Comparative Effectiveness of Lifestyle Intervention Efforts in the Community

Results of the Rethinking Eating and ACTivity (REACT) study

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OBJECTIVE—To determine the comparative effectiveness of three lifestyle intervention modalities in decreasing risk for diabetes.

RESEARCH DESIGN AND METHODS—Five hundred and fifty-five individuals (86.1% female, 95.1% white, and 55.8% obese) from eight rural communities were screened for BMI \geq 25 kg/m² and waist circumference >40 inches in men and >35 inches in women. Communities with their eligible participants (*n* = 493; mean age 51 years, 87.6% female, 94.1% Caucasian) were assigned to four Group Lifestyle Balance (GLB) intervention groups: face to face (FF) (*n* = 119), DVD (*n* = 113), internet (INT) (*n* = 101), and self-selection (SS) (*n* = 101). SS participants chose the GLB modality. GLB is a comprehensive lifestyle behavior–change program.

RESULTS—A marked decline was observed in weight after the intervention in all groups (FF -12.5 lbs, P = 0.01; DVD -12.2 lbs, P < 0.0001; INT -13.7 lbs, P < 0.0001; and SS -14 lbs, P < 0.0001). Participants in SS experienced the largest average weight loss. Weight loss was sustained in >90% of participants in each group at 6 months (FF 90.7%, DVD 90.9%, INT 92.1%, and SS 100%). All groups experienced improvements in the proportion of participants with CVD risk factors. The proportion of individuals with CVD risk factors remained steady between 3 and 6 months in all groups and never returned back to baseline. All associations remained after multivariate adjustment.

CONCLUSIONS—Despite the modality, the GLB intervention was effective at decreasing weight and improving CVD risk factor control. SS and FF participants experienced greater improvements in outcomes compared with other groups, establishing the importance of patient-centered decision making and a support network for successful behavior change.

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s the obesity epidemic continues to worsen in the U.S., the health of communities is increasingly in a to obesity alone currently exceed 147 billion USD annually in the U.S (2). Efficacy-based trials demonstrate an

extensive amount of evidence for lifestyle interventions aimed at preventing or delaying diabetes (3–5). Moreover, the positive outcomes observed initially in these trials appear sustainable in the long term. Data from the Da Qing Diabetes Prevention Study and the Finnish Diabetes Prevention Study demonstrate a 43% lower incidence of diabetes for up to 14 and 7

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state of jeopardy. Approximately 65% of

Americans are overweight or obese, 65

million have prediabetes, and roughly

one-third of individuals in the U.S. have

metabolic syndrome (1). All of these con-

ditions substantially increase the risk for

developing diabetes and/or cardiovascular

disease (CVD) (1). The economic burden of

these conditions is staggering; costs related

years, respectively (6,7). Similarly, the Diabetes Prevention Program Outcomes Study (DPPOS) demonstrated a reduction in diabetes incidence by 34% in the lifestyle group at 10-year follow-up (8). However, nearly all of these efficacy trials used individual behavior-change counseling in a highly selected group of participants.

Multiple interventions adapted from these efficacy trials demonstrate the effectiveness of weight loss and diabetes and/or CVD risk reduction in real-world settings (9-16). Indeed, health professionals, payers, and policy makers worldwide increasingly recognize the need for these efforts. However, for a meaningful impact on public health policy and clinical care for primary prevention, determining the comparative effectiveness of real-world primary prevention efforts in community settings is critical (17). This knowledge will assist consumers, clinicians, purchasers, and policy makers in making informed decisions about primary prevention that will improve health care at both the individual and population levels.

To address the need for evidence of the comparative effectiveness of different lifestyle intervention modalities, we conducted a prospective, multisite, quasiexperimental study with four parallel lifestyle intervention groups. Modalities included face-to-face group education (FF), DVD education, and internet education (INT). We aimed to determine which modality of lifestyle intervention was most effective at reducing risk of diabetes and/or CVD. We further aimed to understand whether participants who were given the option to choose the modality that best suited their lifestyle experienced greater improvements in outcomes compared with those in groups in which the modality was predetermined.

RESEARCH DESIGN AND METHODS

Study setting and patient population

The study population consisted of overweight (BMI \geq 25 kg/m²) adults without diabetes who were abdominally obese

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(waist circumference >40 inches in males and >35 inches in females) and who lived in eight rural underserved communities in southwestern Pennsylvania. We excluded individuals who reported a diagnosis of diabetes or had a current prescription for glucose-lowering medication, were pregnant, could not walk one-quarter mile without stopping, had bariatric surgery, were currently using weight loss medications, or could not provide informed consent. In general, the eligibility criteria for the study were more flexible than those typically used in efficacy trials (3,18–20). Additionally, there was no requirement that participants attend the group sessions. All study communities were socioeconomically depressed areas with high prevalence rates of chronic disease.

Study design

The study was a prospective, multisite, quasi-experimental study with four parallel lifestyle-intervention groups (Fig. 1). The community in which the participant lived determined the lifestyle-intervention group to which they were allocated. Allocation of communities to the intervention groups was based on community characteristics (population size, ethnic majority, education level, median household income, persons below poverty, and the age-adjusted prevalence of obesity [21]) and the community's capacity to carry out the respective interventions. For example, it was not practical for a community that did not have adequate access to high-speed internet to be allocated to the INT group. The study was implemented in three phases: phase 1, training and certification in the Group Lifestyle Balance (GLB) program and in standardized measurement techniques; phase 2, community-based screening to

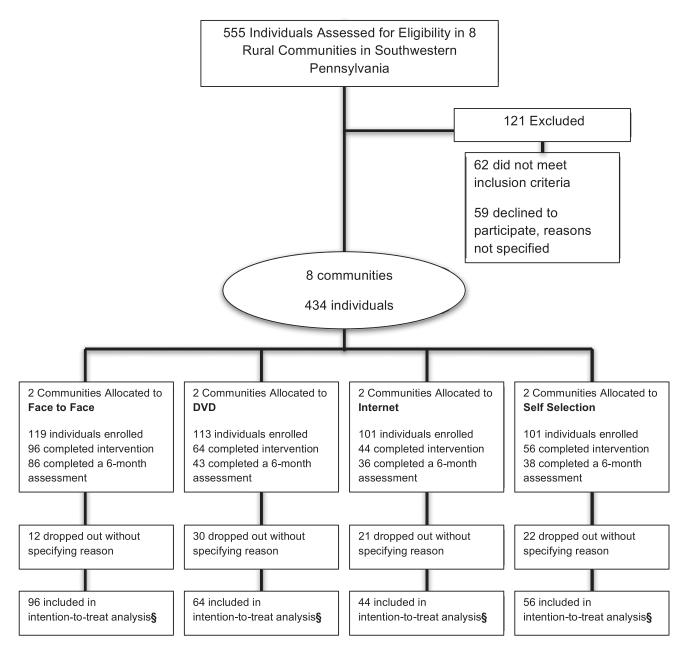


Figure 1—Flow diagram. §Three-month assessment results carried forward to 6-month assessment if data were missing.

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determine eligibility of individuals to take part in the intervention; and phase 3, provision of the intervention with 3- and 6-month follow-up including clinical assessment. The three phases of the study are described below.

Phase 1: training and certification. Phase 1 consisted of GLB training provided by the University of Pittsburgh Diabetes Prevention Support Center (22). Trained community preventionists (registered nurses and dietitians from each community site) delivered all GLB content for the intervention, while lay health coaches (also from the communities) were used in a support role to aid preventionists and to provide informational and emotional support to study participants. Lay health coaches were trained by the preventionists and research staff on GLB content, active listening skills, research fundamentals, and The Health Insurance Portability and Accountability Act requirements. For maintenance of a high level of treatment fidelity in the

community, four research study coordinators were implemented to work closely with the preventionists and lay health coaches at each community site. The research team received training in standardized measurement consistent with the Diabetes Prevention Program (DPP) by the University of Pittsburgh Diabetes Prevention Support Center staff or their designees.

Phase II: community-based screening. Individuals who met the inclusion criteria were targeted for screening between October 2009 and June 2010 through recruitment flyers and local newspaper and radio station advertisements. Screenings were offered at no cost at hospitals, churches, work sites, and other locations throughout the eight study communities and were facilitated by study staff (study coordinators, preventionists, and lay health coaches). Five hundred and fifty-five individuals were screened for BMI ≥25 kg/m² and abdominal obesity at 1 of

44 screenings held in the study communities. Four hundred and ninety-three individuals were eligible and were invited to participate in phase III of the study (lifestyle interventions). Those who were not eligible were referred to other exercise and healthy-lifestyle programs in their communities (Fig. 1). For most participants, the intervention visits were held at the same site where they were screened for study eligibility. In instances when the screening sites were not available or could not facilitate a group class, intervention sites in the same community as the screening sites were chosen. There were a total of 26 intervention sites across the eight study communities.

Phase III: interventions. The GLB program is a comprehensive lifestyle behavior– change program adapted from the lifestyle intervention used in the DPP that focuses on healthy food choices, fat and calorie intake, and physical activity. Members from the original DPP lifestyle team

Table 1-Baseline characteristics of REACT intervention participants

| | | Study group | | | | |
|---|------------------|------------------|------------------|------------------|------------------|----------|
| Characteristics | All | FF | DVD | INT | SS | Р |
| n | 434 | 119 | 113 | 101 | 101 | |
| Age (years) | 51.1 ± 11.3 | 50.9 ± 11.3 | 52.4 ± 10.9 | 48.7 ± 9.7 | 52.3 ± 12.7 | 0.07 |
| Weight (lbs) | 215.3 ± 44.4 | 216.7 ± 46.4 | 215.2 ± 47.4 | 218.9 ± 43.7 | 209.9 ± 39.2 | 0.52 |
| $BMI(kg/m^2)$ | 36.3 ± 6.6 | 37 ± 6.9 | 36.2 ± 7.2 | 36.1 ± 6.4 | 34.9 ± 5.7 | 0.08 |
| Waist circumference (inches) | 44.2 ± 6.0 | 44.1 ± 5.9 | 44.7 ± 6.7 | 44.3 ± 5.7 | 43.5 ± 5.4 | 0.58 |
| Glucose (mg/dL) | 98.1 ± 12.9 | 93.9 ± 10.8 | 100.8 ± 12.7 | 97.5 ± 15.2 | 101.4 ± 11.6 | < 0.0001 |
| Women | 374 (86.2) | 106 (87.6) | 96 (85.0) | 89 (88.1) | 98 (97) | 0.45 |
| Non-Hispanic white | 420 (96.8) | 119 (100) | 106 (93.8) | 100 (99.1) | 98 (97) | 0.06 |
| Education | | | | | | |
| ≤High school graduate | 108 (24.9) | 41 (34.5) | 25 (22.1) | 19 (18.8) | 23 (22.8) | 0.15 |
| Some college | 189 (43.6) | 46 (38.7) | 51 (45.1) | 51 (50.5) | 41 (40.6) | |
| ≥College graduate | 137 (31.6) | 32 (26.9) | 37 (32.7) | 31 (30.7) | 37 (36.6) | |
| Income (USD) | | | | | | |
| <20,000 | 37 (9.0) | 9 (8.0) | 10 (8.9) | 6 (6.1) | 12 (13.2) | 0.25 |
| 20,000–39,999 | 90 (21.8) | 27 (24.1) | 31 (27.9) | 18 (18.2) | 14 (15.4) | |
| 40,000–69,999 | 160 (38.7) | 47 (42) | 37 (33.3) | 44 (44.4) | 32 (35.2) | |
| >70,000 | 126 (30.5) | 29 (26) | 33 (29.7) | 31 (31.3) | 33 (36.3) | |
| Current smoker | 40 (9.3) | 11 (9.3) | 10 (8.9) | 14 (13.9) | 5 (5.0) | 0.19 |
| Family history of diabetes | 270 (66) | 74 (62.6) | 70 (68.6) | 66 (70.2) | 62 (63.3) | 0.58 |
| Class attendance/session views | | | | | | |
| FF class attendance (range 1–12) | | 9.6 ± 3.3 | | | | |
| DVD review session attendance (range 1–4) | | | 2.9 ± 1.2 | | | |
| INT sessions viewed (range 0–12) | | | | 6.8 ± 4.5 | | |
| SS FF class attendance (range 1–12) | | | | | 8.4 ± 3.3 | |
| SS INT sessions viewed (range 3-12) | | | | | 9.2 ± 3.3 | |
| Medical conditions | | | | | | |
| Hyperlipidemia | 244 (63.4) | 81 (69.8) | 73 (70.1) | 48 (54.6) | 42 (53.9) | 0.01 |
| Hypertension | 123 (46.2) | 43 (44.8) | 25 (39.1) | 21 (42.9) | 34 (59.7) | 0.04 |
| Weight loss attempted in last 12 months | 295 (68.9) | 86 (72.9) | 73 (65.8) | 65 (65.7) | 71 (71) | 0.57 |

Data are means \pm SD or *n* (%) unless otherwise indicated. Boldface data indicate statistically significant differences between study groups (*P* < 0.05).

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collaborated to adapt and update the individual intervention to a 12-week group-based program (22). The GLB was delivered via three modalities (FF, DVD, and INT) for the purposes of this study. Despite the modality, all content was the same. The theoretical framework for all modalities was based on social cognitive theory and incorporated behavioral selfmanagement approaches designed to help participants set goals, problem solve, make behavior changes, and increase their self-efficacy. The weight loss goal for the GLB is for participants to lose at least 5% of their body weight and/or decrease at least one cardiovascular risk factor after the lifestyle intervention.

All participants, in all groups, received a copy of the GLB handouts, a fat and calorie counter, self-monitoring books for keeping track of food and physical activity, a pedometer, measuring cups and spoons, and a chart for recording weekly weights. Participants were asked to self-monitor food intake and physical activity throughout the 12-week intervention and were given feedback concerning progress. A description of each GLB modality is outlined below.

Face to face. One hundred and nineteen participants from two communities participated in FF, which consisted of 12 group-education sessions that took place over the course of 12–14 weeks. Participants met as a group for up to 90 min/session each week. One trained

preventionist per community delivered the intervention. One lay health coach per community communicated with participants and identified barriers and solutions to promote program engagement and retention and provided informational and emotional support to participants upon their request. In addition, the lay health coaches aided in the logistics of the study and shared relevant experiences to initiate class discussion.

DVD. One hundred and thirteen participants from two communities took part in the DVD intervention. The DVD series was based on the GLB program, covering all 12 weekly sessions. Professional actors portrayed the preventionist and participants in the sessions. Participants completed the program over a 12- to 14-week period. They were provided with a set of DVDs that contained four weekly sessions at a time. It was recommended that participants watch one session per week, perhaps setting aside a specific day and time each week to view each session. Participants then met as a group at four time points throughout the 12-week period to debrief the previous sessions they watched and receive a new 4-week set of DVDs. All activities were completed as if they were attending an FF group session, including keeping track of what they ate and their physical activity levels. Preventionists and lay health coaches called participants weekly to offer information, support, and reminders as needed.

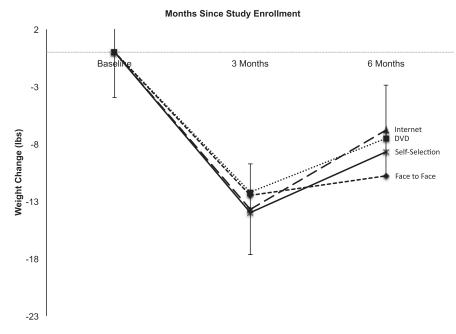


Figure 2—Mean weight change by intervention group.

Internet. One hundred and one participants from two communities took part in the INT intervention. INT was developed specifically for Results of the Rethinking Eating and ACTivity (REACT) and consisted of the use of the DVDs as described above but through internet access. In addition to viewing of the DVDs online, the INT incorporated behavioral tools such as e-mail prompts for online selfmonitoring of eating patterns, physical activity, and weight and a graphing capability to visualize progress made toward stated goals. Participants met as a group at baseline and again after finishing the 12to 14-week intervention. Preventionists and lay health coaches supported participants via online counseling. If staff found that a participant did not log onto the REACT website for >1 week and did not respond to an e-mail inquiry, a phone call was made.

Self-selection. One hundred and one participants from two communities in this study arm were able to self-select the intervention modality (as described above) of their choosing. Participants were limited to one modality to avoid contamination and bias in the results. Of participants, 60% chose FF, 0% chose DVD, and 40% chose INT.

Data collection. Eligibility, baseline, and follow-up data were collected through inperson visits. Participants were asked to make in-person visits at 3 and 6 months after enrollment into the study. At each visit, anthropometric measures (height, weight, blood pressure, and waist circumference) were collected. Weight was measured on a high-quality calibrated digital scale with the participant wearing clothes but no shoes. Height was measured using a stadiometer. Blood pressure was measured using the auscultatory method (23), and waist circumference was measured at the umbilical waist (24). Trained research staff completed the measurements. Questionnaires that assessed sociodemographic characteristics, quality of life, and other comorbidities were completed. Physical and mental functioning was measured with the Medical Outcomes Study Short Form 12 (25). All instruments are validated and are deemed reliable in similar populations (25-27). Trained research staff performed the measurements. CVD risk factors were defined using the National Cholesterol Education Program's Adult Treatment Panel III definition of metabolic syndrome (28). More specifically, hypertension was defined as systolic

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blood pressure \geq 130 mmHg and/or diastolic blood pressure \geq 85 mmHg. Hyperlipidemia was defined as triglyceride levels \geq 150 mg/dL.

During the in-person data collection visits, participants were provided with a laboratory requisition to have their blood drawn at baseline and again at 3 and 6 months after study enrollment. Blood samples were collected after an 8-h fast to determine glucose, triglycerides, and HDL cholesterol levels. Triglycerides and HDL cholesterol were measured by enzymatic assays using the Dade Behring RXL. Blood glucose was measured by the hexokinase method using the Dade Behring RXL. All results were mailed to participants and their physicians. The overall 3-month response rate was 60% (260 of 434) and 6-month response rate was 46.8% (203 of 434). Three-month response rates by group were as follows: FF 80.7%, DVD 56.7%, INT 43.6%, and SS 55.4%. Six-month response rates by intervention group were FF 72.2%, DVD 38.1%, INT 35.6%, and SS 37.6%) (Fig. 1). Analyses. The primary outcome of this study was change in weight from baseline to 3- and 6-month follow-up. Secondary outcomes included changes in CVD risk factors, including glucose, triglyceride levels, waist circumference, blood pressure values, and HDL cholesterol.

The primary analysis was based on the intention-to-treat principle. Imputation analyses that carried baseline values forward and the mean values forward provided no change in interpretation of results. The statistical analysis of the study incorporated both descriptive and inferential techniques. Data are presented using descriptive statistics (e.g., proportions, means, SDs) by lifestyle group and by reassessment time. The analyses examined whether there were within-group differences from baseline to 3-month follow-up and whether improvements could be maintained at 6-month followup. For examination of differences between study groups, a combined between- and within-group repeated-measures ANOVA was performed for each outcome of interest. Statistical modeling was then used to investigate whether there were differential effects on outcomes due to process or demographic differences. For investigation of the possible effect of the clustering of individuals within communities, mixed modeling (SAS PROC MIXED) was used. Models were adjusted for the baseline value of the dependent variable, age, sex, community, and the clustering of participants

within communities. The study was designed to have 80% power to detect a between-group difference of 5% change in weight, with a two-sided significance level of 0.05.

RESULTS—Five hundred and fifty-five individuals were screened for BMI ≥ 25 kg/m² and abdominal obesity. Of screened individuals, 86.1% were female and 95.1% were non-Hispanic white, reflecting the racial makeup of the study area. Mean weight and waist circumference were 209.5 \pm 45.6 lbs and 43.1 \pm 18.8 inches, respectively. Of those who were screened, 493 (88.8%) were eligible to participate in the intervention and 434 (88%) enrolled (Fig. 1). When the screening population (n = 555) was compared with the intervention population (n =434) to determine generalizability, there were no statistical differences in mean weight (209.5 \pm 45.6 vs. 215.3 \pm 44.4 lbs), waist circumference $(43.1 \pm 18.8 \text{ vs.})$ 44.2 ± 12.4 inches), sex distribution (86.1% female vs. 86.2% female), or race (95.1 vs. 96.8% non-Hispanic white).

Mean age of intervention participants (n = 434) was 51.1 years; 86.2% were female and 96.8% non-Hispanic white. Mean weight, BMI, and waist circumference at baseline was 215.3 ± 44.4 lbs, $36.9 \pm 9.2 \text{ kg/m}^2$, and $44.2 \pm 12.4 \text{ in-}$ ches, respectively (Table 1). Baseline sociodemographic characteristics of the intervention participants are presented in Table 1 overall and by intervention group. Average class attendance for FF was 9.6 sessions. Participants in INT viewed an average of 6.8 sessions online, and participants in DVD attended an average of 2.9 DVD debriefing sessions out of 4 possible. SS participants who chose FF attended an average of 8.4 classes, while those who chose INT viewed an average of 9.2 sessions online (Table 1). There were no differences between groups in sex distribution, education level, income, smoking status, family history of diabetes, or whether participants attempted weight loss during the 12 months preceding the study (Table 1).

Weight loss

There was a marked decline in weight from baseline to 3 months in all intervention groups (FF -12.5 lbs, P = 0.01; DVD -12.2 lbs, P < 0.0001; INT -13.7 lbs, P < 0.0001; and SS -14 lbs, P < 0.0001), with participants in SS experiencing the largest average weight loss. At 6 months, the mean weight loss from baseline was

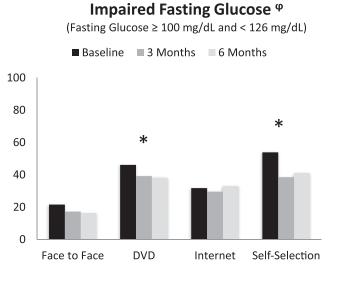
-10.8 lbs in FF (P < 0.0001), -7.5 lbs in DVD (P < 0.0001), -6.8 lbs in INT (P < 0.0001), and -8.7 lbs in SS (P <0.0001) (Fig. 2). Significant differences in mean weight loss between groups at 3 and 6 months were observed, with SS having the greatest average weight loss at $\overline{3}$ months (P = 0.03) and FF having the greatest average loss at 6 months (P =0.05) compared with other groups. When the effect of group was adjusted for the clustering of participants within communities, baseline weight, age, and sex, the magnitude of the association remained strong at 3 (P = 0.004) and 6 (P = 0.004) months in favor of FF.

When weight loss goals were examined at 6 months, the proportion of participants with a weight that was lower than their baseline weight was 71.4% in FF compared with 53.1, 42.6, and 55.5% in DVD, INT, and SS, respectively. Of the participants who achieved the 5% weight loss goal at 3 months (FF 57.2%, DVD 56.7%, INT 62%, and SS 66.7%), >90% in each group sustained the weight loss at 6 months (FF 90.7%, DVD 90.9%, INT 92.1%, and SS 100%) (data not shown).

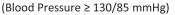
Cardiovascular risk factors

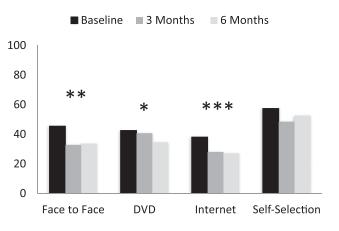
All groups experienced significant improvements in the proportion of participants with CVD risk factors after the intervention. The proportion of participants with abdominal obesity significantly decreased in all groups from baseline to 3 and 6 months (Fig. 3). Similarly, the proportion of participants with hypertension decreased in all groups and significantly in FF (P < 0.01), DVD (P < 0.05), and INT (P < 0.0001). Triglyceride and HDL cholesterol levels also improved but not in INT. Indeed, INT experienced significant increases (P <0.01) in the proportion of participants with abnormal triglyceride levels over time (Fig. 3). Additionally, the proportion of participants with impaired fasting glucose (IFG) decreased in all groups from baseline to 3 and 6 months except for INT. SS had the largest decrease in the proportion of participants with IFG. In fact, of the 41 individuals who had IFG at baseline in SS, 26 no longer had IFG at 3 months (data not shown). All associations remained after adjustment for the effect of clustering of participants within communities, age, sex, and baseline CVD risk factors. The proportion of individuals with CVD risk factors remained steady between 3 and 6 months in all groups and never returned back to baseline

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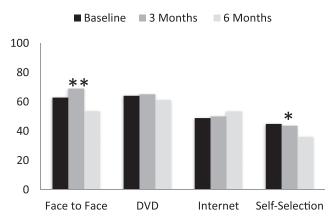
Hypertension







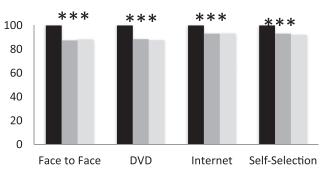
(<40 mg/dL in men, <50 mg/dL in women)





(Waist Circumference > 40 inches in males, > 35 inches in females)

■ Baseline ■ 3 Months ■ 6 Months



Triglycerides ≥ 150 mg/dL

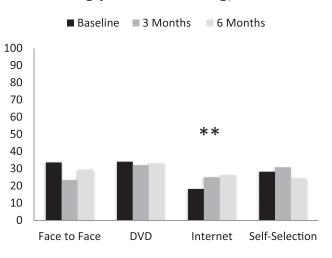


Figure 3—*Changes in proportion of participants with cardiovascular risk factors across study groups after lifestyle intervention (baseline to 6-month follow-up).* §P values represent within-group differences from baseline to 6-month follow-up. *P < 0.05, **P < 0.01, ***P < 0.0001. φ Associations remained after adjustment for the effect of clustering of participants within communities, age, sex, and baseline values. HDLc, HDL cholesterol.

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(Fig. 3). When weight loss and CVD risk factors were examined within the SS group and stratified by intervention modality (FF versus INT), no differences in associations were found.

CONCLUSIONS—In this comparative effectiveness study, in which overweight and abdominally obese participants from eight underserved rural communities were enrolled, four modalities (FF, DVD, INT, and SS) of lifestyle intervention achieved statistically and clinically significant weight loss, despite the modality. The observed weight loss was similar to weight loss observed in efficacy studies (3-8), with SS participants experiencing the largest average weight loss at 3 months and FF participants experiencing the largest average weight loss at 6 months. More than onehalf of all participants lost at least 5% of their total body weight after the intervention, weighing on average 20 lbs less than they did at baseline.

Evidence demonstrates that 5% weight loss is clinically meaningful and has documented health benefits, including improved diabetes and CVD risk factors (29). All groups experienced reductions in the proportion of individuals with impaired fasting glucose, abdominal obesity, and hypertension after the intervention. FF and SS were the only groups to achieve significant improvements in HDL cholesterol.

The data presented in this study support the work of others who designed and implemented lifestyle interventions based on the DPP in community settings. Numerous studies have reported initial weight loss and CVD risk reduction after a lifestyle intervention (9,13,14,30) and demonstrated that these types of interventions are feasible and can be effectively implemented in a number of settings and populations. However, few studies have made head-to-head comparisons of modalities of lifestyle intervention (31,32). We believe that the REACT study is the first scalable public health attempt at examining the comparative effectiveness of previously developed lifestyle intervention modalities so that informed decisions can be made regarding primary prevention of diabetes and CVD. Additionally, it is one of the first studies to examine the effectiveness of empowering a group of participants to choose the intervention modality that best suited their lifestyle.

In conducting community interventions, there are various limitations that may affect the study results. Although we implemented standardized interventions and data collection across all communities and study groups, we had to tailor our approach to reflect the setting (e.g., community-based hospitals, community gathering places, community work sites, etc.). Additionally, because of the realworld setting of our study, we had to increase our flexibility at times. For example, we encouraged all participants to attend the group sessions and the datacollection reassessments that were part of their study group; however, we could not mandate it. Although attendance was highly encouraged, average attendance/ curriculum viewing was ~9 of 12 sessions. As attrition may be perceived as a limitation in our data with decreasing response rates at 3 and 6 months, all analyses were carried out using intention-to-treat methodology and included the use of mixed models that addresses attrition while not overestimating the intervention effect (33,34). We were powered at 80% to detect significant differences in the primary and secondary outcomes. Therefore, it is unlikely that the reported findings are subject to type II error. Indeed, the findings that showed statistically significant differences represent true differences.

The time frame of this REACT report also poses a limitation. A 6-month time frame limits generalizability of the results, as many improvements in clinical outcomes cannot be determined in this short period. A future report is in progress that will describe the 18-month results.

Although all REACT study groups achieved notable improvements in outcomes, the largest and most significant improvements were observed in the FF and SS groups. To that end, the REACT study provides a sort of template for what may be needed for successful communitybased primary prevention efforts. Our results suggest that individuals who are attempting to lose weight and decrease their risk for diabetes and CVD benefit from accountability to their peers and health care providers in a group-based format and the option to choose the type of intervention that best suits their lifestyle. Future reports will focus on the long-term maintenance of the observed improvements and the comparative costeffectiveness of the lifestyle-intervention modalities.

Health professionals, payers, and policy makers worldwide increasingly recognize the need for cost-effective, scalable, community-based primary prevention efforts. The REACT study provides the first opportunity to compare the effectiveness of several lifestyle interventions in multiple underserved rural communities. For a meaningful impact on public health policy and clinical care, understanding the comparative effectiveness of each primary prevention modality in multiple community settings is critical. Efforts to make primary prevention a billable and reimbursable service are ongoing at the local and national levels.

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G.A.P. wrote the manuscript and researched data. M.C.S. and R.O.P. researched data and reviewed and edited the manuscript. J.C.Z. reviewed and edited the manuscript. G.A.P. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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