The challenge of sustainability: Long-term results from the Fifty-Fifty peer group-based intervention in cardiovascular risk factors

Juan Miguel Fernández-Alvira, PhD[a], Rodrigo Fernández-Jiménez, MD, PhD[a,b], Mercedes de Miguel, MSc[a,c], Gloria Santos-Beneit, PhD[a,c,d], Patricia Bodega, MsC[a,c], Christopher A Hill, BA[d], Vanesa Carral, PhD[c], Carla Rodríguez, MSc[c], Isabel Carvajal, MSc[c], Xavier Orrit, PhD[c], Amaya de Cos-Gandoy, MsC[a,c], Marian Dal Re, BSc[e], Teresa Robledo, MD[e], and Valentín Fuster, MD, PhD[a,c,d] ***Madrid, Spain; Barcelona, Spain; New York, NY***

Background The Fifty-Fifty trial demonstrated that a peer-group-based intervention was able to improve healthy behaviors in individuals with cardiovascular (CV) risk factors immediately post-intervention.

Objectives To determine the long-term sustainability of a one-year peer-group-based intervention focused on CV health and behavior.

Methods A total of 543 adults aged 25 to 50 years with at least 1 CV risk factor were screened and recruited, received initial training through workshops, and were then randomized 1:1 to a peer-group–based intervention group (IG) or a self-management control group (CG) for 12 months. At a median of 52 months from baseline, 321 participants were re-assessed (~60% retention). The primary outcome was the mean change in a composite health score related to blood pressure, exercise, weight, alimentation, and tobacco use (Fuster-BEWAT score [FBS], range 0-15). Intervention effects were assessed using linear-mixed effects models.

Results The mean age of retained participants was 48.0 years (SD: 5.4), and 73% were female. Consistent with previous results, the change of overall FBS was significantly greater in the IG than in the CG at 12-month follow-up (between-group difference, 0.60 points; 95% CI, 0.08-1.12; $P = .025$). Assessment of long-term sustainability (52-month follow-up) showed that there were no between-group differences in the mean overall FBS (IG mean score, 8.52; 95% CI, 7.97-9.07 vs CG mean score, 8.51; 95% CI, 7.93-9.10; $P = .972$) or in the change of overall FBS from screening (IG mean change, 0.64; 95% CI, 0.00-1.28; CG mean change, 0.46; 95% CI, -0.20-1.12; $P = .497$).

Conclusions A one-year peer-group-based intervention showed favorable results at immediate post-intervention but did not demonstrate significant differences between the IG and CG at 52 months. Combination of an initial training period (workshops) with the maintenance of peer-support groups or other re-intervention strategies may be required to achieve sustained effects on healthy behaviors.

Trial registration ClinicalTrials.gov identifier NCT02367963. Registered (https://clinicaltrials.gov/show/NCT02367963). (Am Heart J 2021;240:81–88.)

The alarmingly poor cardiovascular (CV) health of the general population is associated with poor outcomes,[1] with CV disease (CVD) remaining the leading cause of death worldwide.[2] There is therefore an urgent need for affordable and effective strategies to promote healthier lifestyles in individuals and popula-

From the [a]Centro Nacional de Investigaciones Cardiovasculares (CNIC), Madrid, Spain, [b]Hospital Universitario Clínico San Carlos, Madrid, Spain, [c]Foundation for Science, Health and Education (SHE), Barcelona, Spain, [d]The Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, NY, [e]Spanish Agency for Food Safety and Nutrition (AESAN), Madrid, Spain

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Reprint requests: Rodrigo Fernández-Jiménez, MD, PhD. Centro Nacional de Investigaciones Cardiovasculares (CNIC), & The Zena and Michael A. Wiener Cardiovascular Institute Icahn School of Medicine at Mount Sinai. 1 Gustave L Levy Pl. New York, NY 10029, USA.

Reprint requests: Valentin Fuster, MD, PhD. Centro Nacional de Investigaciones Cardiovasculares (CNIC), The Zena and Michael A. Wiener Cardiovascular Institute Icahn School of Medicine at Mount Sinai. 1 Gustave L Levy Pl. New York, NY 10029

E-mail addresses: rodrigo.fernandez@cnic.es.

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tions.[3,4] Among other approaches to meeting this challenge, peer-support strategies have been applied successfully in a variety of conditions.[5] Benefits of peer support interventions have mostly been demonstrated for the long-term self-management of chronic diseases including diabetes, stroke, and mental health.[6]

Peer support has the potential as a tool for improving self-management of health and facilitating behavioral change, and this has spurred support initiatives aimed at enhancing specific health behaviors (physical activity, diet, etc.) in individuals at high risk of adverse outcomes.[7,8] However, information is scarce regarding the effectiveness of peer support strategies for the improvement of overall CV health, as well as regarding the sustainability of this particular type of intervention.

The Fifty-Fifty Program was a multicenter, randomized controlled trial focusing on the improvement of CV health in individuals without known CVD. The program recruited 543 adults, who received an initial training in the form of workshops and were then randomized 1:1 to receive a peer-group-based intervention or to self-manage (controls). The core of the intervention program consisted of monthly peer-group meetings over a 12-month period. At the end of the intervention, the program showed a beneficial effect on overall CV health, mainly due to greater improvements in the intervention groups in the behavioral components (smoking, physical exercise, and diet).[9]

The aim of the present study was to determine the sustainability of the effects associated with the Fifty-Fifty peer group-based intervention.

Methods

Study design and population

The Fifty-Fifty study included 543 adults aged 25 to 50 years with at least 1 of the following CV risk factors: hypertension (blood pressure $\geq$140/90 mm Hg), overweight or obesity (body mass index $\geq$25 kg/m^2), active smoking, or physical inactivity ($\leq$150 min/week of moderate-to-vigorous physical activity). The study was a multi-center (7 municipalities located in different Spanish regions) randomized controlled trial with a 12-month intervention period. After an initial screening assessment, all enrolled participants attended six weekly, health-expert-led 2-hour workshops focused on lifestyle and risk factor education related to motivation to change, the health benefits of physical activity, healthy diet, smoking cessation, stress management, and self-control of blood pressure. The main topics of each workshop are listed in **Supplemental Table I**. The first workshop focused on participant motivation and taking steps toward behavioral change. Subsequent workshops examined the health effects of the risk factors and the benefits of specific behaviors and techniques that can be adopted to avoid or reduce each one. To facilitate participant engagement, workshops were limited to a maximum of 30 participants.

After the training period, participants were re-assessed (baseline) and randomized 1:1 to a peer-based intervention (intervention group, IG) or self-management (control group, CG), stratified according to sex. IG participants met once a month for 60 to 90 minutes in groups of 8 to 10, with 2 participants in each meeting being previously selected and trained as peer educators or leaders. Follow-up assessments were scheduled for 12 months (immediate post-intervention) and approximately 52 months (sustainability). Participants were thus assessed at 4 time points: initial (screening), post training workshops (baseline / randomization), immediate post-intervention (12-month follow-up), and sustainability (52-month follow-up) (Figure 1). Complete details of the intervention program and group activities are published elsewhere[9] and are summarized in the Supplemental Methods.

All participants provided informed written consent for participation. Ethical approval was obtained from the ethics committee at the Hospital de la Princesa, Madrid, Spain.

Data collection

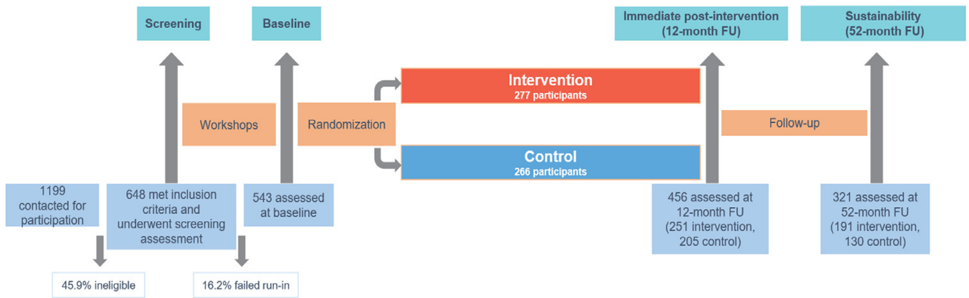
Blood pressure was measured with a digital blood pressure monitor (Panasonic EW-BU15), with participants in a sitting position. Three readings were recorded, and the mean value was used for the analysis. Participant height (cm) was recorded with a SECA 213 portable stadiometer, and weight (kg) was recorded with a SECA 803 scale. Waist circumference (cm) was measured with a Holtain tape. BMI was calculated as body weight in kg divided by height squared in meters (kg/m^2), and participants were classified as normal weight, overweight, or obese according to World Health Organization definitions . Habitual physical activity was assessed with the short version of the self-administered International Physical Activity Questionnaire.[10] Tobacco use was assessed with shortened Fagerstöm dependency and Richmond questionnaires,[11,12] and adherence to the Mediterranean diet was assessed with the PREDIMED (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet) screening tool.[13]

Outcomes

The primary outcome was mean change from screening in a validated composite score including blood pressure, exercise, (body) weight, diet (alimentation), and tobacco use (Fuster-BEWAT score; FBS).[9] Each score component is graded from 0 to 3, with 3 being the optimal value (**Supplemental Figure 1**). The overall score (0-15 points) is the sum of individual components, with 15 being the healthiest score possible.

The secondary outcome measures were the mean changes in individual FBS components and the between-

Figure 1



Flowchart of the study from start to final follow-up.

group differences in mean FBS values at follow-up. Further details of the calculation of FBS at screening and follow-up and its association with the presence of subclinical atherosclerosis have been published elsewhere[9,14] and are summarized in **Supplemental Figure 1**.

Statistical analysis

General characteristics of the study population are presented as mean and standard deviation for continuous variables and as frequencies and percentages for categorical variables. Possible intervention effects were tested by linear mixed-effects models (change in overall FBS). Fixed effects were age, sex, educational attainment, screening FBS, and randomization group (control or intervention); municipality was handled as a random effect. Similar models were used to assess differences in each of the individual FBS components and to assess differences in the change of FBS and its components between IG participants showing high versus low program adherence (the number of monthly meetings attended).

Every attempt was made to follow up all enrolled participants irrespective of group allocation or withdrawal from the program. All participants were included in the analysis in the groups to which they were randomized. Thus, the main analysis was the complete-case intention-to-treat analysis. As a sensitivity analysis, multiple imputation procedures using multivariate normal distribution were applied to include all randomized enrolled participants. Details of multiple imputation procedures are provided in Supplemental Methods.

Statistical significance was assigned at $P < .05$. All analyses were performed with SPSS version 23 (IBM SPSS Statistics, IBM Corporation, Armonk, New York).

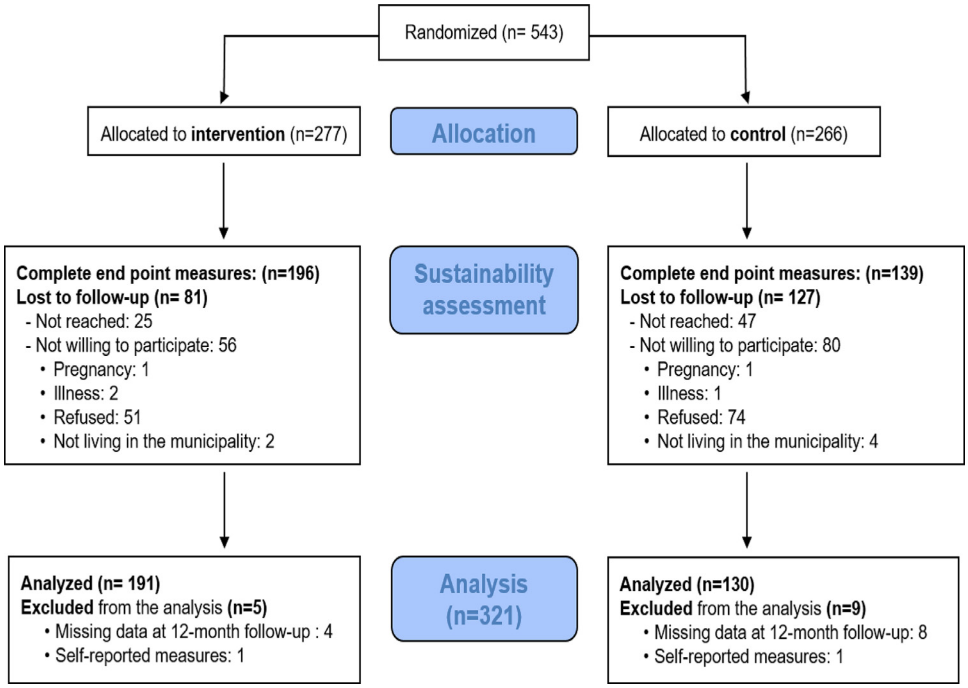
Results

The participant assessment schedule is summarized in Figure 1. After a median follow-up of 52 months, approximately 59% of all enrolled participants attended the sustainability assessment. Therefore, the main analysis (complete-case intention-to-treat analysis) of the primary outcome included 321 adults (130 in the CG and 191 in the IG) out of the 543 originally randomized participants (Figure 2).

General population characteristics are shown in Table I. IG participants were slightly older, but no other significant differences in baseline characteristics were observed between the CG and the IG. The initial mean FBS in the screening assessment was 7.95 ± 2.23, increasing to 8.57 ± 2.32 after the educational workshops (baseline assessment), with no differences between the IG and CG. At 12-month follow-up (immediate post-intervention), the IG showed a trend toward a higher (healthier) mean FBS than the CG with the change in FBS from screening significantly larger in the IG at this time-point: between-group change difference of 0.60 points (95% CI, 0.08-1.12, $P = .025$, **Supplemental Table II**).

Between-group differences in mean FBS and FBS changes at sustainability are shown in Table II. Although the mean FBS and FBS change from screening was greater in the IG than in the CG, the between-group difference in FBS means and FBS changes were not significant: between-group difference in FBS means of 0.00 points (95% CI, -0.54 to 0.56, $P = .972$) and between-group difference in FBS change of 0.18 points (95% CI, -0.34 to 0.70, $P = .497$, Figure 3). Similar results were observed after multiple imputation including all randomized enrolled participants (n = 543; between-group difference in FBS means of -0.02 (95% CI, -0.51 to 0.48, $P = .948$) and between-group difference in FBS change of 0.07 (95% CI, -0.48 to 0.62, $P = .811$). No between-group differences were detected in the change of individual FBS components with the exception of the weight component, which improved more in the IG than in the CG: between-group difference in the weigh component of 0.23 points (95% CI, 0.04-0.42, $P = .017$). Values of measured parameters comprising the FBS at each time-point are summarized in **Supplemental Table III**.

Figure 2



Participant flow diagram.

Table I. Baseline characteristics of the study sample

	Total (n = 321)	Control (n = 130)	Intervention (n = 191)
Age, years, mean (SD)	42.93 (5.73)	41.70 (6.11)	43.77 (5.31)
Age groups, n (%)			
25-29	6 (1.9)	3 (2.3)	3 (1.6)
30-39	75 (23.4)	42 (32.3)	33 (17.3)
40-50	240 (74.8)	85 (65.4)	155 (81.2)
Women, n (%)	235 (73.2)	94 (72.3)	141 (73.8)
BMI classification*, n (%)			
Normal weight	143 (44.5)	52 (40.0)	91 (47.6)
Overweight	123 (38.3)	51 (39.2)	72 (37.7)
Obesity	55 (17.1)	27 (20.8)	28 (14.7)
Educational level, n (%)			
Low	15 (5.3)	3 (2.3)	12 (6.3)
Medium	153 (47.4)	56 (43.1)	97 (50.8)
High	153 (47.4)	71 (54.6)	82 (42.9)
Municipality, n (%)			
Barcelona	42 (13.1)	18 (13.8)	24 (12.6)
Cambrils	44 (13.7)	21 (16.2)	23 (12.0)
Guadix	35 (10.9)	11 (8.5)	24 (12.6)
Manresa	48 (15.0)	17 (13.1)	31 (16.2)
Molina de Segura	57 (17.8)	23 (17.7)	34 (17.8)
San Fernando de Henares	39 (12.1)	13 (10.0)	26 (13.6)
Villanueva de la Cañada	56 (17.4)	27 (20.8)	29 (15.2)
FBS at screening, mean (SD)	7.95 (2.23)	8.08 (2.27)	7.86 (2.26)
FBS at baseline, mean (SD)	8.57 (2.32)	8.61 (2.25)	8.54 (2.37)

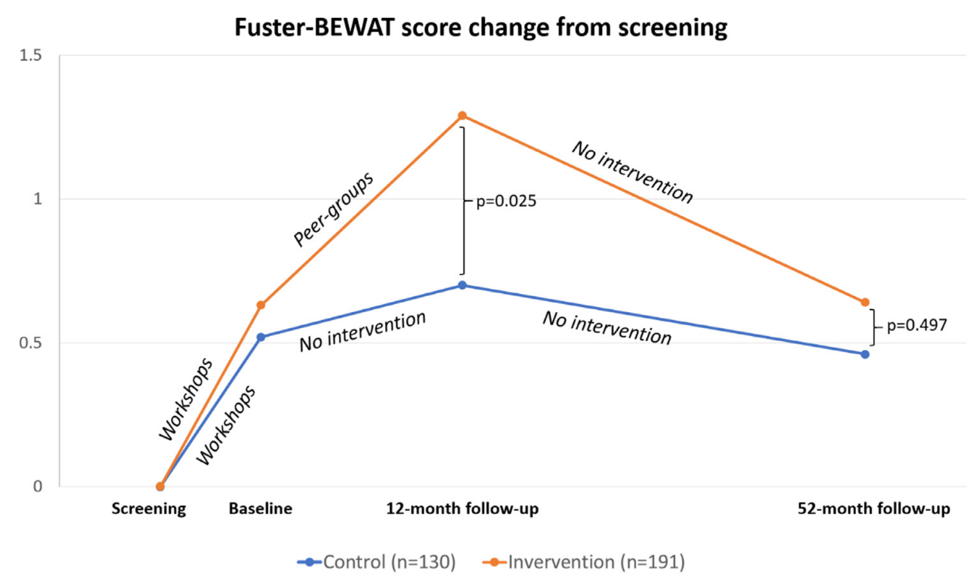
Values are mean (SD) for continuous variables and frequencies (percentages) for categorical variables.
BMI, body-mass-index; FBS, Fuster-BEWAT score.
* Normal weight BMI <25; Overweight BMI ≥25<30; Obesity BMI ≥30.

Table II. Overall Fuster-BEWAT and component score means, and between-group means and change differences, at sustainability (52-mo follow-up) in intervened vs control participants (complete-case intention-to-treat analysis)

FBS at sustainability				Between-group differences	
	Score range	Control (n = 130) mean (95% CI)	Intervention (n = 191) mean (95% CI)	Means difference mean (95% CI)	Change Difference mean (95% CI)
Overall FBS	0-15	8.51 (7.93, 9.10)	8.52 (7.97, 9.07)	0.00 (-0.54, 0.56)	0.18 (-0.34, 0.70)
Blood pressure	0-3	1.65 (1.41, 1.88)	1.55 (1.34, 1.77)	-0.09 (-0.34, 0.15)	-0.10 (-0.36, 0.16)
Exercise	0-3	1.29 (0.98, 1.59)	1.27 (0.98, 1.55)	-0.02 (-0.32, 0.28)	-0.05 (-0.37, 0.28)
Weight	0-3	0.90 (0.71, 1.09)	0.93 (0.76, 1.09)	0.03 (-0.21, 0.27)	0.23 (0.04, 0.42)
Alimentation	0-3	2.13 (2.00, 2.26)	2.21 (2.09, 2.33)	0.08 (-0.06, 0.21)	0.05 (-0.11, 0.20)
Tobacco	0-3	2.58 (2.41, 2.74)	2.57 (2.43, 2.71)	0.01 (-0.21, 0.19)	0.04 (-0.11, 0.19)

Values are marginal mean (95% confidence interval) FBS at 52-mo follow-up and mean (95% confidence interval) changes in FBS at 52-mo follow-up from screening, as derived from linear mixed-effects models. Fixed effects were age, sex, educational attainment, randomization group (control or intervention) and screening FBS values (only for the model of change in FBS); municipality was handled as a random effect.
FBS, Fuster-BEWAT score.

Figure 3



Change in the overall Fuster-BEWAT score at baseline, 12-month follow-up, and 52-month follow-up (sustainability assessment). The line-plot represents mean change (dots) for the Fuster-BEWAT score (FBS) at different follow-up times relative to values at the initial screening for intervened participants (orange) and controls (blue). *P*-values as derived from between-group differences of FBS change at 12-month and 52-month follow-up assessments from screening (square brackets) (Color version of figure is available online.)

A lower proportion of CG participants (49%) than IG participants (69%) attended the sustainability (52-month) assessment. CG participants who attended follow-ups had registered a higher overall FBS at screening than the overall CG average (mean FBS at screening, 7.83, 7.92, and 8.08 for CG individuals attending baseline, 12-month, and 52-month follow-up assessments; **Supplemental Figure 2**). This trend was weaker in the IG (mean FBS at screening, 7.75, 7.80, and 7.86 for IG individuals attending baseline, 12-month, and 52-month follow-up).

Overall, participants who did not complete follow-up had a lower FBS at screening and 12-months than participants included in the main analysis (**Supplemental Table IV**). Moreover, the IG population not attending the sustainability assessment included a higher proportion of low adherent individuals (low-adherent non-completing participants, 62%; low-adherent completing participants, 39%; $P < .001$). Among IG participants completing follow-up, those with high program adherence showed a significantly greater (healthier) change and had a higher mean final score in the alimentation component

Table III. Overall Fuster-BEWAT and component score means, and between-group means and change differences, at sustainability (52-mo follow-up) in high vs low adherence-to-intervention participants

FBS at sustainability				Between-group differences	
	Score range	Low adherence (n = 80) mean (95% CI)	High adherence (n = 111) mean (95% CI)	Means difference mean (95% CI)	Change difference mean (95% CI)
Overall FBS	0-15	8.33 (7.79, 8.86)	8.66 (8.21, 9.11)	0.33 (-0.37, 1.03)	0.12 (-0.57, 0.80)
Blood pressure	0-3	1.14 (1.16, 1.66)	1.65 (1.43, 1.87)	0.24 (-0.08, 0.55)	0.01 (-0.31, 0.33)
Exercise	0-3	1.29 (0.97, 1.62)	1.25 (0.95, 1.54)	-0.05 (-0.43, 0.34)	-0.19 (-0.60, 0.22)
Weight	0-3	0.88 (0.64, 1.11)	0.96 (0.76, 1.17)	0.09 (-0.22, 0.40)	0.07 (-0.17, 0.32)
Alimentation	0-3	2.09 (1.95, 2.24)	2.29 (2.16, 2.43)	0.20 (0.03, 0.36)	0.27 (0.07, 0.47)
Tobacco	0-3	2.64 (2.44, 2.84)	2.51 (2.34, 2.68)	-0.12 (-0.39, 0.14)	0.07 (-0.29, 0.14)

Values are mean (95% confidence interval) FBS at 52-mo follow-up and mean (95% confidence interval) changes in FBS at 52-mo follow-up from screening, as derived from linear mixed-effects models. Fixed effects were age, sex, educational attainment, intervention adherence (low- or high-adherence) and screening FBS values (only for the model of change in FBS); municipality was handled as a random effect.
FBS, Fuster-BEWAT score.

(Table III); however, no significant differences were observed for the other individual components or for overall FBS.

Discussion

This study is one of the first to assess the sustainability of a peer-group strategy for promoting health and controlling CV risk factors. The results of the Fifty-Fifty Program immediately after the end of the intervention showed a beneficial effect on overall CV health as estimated with the FBS in the IG, mainly due to improvements in the behavioral components.[9] In line with these results, in the present analysis the change in FBS at 12-month follow-up from screening was significantly larger in the IG than in the CG. At sustainability, the residual beneficial effect in the IG versus the CG was negligible. However, our results suggest that effect sustainability is dependent on the maintenance of peer-group support. The purpose of peer-support is to provide practical and emotional support to help individuals adhere to management plans, boost their motivation, and help them to cope with stressors of chronic conditions.[5] It is therefore predictable that beneficial effects on individuals will disappear once the peer-support is withdrawn, in line with our results.

The broad heterogeneity of peer-group study designs and the variety in methodological procedures make comparisons rather complex. Beneficial effects have been reported for peer support relative to conventional care or individual support in the management of type 2 diabetes and other conditions;[15,16] however, the evidence for these benefits is limited and insufficiently consistent to support firm recommendations.[17] An important limitation in the study of peer-group support is the broad range and widely varying formats of intervention models, ranging from face-to-face management programs, through peer coaching, to telephone-based and web- and email-based support.[18] A recent systematic review on the effectiveness of peer-supported interventions for health promotion and disease prevention found more null than positive effects across peer interventions, with the exception of group-based interventions that use peers as educators or group facilitators; these interventions showed significant improvements in knowledge, attitudes, beliefs, and perceptions.[6] There is also variation in the duration and frequency of peer-group meetings, and the need to culturally tailor programs makes comparison even more difficult.

The theoretical framework underpinning peer-group support is based on the reciprocal relationship between peers that emerges through the sharing of life experiences related to participants' conditions.[17,19] Reflecting this, most of the literature on peer-group support in health care focuses on participants with a specific condition such as diabetes,[15] heart disease,[20] alcoholism and drug addiction,[21] cancer,[22] obesity,[23] depression,[24] HIV,[25] etc. An alternative focus of some programs is the promotion in at-risk individuals of specific behaviors such as healthy diet[26] or more frequent physical activity.[27-29] The Fifty-Fifty program covered a number of health behaviors related to CV health in a relatively young and low-risk population, independently of the specific interests of the participating individuals. Thus, even if the results showed a clear overall positive effect in the IG, the disparity of participants' profiles might have resulted in lower engagement.

To improve the evidence base for peer-support interventions, the American Academy of Family Physicians Foundation developed the Peers for Progress program.[5] Based on the results of 14 evaluation and demonstration projects, the American Academy of Family Physicians Foundation defined four key functions of support that peer-support programs should include to be successful: 1) help in daily self-management, 2) social and emotional support to encourage self-management and coping with negative emotions, 3) linkage to clinical care and community resources, and 4) ongoing support that reflects the lifelong nature of most non-communicable diseases.[30] In the present study, the last of these support functions was not sustained, since IG participants did not continue with peer meetings after the end of the intervention period, effectively ending peer support. To our knowledge, there is very little available information about the long-term effects of peer-group support in relation to health conditions, and the literature shows that positive effects tend to disappear over time after peer support stops.[31] The lack of ongoing support might explain why between-group differences diminished over time in the present study. In addition, all Fifty-Fifty program participants, including the CG, received health promotion and prevention messages as part of the initial training. The increase in FBS after this initial training in both the CG and IG supports the idea that health knowledge and awareness can serve as triggers for behavior change.[32] Other factors that might have contributed to the lack of differences between the CG and IG at sustainability include the long timespan between the end of the peer support intervention and the assessment, as well as the relatively low adherence to the intervention (˜40% of IG participants who attended the sustainability assessment had a low intervention adherence). Adherence to the intervention seems to be a critical factor for achieving a beneficial effect in health promotion and prevention programs.[9,32,33] Factors that might influence intervention adherence therefore warrant further research.

Study strengths and limitations

The attrition rate at sustainability follow-up was high, which might affect the interpretability of the results. Nevertheless, a sensitivity analysis including all randomized enrolled participants provided similar results. There was an apparent follow-up bias that particularly affected the CG, limiting the chances of observing between-group differences. The proportion of CG participants attending the sustainability assessment was lower than that for the IG. These CG participants also had better baseline CV health profiles than the whole CG, and this might be related to their involvement in the study. Moreover, IG participants attending the sustainability assessment were likely to be highly motivated individuals compared with those who did not complete the follow-up, since the proportion of low-adherents was higher among those who did not attend the sustainability follow-up assessment (62% low adherents among non-completing participants vs 39% of low-adherents among completing participants). The long-term follow-up in this study allowed us to detect these differential follow-up rates within groups and between the control and intervention groups, which may have an important influence on the long-term sustained effects of health promotion programs.

Conclusion

Although the one-year Fifty-Fifty peer-group-based intervention showed a beneficial effect on CV health immediately after the intervention, the residual effect at a median follow-up of 52 months was negligible compared with the CG. It appears likely that initial training workshops will need to be combined with ongoing peer-support to achieving sustained positive effects on healthy behaviors.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ahj.2021.06.006.

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