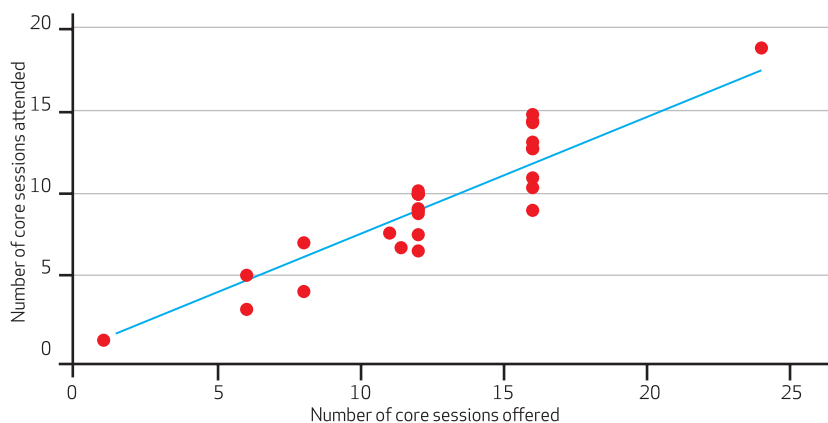
SOURCE Authors' analysis. NOTES Scatter plot of number of core sessions offered (x axis) and number of core sessions attended (y axis). Spearman Rank Correlation Test result is displayed. The blue line represents the best fit through the plot ($r^2 = 0.902$; $p < 0.001$).

peared to achieve similar weight loss as medical and allied health personnel. These findings have important implications for implementation and scalability of diabetes prevention in the United States.

Previous reports[18,33,41] found that the magnitude of weight loss is associated with the number and frequency of sessions attended. However, some contend that programs of longer duration will experience higher dropout rates.[42]

In our review, sixteen- and even twenty-four-session programs[29,34,43] were as effective as or more effective than shorter-duration programs. Also, qualitative feedback in some studies suggests that attrition was unrelated to program length but rather was related to participants' perceptions of how likely they were to get diabetes and the effectiveness of behavioral techniques (for example, readiness-to-change assessments or motivational interviewing) and incentives (both financial and nonmonetary). These findings echo themes from the behavioral economics literature evaluating incentives and motivations for weight loss.[44,45]

The main drivers of costs were high material costs for glucose-based eligibility testing and salaries for intervention staff. Future translation studies should be encouraged to do rigorous cost evaluations of lifestyle programs to be able to provide reliable information for health-system payers.

Our finding that lay community members are as effective at motivating weight loss as higher-salaried professionals has enormous importance for the scalability and economic sustainability of diabetes interventions. Also, the short-course

Meta-Regression Analysis Investigating Factors Influencing Weight Change Achieved Across Diabetes Prevention Programs

Program feature	All studies (N = 26)		Studies with 9 months of follow-up or more (n = 15)	
	Coefficient	95% CI	Coefficient	95% CI
Mean number of sessions attended	−0.26	−0.54, 0.01	−0.22	−0.56, 0.13
Maintenance component in the intervention	−0.46	−2.99, 2.08	0.36	−3.38, 4.09
Mode of delivering the intervention				
Medical and allied health professionals	Reference		Reference	
Lay community members	−0.36	−3.04, 2.32	−1.84	−5.91, 2.23
Electronic media–assisted	1.11	−3.02, 5.25	1.93	−4.53, 8.40
Proportion of participants who were male	0.02	−0.06, 0.10	0.09	−0.04, 0.22
Proportion of participants who were non-Hispanic white	−0.03	−0.06, −0.01	−0.04	−0.08, −0.01

SOURCE Authors' analysis. **NOTES** All estimates were adjusted for all variables simultaneously. CI is confidence interval.

experiential training for community members to coach participants was neither costly nor time consuming (range: 20–36 hours).[29,46]

In light of these findings, we propose that minimum core competencies (such as basic knowledge, organizational skills, and empathy) be emphasized when training intervention staff.[47,48] With training standardization, program structure, and defined roles, we may avoid the reduced effectiveness noted in some studies.[49,50]

It was difficult to classify program locations unequivocally because descriptions of where study coordination and actual program delivery took place were sometimes unclear. In the real world, settings are of great importance because effective detection and recruitment of people with prediabetes requires channels that people can culturally relate to, through which high-risk individuals can be identified and can gain access to programs.[51]

Electronic media–assisted approaches (DVD or online delivery) may offer alternative access to segments of educated, insured people who potentially have less time to devote to in-person sessions than their less educated, uninsured peers. Media-assisted interventions exhibited weight loss similar to in-person interventions; more important, attrition was consistently low among those using DVD and online formats.[25–27]

Nationally representative data show that 30 percent of US adults have prediabetes but that only a quarter of them are aware of their status.[52] Of those advised to modify their lifestyles, 71–82 percent actually attempt lifestyle modification, which shows that communicating risk is an important stimulus. Of twenty-one studies reporting screening data, 70.4 percent ($n = 2,492$) of eligible candidates enrolled; of these, approximately 70–75 percent continued to participate throughout the intervention.

In theory, if access-related barriers were eliminated, approximately fifty-five million adults with prediabetes would consider enrolling in lifestyle programs. Therefore, the capacity, affordability, and long-term sustainability of prevention programs will be critical concerns going forward.[53]

Our review emphasizes important elements that are required if national capacity for delivering diabetes prevention interventions is to be achieved. These include improving diabetes risk awareness; developing systems for identifying and communicating risk; providing structured, sustainable, and effective programs; and maintaining motivation among participants. Intervention curricula (format, duration, and intensity of core sessions); attendance; and delivery personnel are all critical aspects that must be optimized.

To date, there is no convincing evidence that eight, twelve, sixteen, or more core sessions are most cost-effective. Neither is there evidence that specially trained lifestyle professionals are any more effective than lay educators in achieving lifestyle intervention goals. Resolving these issues would require a large, well-designed comparative effectiveness trial among participants randomized to different program lengths and types of lifestyle intervention staff.

Even without definitive scientific evidence, real-world progress continues. A scaled-up program based on the Diabetes Prevention Program trial, which was adapted for the YMCA,[46] is being implemented in partnership with a large US insurer, UnitedHealthcare.[54] Initiatives led by the Centers for Disease Control and Prevention, meanwhile, are focused on developing capacity and standards to increase consistency and effectiveness in program delivery.[55]

Conclusion

Clinically significant weight reduction in people at high risk for diabetes can be achieved in the real world. Structured lifestyle interventions tested in the Diabetes Prevention Program clinical trial and adapted to real-world use have shown significant and sustained benefits. Costs may be lowered by using lay staff, without sacrificing effectiveness. Meanwhile, the rigorous pursuit of innovative diabetes risk–reduction policies and systems to link high-risk groups to effective and affordable diabetes prevention programs must continue.[56] ∎

NOTES

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14 To access the Appendix, click on the Appendix link in the box to the right of the article online.

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ABOUT THE AUTHORS: MOHAMMED K. ALI, JUSTIN B. ECHOUFFO-TCHEUGUI & DAVID F. WILLIAMSON

Mohammed K. Ali is an assistant professor of global health at Emory University.

In this month's *Health Affairs*, Mohammed Ali, Justin Echouffo-Tcheugui, and David Williamson assess the evidence for lifestyle interventions modeled on the Diabetes Prevention Program, a major clinical trial that showed that modest weight loss could halt progression to diabetes in people at high risk for the disease. Reviewing twenty-eight studies of various interventions, the authors found that the lifestyle change and weight loss programs could be delivered effectively and at lower cost than the original trial through innovative means—such as the use of nonmedical personnel and online education programs.

Ali is an assistant professor of global health at the Rollins School of Public Health, Emory University, and a consultant for the Division of Diabetes Translation at the US Centers for Disease Control and Prevention (CDC). His current work involves scientific aspects of translating diabetes prevention and control in the United States; development of surveillance, etiology, and translation study platforms in South Asia; and quality of life and costs of diabetes. He also coleads the Global Burden of Disease expert group on diabetes complications.

Ali completed his medical degree and early clinical training at the University of Cape Town, in South Africa, and, as a Rhodes Scholar, earned a master's degree in cardiovascular medicine and global health at the University of Oxford.

Justin B. Echouffo-Tcheugui is a postdoctoral research fellow at Emory University.

Echouffo-Tcheugui is a postdoctoral research fellow at the Rollins School of Public Health. His work focuses on risk prediction for diabetes and cardiovascular diseases, the translation of these tools into policies and interventions, and the costs and effectiveness of early detection strategies.

Echouffo-Tcheugui earned his medical degree from the Medical School of the University of Yaoundé I, in Cameroon, and trained in epidemiology at the Pierre and Marie Curie University in France and the University of Cambridge, where he was a Gates Scholar.

David F. Williamson is a visiting professor at Emory University.

Williamson is a visiting professor at the Rollins School of Public Health and senior science adviser for diabetes prevention to the CDC Division of Diabetes Translation. He was a consultant to the Diabetes Prevention Program clinical trial, for which he helped develop the first economic analyses of the lifestyle intervention. He received a master's degree and a doctorate in international nutrition, both from Cornell University.