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A Comprehensive Lifestyle Peer Group–Based Intervention on Cardiovascular Risk Factors

The Randomized Controlled Fifty-Fifty Program

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ABSTRACT

BACKGROUND Cardiovascular diseases stem from modifiable risk factors. Peer support is a proven strategy for many chronic illnesses. Randomized trials assessing the efficacy of this strategy for global cardiovascular risk factor modification are lacking.

OBJECTIVES This study assessed the hypothesis that a peer group strategy would help improve healthy behaviors in individuals with cardiovascular risk factors.

METHODS A total of 543 adults 25 to 50 years of age with at least 1 risk factor were recruited; risk factors included hypertension (20%), overweight (82%), smoking (31%), and physical inactivity (81%). Subjects were randomized 1:1 to a peer group–based intervention group (IG) or a self-management control group (CG) for 12 months. Peer-elected leaders moderated monthly meetings involving role-play, brainstorming, and activities to address emotions, diet, and exercise. The primary outcome was mean change in a composite score related to blood pressure, exercise, weight, alimentation, and tobacco (Fuster-BEWAT score, 0 to 15). Multilevel models with municipality as a cluster variable were applied to assess differences between groups.

RESULTS Participants' mean age was 42 ± 6 years, 71% were female, and they had a mean baseline Fuster-BEWAT score of 8.42 ± 2.35. After 1 year, the mean scores were significantly higher in the IG (n = 277) than in the CG (n = 266) (IG mean score: 8.84; 95% confidence interval (CI): 8.37 to 9.32; CG mean score: 8.17; 95% CI: 7.55 to 8.79; p = 0.02). The increase in the overall score was significantly larger in the IG compared with the CG (difference: 0.75; 95% CI: 0.32 to 1.18; p = 0.02). The mean improvement in the individual components was uniformly greater in the IG, with a significant difference for the tobacco component.

CONCLUSIONS The peer group intervention had beneficial effects on cardiovascular risk factors, with significant improvements in the overall score and specifically on tobacco cessation. A follow-up assessment will be performed 1 year after the final assessment reported here to determine long-term sustainability of the improvements associated with peer group intervention. (Peer-Group-Based Intervention Program [Fifty-Fifty]; NCT02367963) (J Am Coll Cardiol 2016;67:476–85) © 2016 by the American College of Cardiology Foundation.

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Cardiovascular disease (CVD) is the leading cause of death in the world, affecting not only industrialized but also low- and middle-income countries (1,2). A multisectoral strategy that promotes a healthy lifestyle by reducing cardiovascular risk factors and reduces mortality and morbidity through quality health care services needs to be urgently implemented. Although significant improvements have been made in the treatment of CVD, the number of people diagnosed with the disease continues to rise, highlighting the greater need for efforts to be directed toward primordial and primary prevention.

In Spain, cardiovascular health (CVH), as defined by the American Heart Association (3), is poor, particularly regarding lifestyle. Only 0.2% of Spaniards attained ideal values for all 7 cardiovascular disease health metrics, and <1% have a completely healthy lifestyle (4). Physical inactivity, smoking, and obesity affect one-fourth of the population (5). These adverse health behaviors have contributed to the rising number of CVD-related deaths in Spain (6).

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Diverse interventions designed for health habit modification have been implemented in recent years (7–9), but interventions addressing CVH as a whole are few (10,11). Those interventions that include peer-based strategies have only been explored for chronic disease conditions (12,13). Peer support is widely used and has been found to have a positive effect on subjects with shared diseases (14), conditions, or situations (15–17). Peer support has also been proven as 1 of the best strategies for long-term management of chronic diseases (18). To the best of our knowledge, the present study is the first to analyze the effectiveness of a peer support strategy in modifying the behavior of healthy individuals at risk of CVD.

METHODS

ADOPTION AND IMPLEMENTATION PLAN. A 12-month pilot study was conducted in Cardona, Spain, to determine the feasibility of the intervention (V. Fuster et al., unpublished data, June 2012). The experience yielded strengths and weaknesses of the implementation plan and was instrumental in the design of the present study.

The Fifty-Fifty Study was conducted in cooperation with 7 municipalities (Barcelona, Cambrils, Guadix, Manresa, Molina de Segura, San Fernando de Henares, and Villanueva de la Cañada).

STUDY DESIGN AND PARTICIPANTS. The Fifty-Fifty Study was a peer group (PG)-based, multicenter, randomized controlled trial with a 12-month intervention and 1 additional year of follow-up. Eligible participants were 25 to 50 years of age with at least 1 of the following risk factors: hypertension (blood pressure [BP] ≥140/90 mm Hg or receiving treatment), overweight or obese (body mass index ≥25 kg/m^2), smoking, or physical inactivity (≤150 min/week).

Volunteers were invited to an in-depth information session, and interested subjects completed the written consent forms. Enrolled participants were entered in a run-in training period consisting of 6 workshops on core lifestyle and risk factor education related to: motivation to change, physical activity, healthful diet, smoking cessation, stress management, and self-control of BP. Once this process was completed, participants were randomized 1:1 to a peer-based intervention versus self-management, stratified according to sex (**Figure 1**). The control group (CG) went through these initial 6 workshops only, and no further support was organized during the intervention.

STUDY INTERVENTION. The intervention is based on elements of social cognitive theory (19). This theory explains human behavior in terms of a 3-way, dynamic, reciprocal model in which personal factors, environmental influences, and behavior continually interact. Key constructs of social cognitive theory that are relevant to behavior change interventions include observational learning, reinforcement, self-control, and self-efficacy.

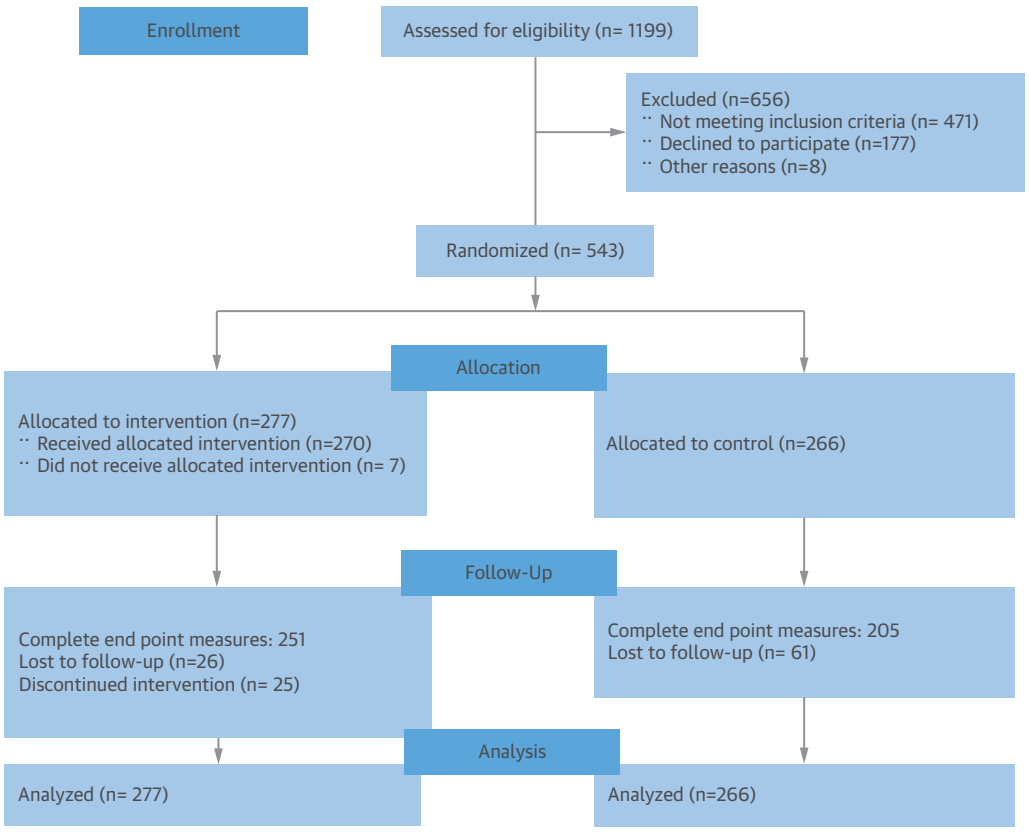
To promote CVH, the program used evidence-based recommendations, including: 1) increase in the periods of physical activity to reach the World Health Organization guidelines of 150 min/week; 2) improving dietary behavior to meet the guideline of 5 servings (400 g) of fruits and vegetables per day; and 3) smoking cessation. Both the improvement in healthy habits and the reduction in established CVD risk factors are scored to evaluate success in achieving medium- and long-term reduced risk of CVD (20,21).

Intervention participants were randomly assigned to small PGs composed of approximately 10 subjects, 2 of whom were selected to be peer educators or leaders (22). Health and psychology professionals led each group through a group dynamics education session, aimed at assessing group members for leadership, availability for the peer educator role, and clear understanding of the intervention. Each peer educator attended a 3-h session on relevant health and health promotion information, leadership, and communication skills. A holistic approach was used,

ABBREVIATIONS AND ACRONYMS

BP = blood pressure
CG = control group
CI = confidence interval
CVD = cardiovascular diseases
CVH = cardiovascular health
FBS = Fuster-BEWAT score
IG = intervention group
PG = peer group

FIGURE 1 CONSORT Flow Diagram



The flow of participants from screening, through randomization and final follow-up. CONSORT = Consolidated Standards of Reporting Trials.

including physical, nutritional, and psychological aspects of lifestyle change, aimed at improving the associated risk factors (11,23). Armed with these skills, the peer educators then engaged their peers in conversations about the issues of concern, seeking to promote health-enhancing knowledge and skills (24). The goal was for each group to identify potential barriers and determinants of lifestyle improvement and subsequently take actions to reduce their CVD risk.

Additional midterm training was provided to reinforce the group and increase adherence (25). This training consisted of a 3-h motivational session led by the psychologist for refreshing peer supporters on their skills and allowing the sharing of learned concepts (26) (**Table 1**).

PG meetings were held on a monthly basis, and each meeting lasted 60 to 90 min. During the monthly meetings, each participant explained the improvements in healthy habits and difficulties during the last month; group leaders and participants were supposed to support, encourage, and help. Each leader monitored the progress of the group members. The activities involved in the group dynamics included, of their own choice, group discussions, role-playing, brainstorming, relaxation techniques, menu design, joint sporting activities, and others. At each meeting, participants addressed emotion management, problem resolution, relapse prevention, diet control, and physical activity engagement. Through these reflections, participants proposed achievable goals that would improve their lifestyle. To promote management of risk factors, members of the IG were provided with a health handbook containing information on evidence-based prevention; these handbooks were also to be used for recording the participants' lifestyle behavior, health parameters, and immediate goals at each meeting (27,28).

OUTCOME PARAMETERS. Assessments were performed at 4 time points: initial (screening), post-workshops (randomization / baseline), final assessments (1-year follow-up), and follow-up assessments (2 years). There were thus 4 measurements in total.

The primary outcome measure was the mean change, from baseline to 1-year follow-up, in a newly designed score reporting a combination of the 5 main variables under study: BP, exercise, weight, alimentation, and tobacco (i.e., the Fuster-BEWAT Score [FBS]). The FBS compiles the 5 individual variables into a 15-point simple ordinal scale for the monitoring of global changes in healthy behaviors and nonlaboratory-based CVH factors. For each variable, a numeric grading system (0, 1, 2, or 3) has been adopted in relation to the international guidelines for cardiovascular risks and habits; the optimal value is 3 (Online Table 1). The score reports on both healthy habits and biological parameters. The independent consideration of the individual components of the score determines whether changes take place in lifestyle, biological parameters, or both.

The secondary outcome measures were the mean changes in the individual components of the FBS and mean changes in anthropometric measures and health behaviors.

DATA COLLECTION AND SCORING. The data obtained included: 1) anthropometric data (BP, weight, height, and waist circumference); 2) socioeconomic data; 3) healthy habits, collected by using the Fuster-BEWAT Questionnaire, the standardized International Physical Activity Questionnaire (29), the shortened Fagerström dependency and Richmond questionnaires regarding smoking (30,31), the PREDIMED (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet) validated 14-item screening tool for measuring adherence to the Mediterranean diet (32), and a reduced and adapted version of the Short-Form 36 questionnaire for measuring quality of life (33).

STATISTICAL ANALYSIS. Summary statistics describing baseline characteristics of all study participants are presented as mean ± SD or frequencies for continuous and categorical variables, respectively. In accordance with the intention-to-treat analysis, missing values for the FBS after randomization (dropouts, n = 87) were assigned by means of multiple imputation (with sex, age, and municipality as predictive variables). Mixed models accounting for municipality as random effects were used to determine whether the mean score and/or the mean score change at the end of the program were significantly different between the IGs and CGs controlling for the effects of other variables (namely, sex, age, educational attainment, and baseline score values). Analogue mixed linear models were applied to assess differences in each of the components of the FBS (BP, exercise, weight, alimentation, and tobacco). In addition, a per-protocol analysis was applied, replicating the previous mixed models (total score and score components) with the sample actually finishing the program (n = 456). Changes in secondary outcomes were also assessed by using analogue mixed models. Finally, to assess a potential dose-response effect of the PG intervention and of the total program, differences in FBS between participants attending ≥7 PG sessions (high adherence) versus participants attending <7 PG sessions (low adherence) were also explored (n = 251).

All analyses assumed a statistical significance value of $p < 0.05$ and were performed by using SPSS version 20 (IBM SPSS Statistics, IBM Corporation, Armonk, New York).

ETHICAL CONCERNS. Informed written consent for participation was required from all participants. Ethical approval was received from the ethics committee of the Hospital de la Princesa, Madrid, Spain.

TABLE 1 Summary of Key Issues of Leaders' Selection, Their Training, and Motivational Session

Leader selection and training/session content
Leader selection (all participants)
Leaders are selected in 2-h session through
Introduction to session and to the Fifty-Fifty Program
Roles of a leader (e.g., set peer group meetings, motivate participants, offer support)
Role play to know each participant and select a leader
Provision of a list of abilities for the characteristics of a leader for each participant
Leader training (participants selected to be the leaders)
Training of leaders is undertaken in 3-h session and included
Exploring the leadership concept
Role play to practice communication abilities and support the people of their groups
Specific coach for groups' management, pep-up techniques, coordinating meetings, misgivings, and advice
Technical preparation for the monthly meetings management
Provision of a handbook for leadership and a group sheet for monitoring
Motivational session
Only for leaders
Leaders are motivated in 1.5-h session through
Analysis on leadership roles
Achievements, difficulties and proposed strategies
Resources and tools to promote and motivate group commitment
Provision of a guideline for this session, planning sheet, short stories to motivate
All participants
Participants are motivated in 1.5-h session through
Group analysis
Sharing of achievements
To plan remaining meetings

RESULTS

The total study population comprised 543 participants at baseline (after randomization) and included 71% women; 71% of participants were 40 to 50 years of age. According to World Health Organization

criteria (34), 18% of participants were classified as obese and 36% as overweight. No differences were observed between the CG and the IG with respect to baseline characteristics, including FBS (**Table 2**), except for a larger percentage of younger participants in the CG ($p < 0.001$). The initial (screening) mean FBS for the whole sample was 7.78 ± 2.38. After the initial educational workshops (baseline), the total sample increased the FBS to a mean of 8.42 ± 2.35, with no difference between the CG and the IG (**Figure 2**, Online Table 2).

Table 3 displays the mean scores at baseline and 1-year follow-up in the overall FBS and its components in the CG and the IG. As expected, no differences were found between groups in baseline assessment. At the 1-year follow-up, the intervened group exhibited a significantly larger overall FBS compared with the CG (IG mean: 8.84; 95% confidence interval (CI): 8.37 to 9.32; CG mean: 8.17; 95% CI: 7.55 to 8.79; $p = 0.016$). The increase in the overall score was significantly larger in the IG compared with the CG (mean difference: 0.75; 95% CI: 0.32 to 1.18; $p = 0.02$). At the 1-year follow-up, the score in the individual components was uniformly greater in the IG, reaching a significant difference in the tobacco component (IG mean: 2.57; 95% CI: 2.40 to 2.74; CG mean: 2.29; 95% CI: 2.07 to 2.52; $p = 0.003$).

TABLE 2 Characteristics of the Study Sample

	Control Group (n = 266)	Intervention Group (n = 277)	p Value (Chi-Square Test)
Sex			
Male	77 (28.9)	79 (28.5)	0.912
Female	189 (71.1)	198 (71.5)	
Age, yrs			
25-29	17 (6.4)	5 (1.8)	<0.001
30-39	78 (29.3)	58 (20.9)	
40-50	171 (64.3)	214 (77.3)	
Municipality			
Barcelona	37 (13.9)	35 (12.6)	0.994
Cambrils	33 (12.4)	32 (11.6)	
Guadix	29 (10.9)	30 (10.8)	
Manresa	42 (15.8)	45 (16.2)	
Molina de Segura	47 (17.7)	46 (16.6)	
San Fernando de Henares	38 (14.3)	43 (15.5)	
Villanueva de la Cañada	40 (15.0)	46 (16.6)	
Educational level			
Low	13 (4.9)	15 (5.4)	0.064
Medium	115 (43.2)	146 (52.7)	
High	138 (51.9)	116 (41.9)	

Values are n (%).

Taking into account only those participants with data available at the 1-year follow-up (per-protocol analysis, n = 456), the results (Online Table 3) show that the IG also presented a significantly larger overall FBS compared with the CG (IG mean: 9.00; 95% CI: 8.55 to 9.45; CG mean: 8.54; 95% CI: 8.07 to 9.01; $p = 0.05$). As in the intention-to-treat analysis, the increase in the overall score was significantly larger in the IG compared with the CG (mean difference: 0.48; 95% CI: 0.05 to 0.92; $p = 0.03$). The mean scores in the individual components were generally greater in the IG, reaching a significant difference in the tobacco component (IG mean: 2.61; 95% CI: 2.47 to 2.74; CG mean: 2.42; 95% CI: 2.28 to 2.56; $p = 0.02$).

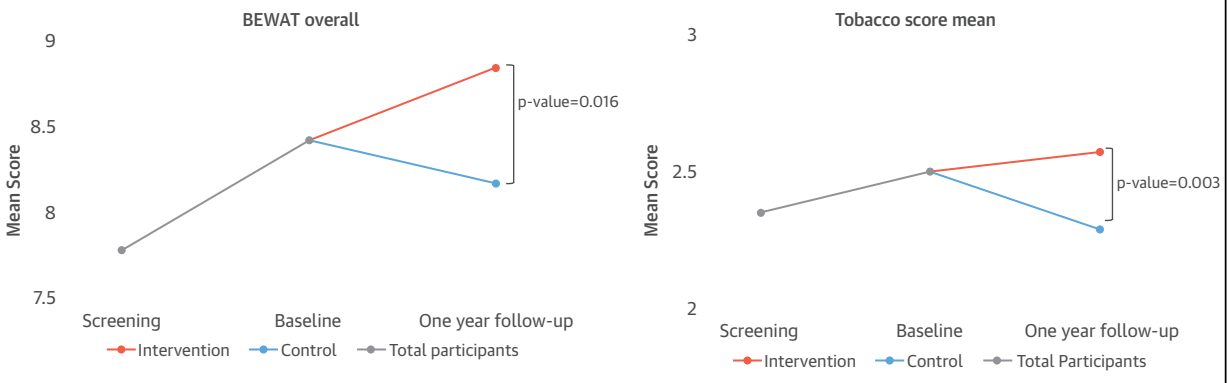
As part of the secondary outcomes, we assessed the mean levels before and after the intervention in the measured health-related variables. After the PG intervention, the IG exhibited a larger mean moderate to vigorous level of physical activity. This difference, however, did not achieve statistical significance (Online Table 4).

To evaluate a potential dose-response effect, the mean scores after the intervention in the primary and secondary outcomes were compared between high- and low-adherence participants (**Tables 4 and 5**). Although the high-adherence group had better scores in all components, the differences between groups did not reach statistical significance.

DISCUSSION

Our study was designed to assess the effect of a 1-year PG intervention. The results obtained indicate a significantly greater improvement in CVH for the intervention arm (**Central Illustration**), which resulted from a cumulative effect of small improvements in several components of the global FBS, mainly involving the behavioral variables. When considering the components separately, all showed improvement, with tobacco cessation exhibiting a significant difference. The initial educational period between screening and randomization resulted in an increase of the overall score; however, after randomization, the CG lost part of the acquired habits, while the intervention group continued to improve (**Figure 2**). This key finding reflects the additional positive effect of group dynamics, in addition to the transiently helpful educational workshops. These results suggest that although education is an essential element of change, it is not enough to maintain the initially achieved improvements. Our results therefore suggest that a combination of educational training and a peer-based intervention targeting individuals in a community setting may be an effective strategy for

FIGURE 2 BEWAT Overall and Tobacco Score Mean at Screening, Baseline, and Follow-Up



The mean BEWAT scores for the entire cohort are illustrated, from screening to randomization and then the scores according to study treatment arm. BEWAT = blood pressure, exercise, weight, alimentation, and tobacco.

enhancing the overall CVH in an adult at-risk population.

To the best of our knowledge, this study is the first to assess the effect of PG dynamics sessions after educational training in a multicenter, randomized controlled trial. Although the magnitude of the impact of our intervention was modest, epidemiological data suggest that even very small changes in health behaviors and risk factors can significantly decrease the long-term risk of CVD (35).

In contrast to previous studies specifically addressing diet or physical activity (25,36,37), our intervention had a broader focus and was based on self-control of unhealthy behaviors. Indeed, the actual content of the PG dynamics varied depending on participants' needs and interests, and it expanded on the specific aspects that the groups decided to focus on. This aspect might help to explain the lower magnitude of the impact of our intervention on adiposity or BP. The larger impact on smoking cessation might be partially explained by the dichotomous nature of smoking cessation. Indeed, many of the study participants succeeded in quitting, thus increasing their tobacco score to the maximum.

The FBS was used to score the Fifty-Fifty intervention, which includes nonlaboratory-based health and lifestyle factors and is therefore easy to understand and use, both for clinicians and patients,

TABLE 3 Overall BEWAT and Components' Mean Values and Mean Differences at Baseline and After PG Dynamics (Intention-to-Treat Analysis) (N = 543)

	Score Range	Control (n = 266)	Intervention (n = 277)	Difference	p Value
Baseline					
BEWAT overall	0–15	8.34 (7.93 to 8.83)	8.41 (7.96 to 8.83)	0.03 (-0.36 to 0.42)	0.88
Blood pressure	0–3	1.73 (1.57 to 1.89)	1.71 (1.54 to 1.87)	-0.02 (-0.21 to 0.17)	0.81
Exercise	0–3	1.08 (0.81 to 1.35)	1.07 (0.80 to 1.34)	-0.01 (-0.22 to 0.20)	0.93
Weight	0–3	0.90 (0.77 to 1.03)	0.86 (0.73 to 0.99)	-0.04 (-0.22 to 0.14)	0.67
Alimentation	0–3	2.22 (2.10 to 2.35)	2.22 (2.09 to 2.34)	-0.00 (-0.10 to 0.10)	0.96
Tobacco	0–3	2.44 (2.31 to 2.57)	2.55 (2.42 to 2.67)	0.10 (-0.04 to 0.25)	0.16
1 year					
BEWAT overall	0–15	8.17 (7.55 to 8.79)	8.84 (8.37 to 9.32)	0.77 (0.35 to 1.20)	0.02
Blood pressure	0–3	1.60 (1.31 to 1.88)	1.63 (1.48 to 1.81)	0.11 (-0.08 to 0.30)	0.71
Exercise	0–3	1.21 (0.98 to 1.44)	1.40 (1.17 to 1.62)	0.18 (-0.04 to 0.40)	0.11
Weight	0–3	1.07 (0.84 to 1.30)	1.04 (0.83 to 1.24)	0.00 (-0.18 to 0.19)	0.73
Alimentation	0–3	2.00 (1.72 to 2.29)	2.20 (2.04 to 2.36)	0.24 (0.10 to 0.39)	0.07
Tobacco	0–3	2.29 (2.07 to 2.52)	2.57 (2.40 to 2.74)	0.24 (0.09 to 0.38)	0.003

Values are mean (95% confidence interval) unless otherwise indicated. MIXED MODELS with cluster variable municipality, adjusted for age educational level, and baseline score.

BEWAT = blood pressure, exercise, weight, alimentation, and tobacco; PG = peer group.

TABLE 4 Overall BEWAT and Components: Means and Mean Differences After PG Dynamics in the High- Versus Low-Adherence Sample at 1 Year (N = 251)

	Score Range	Low Adherence (n = 123)	High Adherence (n = 128)	Difference	p Value
BEWAT overall	0–15	8.71 (7.93 to 9.48)	9.23 (8.45 to 9.99)	0.52 (-0.14 to 1.17)	0.12
Blood pressure	0–3	1.55 (1.35 to 1.75)	1.74 (1.55 to 1.94)	0.19 (-0.09 to 0.47)	0.18
Exercise	0–3	1.31 (0.98 to 1.63)	1.51 (1.18 to 1.83)	0.20 (-0.14 to 0.54)	0.25
Weight	0–3	0.98 (0.76 to 1.19)	1.06 (0.85 to 1.27)	0.08 (-0.19 to 0.35)	0.54
Alimentation	0–3	2.24 (2.05 to 2.44)	2.37 (2.17 to 2.56)	0.12 (-0.04 to 0.28)	0.15
Tobacco	0–3	2.67 (2.53 to 2.80)	2.56 (2.43 to 2.70)	-0.10 (-0.30 to 0.09)	0.29

Values are mean (95% confidence interval) unless otherwise indicated. MIXED MODELS with cluster variable municipality, adjusted for age, educational level, and baseline score.

Abbreviations as in Table 3.

to serially monitor progress toward health. Other measurement tools have also exclusively focused on healthy lifestyle behaviors, such as the Healthy Heart Score (38), which has been used as a screening tool for lifestyle-centered primordial prevention of CVD. In comparison, the FBS compiles 5 individual variables into a 15-point simple ordinal scale for the monitoring of global changes in both healthy behaviors and CVH-related factors that do not require invasive assessment. The lack of invasive measures facilitates the use of this score in primordial and primary prevention.

Despite its popularity, the evidence for peer support success is mixed, and there is no consensus on whether it works or how it works (15,39,40). Only a few of the published studies included randomized trials, and these tend to support the idea that PG interventions represent the best strategy for a positive outcome (41). Evidence supports group interactions as the most effective strategy for promoting self-monitoring and goal setting for recognition and stimulation of progress toward a behavior change (42). Support groups have been generally associated with a single condition (43) (e.g., weight loss, alcohol intake, smoking cessation). Our intervention instead covered multiple health behaviors related to CVH, independent of the specific risk situation of any individual participant. In fact, the Fifty-Fifty Program enrolled participants from different backgrounds (e.g., broad age range, high vs. low socioeconomic status, smokers vs. nonsmokers, physically active vs. sedentary, overweight vs. normal weight, hypertensive vs. nonhypertensive). In this regard, the results presented here demonstrate an overall positive impact of the intervention despite the heterogeneous nature of the participants.

TABLE 5 Overall BEWAT and Health Parameters: Means and Mean Differences After PG Dynamics in the High- Versus Low-Adherence Sample at 1 Year (N = 251)

	Low Adherence (n = 123)	High Adherence (n = 128)	Difference	p Value
MVPA, min/day	19.7 (7.4 to 32.0)	29.1 (17.0 to 41.3)	9.4 (-3.2 to 21.9)	0.14
Body mass index, kg/m^2	30.7 (29.5 to 31.9)	29.7 (28.5 to 30.9)	-1.0 (-2.5 to 0.4)	0.17
Waist circumference, cm	101.6 (97.6 to 105.5)	98.3 (94.4 to 102.1)	-3.3 (-7.1 to 0.4)	0.08

Values are mean (95% confidence interval). MIXED MODELS with cluster variable municipality, adjusted for age, educational level, and baseline score.

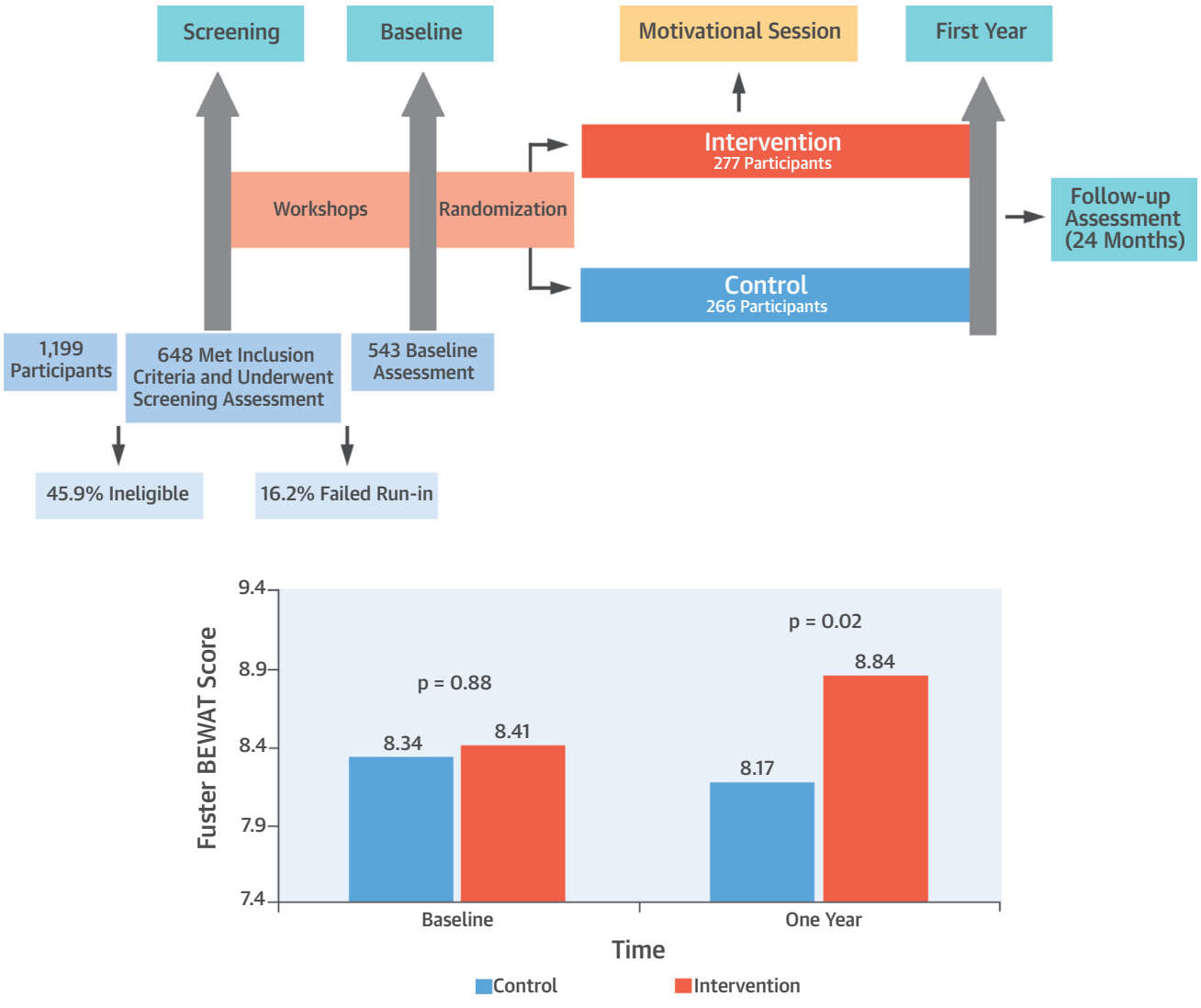
MVPA = moderate to vigorous intensity physical activity; other abbreviations as in Table 3.

Participants displaying high adherence to interventions tend to be more motivated and ready to change compared with nonadherent participants (44). In our study, the high-adherence group exhibited higher scores in the overall FBS and its components, as well as in anthropometric measures, and a substantial larger amount of physical activity levels compared with the low-adherence group; these results were not statistically significant. They suggest that peer interaction (most likely through sustained individual motivation) might be a key factor for the success of interventions (45). Indeed, the main problem affecting long-lasting group interventions is low adherence (46,47). Loss of motivation is driven by the absence of short-term positive results; it is therefore important to reinforce stepwise goals and to improve the self-monitoring of the progress in front of peers (48). The group leaders in our program were thus trained for stimulating a positive circle (success-motivation-attendance) and for sustaining the group dynamics indefinitely beyond our intervention.

The follow-up assessment, to be conducted 1 year after the end of the intervention presented here, will provide further insight regarding the persistence of the effects of the PG dynamics. We hypothesize that the existing peer support groups will continue to have an impact on the intervened participants. In fact, the perceived quality of life after the intervention program was significantly better in the IG than in the CG (measured by means of a validated and adapted questionnaire [33]; data not shown). We anticipate that these findings might provide the motivation for maintenance of the newly acquired health habits.

Clearly, there is no "one size fits all" approach for peer support around the world. This project has a broader goal and has been designed for paving the way for a future CVD prevention community-based program, incorporating local and state health authorities and municipalities in its design and implementation. However, what is appropriate in one country or one population may not be in others, and peer support should be shaped by cultural, organizational, and national factors. A similar PG-based intervention trial is being conducted on the island of Grenada (NCT02428

CENTRAL ILLUSTRATION **Fifty-Fifty Program: Design and Main Results**



Gómez-Pardo, E. et al. J Am Coll Cardiol. 2016; 67(5):476–85.

BEWAT = blood pressure, exercise, weight, alimentation, and tobacco.

920) with 400 subjects who have established cardiovascular risk factors. Simultaneously, and following the success of initiatives such as the SI! Program for CV health promotion (49,50), the FAMILIA (Family-based Approach in a Minority Community Integrating Systems-Biology for Promotion of Health) study is being conducted in Harlem, New York (NCT02343341). This study is evaluating an integrated family-based approach to CVH promotion, targeting preschool children and caregivers; the study comprises structured, yet playful, educational curriculum for children complemented with individual or peer-based intervention strategies targeting parents/caregivers. Ultimately, such novel strategies will have to be married to established principles of behavioral economics, taxation, and health policy that have success in promoting health (51–53).

STUDY LIMITATIONS. First, because participation in the study was voluntary, the composition of the sample might not be fully representative of the whole community but selective for the more

motivated individuals. Unlike most clinical trials, our study cohort included 70% women. Although this factor could be viewed as a strength, it does affect generalizability. A further limitation is the fact that 16% of the baseline cohort did not complete the program and thus did not participate at follow-up. Dropouts (n = 87) included a larger percentage of younger participants and lower overall FBS and alimentation scores at baseline (data not shown). Consequently, a selection bias cannot be ruled out. Finally, the self-reported behavioral variables might be affected by a social desirability bias.

CONCLUSIONS

This study found a positive impact on CVH from a PG-based intervention designed for self-sustainability, independent of long-term supervision or investment, with potential for relevance in different social contexts. The 1-year results demonstrated a significant beneficial effect on cardiovascular risk factors, with significant improvements in the overall score and specifically on the tobacco cessation component. In addition to the short-term positive impact of the initial educational sessions (common for all participants), the PG intervention specifically stimulated the participants not only to maintain the previous achievements but to further reduce their cardiovascular risk factors.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: The results of the Fifty-Fifty Study show that promoting healthier lifestyles focusing on self-control of unhealthy behaviors through PG support can be beneficial to heterogeneous groups without a single condition or specific cardiovascular risk factors.

TRANSLATIONAL OUTLOOK: Although this study involved a relatively short-term intervention, follow-up results will provide insight into long-term sustainability of PG support and long-term effect on CVH.

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APPENDIX For supplemental tables, please see the online version of this article.