Grenada Heart Project–Community Health ActioN to EncouraGe healthy BEhaviors (GHP-CHANGE): A randomized control peer group–based lifestyle intervention

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Background The incidence of cardiovascular (CV) risk factors is increasing globally, with a disproportionate burden in the low and low-middle income countries (L/LMICs). Peer support, as a low-cost lifestyle intervention, has succeeded in managing chronic illness. For global CV risk reduction, limited data exists in LMICs.

Aim The GHP-CHANGE was designed as a community-based randomized trial to test the effectiveness of peer support strategy for CV risk reduction in the island of Grenada, a LMIC.

Methods We recruited 402 adults from the Grenada Heart Project (GHP) Cohort Study of 2827 subjects with at least two CV risk factors. Subjects were randomized in a 1:1 fashion to a peer-group based intervention group (n = 206) or a self-management control group (n = 196) for 12 months. The primary outcome was the change from baseline in a composite score related to **B**lood pressure, **E**xercise, **W**eight, **A**limentation and **T**obacco (FBS, Fuster-BEWAT Score), ranging from 0 to 15 (ideal health = 15). Linear mixed-effects models were used to test for intervention effects.

Results Participants mean age was 51.4 years (SD 14.5) years, two-thirds were female, and baseline mean FBS was 8.9 (SD 2.6) and 8.5 (SD 2.6) in the intervention and control group, respectively (P = .152). At post intervention, the mean FBS was higher in the intervention group compared to the control group [9.1 (SD 2.7) vs 8.5 (SD 2.6), P = .028]. When balancing baseline health profile, the between-group difference (intervention vs. control) in the change of FBS was 0.31 points (95% CI: –0.12 to 0.75; P = .154).

Conclusions The GHP-CHANGE trial showed that a peer-support lifestyle intervention program was feasible; however, it did not demonstrate a significant improvement in the FBS as compared to the control group. Further studies should assess the effects of low-cost lifestyle interventions in LMICs. (Am Heart J 2020;220:xxx.)

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There is a global epidemiologic transition as the major causes of death have shifted from infectious to lifestyle-related diseases. Deterioration in diet and decline in physical activity have led to hypertension, obesity, diabetes, and CV disease.[1] The World Health Organization (WHO) has recently issued reports to raise awareness and called for efforts to halt the rapid progression of noncommunicable diseases, which is disproportionately high in low- and middle-income countries (LMICs).[2] Because lifestyle and cardiovascular risk factors tend to cluster within the same individual,[3,4] cardiovascular prevention strategies should focus on comprehensive interventions addressing multiple risk factors rather than isolated ones.

The call to address the increasing prevalence of noncommunicable diseases worldwide motivated the development of the Grenada Heart Project. With support from the Grenadian Ambassador to the UN, our team initiated a nation-wide survey of CV risk. Among 2827 randomly selected participants, prevalence rates of obesity, hypertension and diabetes significantly exceeded those seen in the United States.[5,6] Nearly 60% of the participants were overweight or obese, one quarter were physically inactive, and 13% had diabetes. The self-reported rate of heart disease was 6%, paradoxically lower than expected given the prevalence of risk factors.[5]

The next step was to design a low-cost scalable intervention and test it. Our research group conducted a community-based health promotion trial in Spain with 543 participants called the "Fifty-Fifty" Program.[7,8] This study demonstrated that an "Alcoholics Anonymous" style peer motivation groups may significantly improve healthy behaviors and therefore decrease CV risk.[8]

The GHP-CHANGE was developed to extend the findings in Spain to a LMIC, and study the effects of peer education groups on their CV risk factors, quality of life, and health-related behaviors.

Methods

Study design and participants

The framework for the Grenada Heart Project has been based on the peer group-based lifestyle intervention in Spain, as reported previously.[8] Eligible participants were 18 to 85 years of age with at least two CV risk factors, which included: elevated blood pressure (systolic ≥120 mm Hg and/or diastolic ≥80 mm Hg), overweight or obese (BMI ≥25 kg/m^2; waist circumference >40 inches for men, >35 inches for women), elevated blood glucose level (random glucose ≥140 mg/dL), low level of physical activity (<150 minutes of at least moderate physical activity/week), low fruit and vegetable intake (<2 servings/day), hyperglycemia (generously defined as fasting glucose >100 mg/dL), dyslipidemia (total cholesterol ≥250 mg/dL or LDL-C ≥130 mg/dL), or current smoking. The participants with ≥2 CV risk factors were contacted from the original GHP cross-sectional study,[5] from five parishes around the island: the parishes of St David's, St Andrew's, St George's, St John's, and St Mark's. All eligible participants were invited to attend an intense educational lecture series. They were required to participate in at least three workshops in order to enroll in the study. The workshop themes included motivation to change, physical activity, healthy diet, smoking cessation, blood pressure, and stress management. The research team, local experts, and respected community members presented a general overview of the lifestyle intervention and participants had an opportunity to ask questions. Interested participants completed the written consent after the educational lectures. Upon consenting, participants received a blank notebook and health literacy materials/brochures provided by the American Heart Association such *Easy Food Tips for Heart-Healthy Eating* (adapted for Grenadian diet), *Just Move*, *Controlling Your Risk Factors*, and *Understanding and Controlling High Blood Pressure*. These materials can be accessed online at the American Heart Association Website (https://www.heart.org/en/health-topics/consumer-healthcare/order-american-heart-association-educational-brochures). The educational materials aimed to promote management of risk factors and the notebook provides a means of recording lifestyle behaviors, such as health goals, blood pressure values, and eating habits.

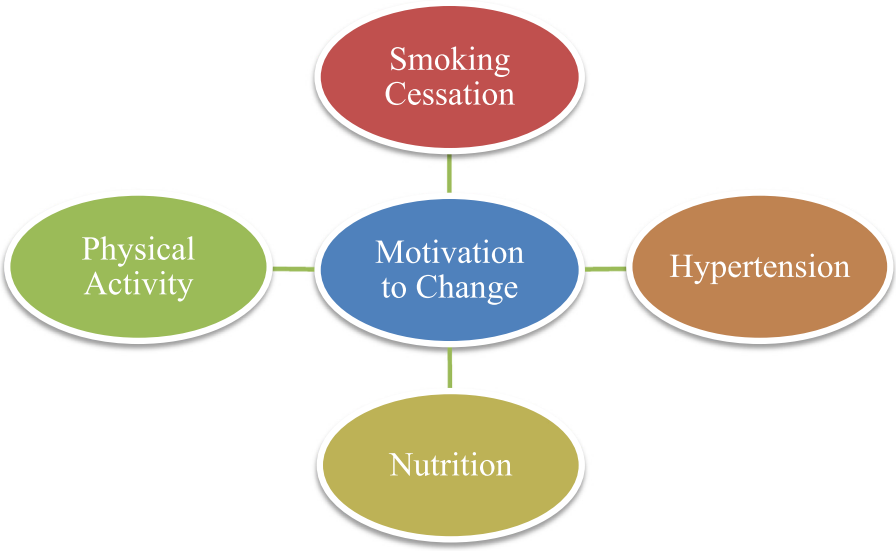
Individuals were then randomized in a 1:1 allocation to the peer group intervention or the self-management control group stratified by parish; the stratification preventing imbalance between the treatment groups in each parish.[9]

Study intervention

We followed the Template for Intervention Description and Replication (TIDieR) guide[10] to describe the intervention (refer to supplemental **TIDieR Checklist**). The control group received the series of educational lectures at the time of enrollment, followed by self-management for 1 year. At enrollment, participants were instructed how to measure their weight and blood pressure accurately, and scales as well as blood pressure machines were distributed at community health centers in each parish for self-monitoring. The intervention group was organized into groups of 8–12 individuals in their local parish. A "peer leader" was a community lay-person selected from motivated individuals willing to undergo additional training from the research staff to moderate the peer groups and take attendance at group meetings. The leaders underwent an additional three-hour training session on leadership and communication skills in addition to the relevant healthy behavior promotion.[8]

The peer group meetings were planned to meet monthly for 1 year. The peer group leaders were educated using evidence-based guidelines, and encouraged to promote 150

Figure 1



Educational lecture topics.

minutes weekly of physical activity, consumption of at least five fruits and vegetables daily, smoking cessation, and blood pressure management (Figure 1).[11-15] Peer leaders were provided topics to discuss at the monthly meetings, such as low salt diet and hypertension, diabetes prevention, coping strategies for stress, and smoking cessation (Supplemental Table I); along a blood pressure machine with two different cuff sizes. Leaders were able to adapt themes for each meeting to their particular interest. For example if they did not have any smokers in their group, they could skip the 'smoking cessation' group meeting. The Project administrator in Grenada made routine visits to each group to encourage and monitor the attendance, and to receive feedback from the group leader. Although group leaders were provided attendance sheets, this information was not systematically collected because of different issues.

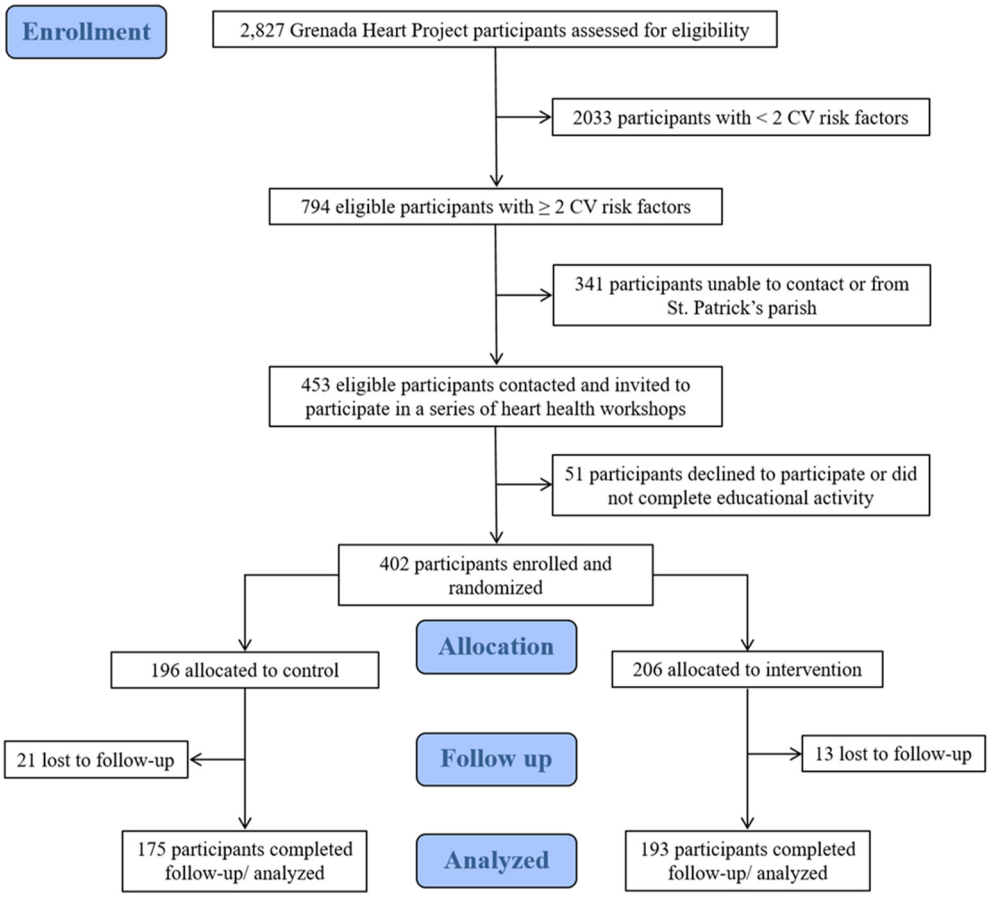
Data collection

The study team in Grenada called individuals by telephone to invite them to participate. All assessments were conducted at the local community health clinics with the cooperation of local nurses. Data were collected at baseline and at 12 months after completion of the intervention, with an interim assessment at 6 months. Blood pressure, anthropometric measures, and a detailed questionnaire were measured at each visit. A lipid panel was assessed at the final visit using a point of care machine (LDX, Abbott). Blood pressure was obtained thrice using an OMRON automatic blood pressure device (OMRON Healthcare Inc) with an appropriate cuff size. Height and weight were measured using a stadiometer and calibrated scale. The survey was administered in the local language by Grenadian personnel and data was recorded on a Samsung Galaxy tablet (2014). This interviewer-administered questionnaire required approximately 20 minutes to complete, and included sociodemographic data, blood pressure, anthropometric measures, a modified World Health Organization Stepwise questionnaire,[16] the International Physical Activity Questionnaire (IPAQ),[17] a lifestyle assessment, and the SF-36 quality of life questionnaire.[18,19] Coronary disease was defined as being told by a healthcare provider of having a heart attack, angina, or chest pain. Elevated blood pressure was defined as systolic blood pressure $\geq$120 mm Hg or diastolic blood pressure $\geq$80 mm Hg. BMI was defined as overweight if BMI was $\geq$25 kg/m^2 and <30 kg/m^2 and obese if BMI was $\geq$30 kg/m^2. Low physical activity was defined as less than 150 minutes of moderate activity per week or less than 75 minutes of vigorous activity. Poor nutritional intake was defined as less than three servings of fruit and/or vegetables daily. Smoking was defined through self-report as smoking any type of tobacco daily.

Outcomes

The primary outcome was the difference between groups in the change from baseline of the Fuster-BEWAT score (FBS) at the completion of the 12-month intervention. FBS is a composite, non-laboratory based score, designed to provide a reliable low cost indicator of CV health.[8,20,21] The overall score ranges from 0 (poor health) to 15 (ideal cardiovascular health), comprising a

Figure 2



CONSORT-style study flow diagram.

score for physical activity (range 0–3), fruit and vegetable consumption (range, 0-3), body-mass index (range, BMI) (0-3), smoking habits (range, 0-3), and blood pressure (range, 0-3). The details for the calculation of the FBS at baseline and follow-up assessments, alongside the inverse association of the FBS with the presence and extent of subclinical atherosclerosis, have been previously published.[8,20] As a secondary outcome, a quality of life score was also calculated, based on the SF-36 survey score (SF-36 ranges from 0 to 100 and converted to a score category 0-3). The physician investigators counseled participants regarding their results at the completion of the survey.

Statistical analysis

The sample size calculation was based on data available to us from the Fifty-fifty study.[8] Assuming a similar and common standard deviation (SD) for the FBS of 2.3, to detect a 10% difference in the change in FBS from baseline to 1 year of follow up between the control and intervention groups, with 80% power and type I error rate of 0.05, a sample size of 342 was determined to be adequate. Accounting for a 10% drop out rate, and allowing for additional loss to follow up, we aimed to randomize approximately 400 participants.

Continuous variables are reported as mean and SD while discrete variables are reported as frequencies and percentages, unless otherwise specified. The Student *t* test was applied to assess the mean score differences at baseline and follow-up between groups. Linear mixed-effects models were used to assess the adjusted change in the composite FBS from baseline to 1 year of follow-up. Fixed effects were the corresponding baseline score (as a continuous variable), and treatment group. The same approach was used for the analysis of the change in the individual components of the FBS and the SF-36 score. Every attempt was made to follow all enrolled participants irrespective of allocation or treatment withdrawal. All participants were included in the analysis in the groups to which they were randomized. A complete-case intention-to-treat analysis was performed as main analysis. Statistical significance was defined as a 2-sided

Table I. Baseline characteristics of the participants enrolled in the GHP-CHANGE trial

Characteristic	Overall	Control	Intervention
No. of participants, n	402	196	206
Age, mean (SD)	51.4 (14.5)	51.8 (14.9)	51.1 (14.2)
Sex, n female (%)	265 (65.9)	131 (66.8)	134 (65.1)
Overweight or obese, n (%)	261 (64.9)	134 (68.4)	127 (61.7)
Diabetes, n (%)	77 (19.5)	45 (23.2)	32 (15.9)
Known hypertension, n (%)	138 (34.4)	68 (34.9)	70 (34.0)
Current smoking, n (%)	18 (4.5)	8 (4.1)	10 (4.9)
Low fruit intake*, n (%)	217 (54.0)	109 (55.6)	108 (52.4)
Low vegetable intake*, n (%)	240 (59.7)	121 (61.7)	119 (57.8)
Low physical activity†, n (%)	196 (50.9)	97 (52.4)	99 (49.5)
Fuster-BEWAT score, mean (SD)	8.7 (2.6)	8.5 (2.6)	8.9 (2.6)
Quality of life score, mean (SD)	2.1 (1.1)	2.1 (1.1)	2.2 (1.0)

*Two servings or less per day of fruits or vegetables. †Less than 150 minutes of moderate or 75 minutes of vigorous exercise per week. Percentages based on total non-missing data available for each variable. Fuster-BEWAT Score (FBS) range 0 to 15. Quality of life score range 0 to 3. SD: standard deviation.

P value less than .05. All analyses were performed using STATA version 15.0 (StataCorp, College Station, Texas).

Recruitment

Of the 2827 original GHP participants, there were 794 participants with 2 or more CV risk factors. Of those, 453 participants were successfully contacted. Of those willing to participate, 402 attended the educational lectures, enrolled in the study, and completed baseline data collection and the survey questionnaire. Informed written consent was obtained from all participants. The Institutional Review Boards of Mount Sinai Hospital and St. George's University in Grenada both approved of the final protocol. The trial is registered at clinicaltrials.gov under NCT02428920.

Results

The GHP-CHANGE study CONSORT flow diagram is presented in Figure 2. The total study population consisted of 402 individuals randomized within parish blocks.

Baseline characteristics of the participants enrolled in the study are described in Table I. Two-thirds of the participants were female, with a mean age of 51.4 years (SD 14.5). A review of the CV risk factors reveals that we recruited a relatively high-risk cohort. Two thirds of the participants qualified as overweight or obese, approximately 50% were physically inactive, 20% reported diabetes, and 35% were hypertensive. Nearly two thirds (62%) of the participants aged 60 and above had three or more risk factors.

Complete follow up data was available for 368 participants (n = 34, 8.5% drop out), who were included in the analysis. Baseline characteristics of the participants included and excluded in the complete-case intention-to-treat analysis are described in Supplemental Table II. Number of participants who attended each group session was recorded, but individual participant level data was not available for analysis.

Overall Fuster-BEWAT and components' mean values and mean differences at baseline and follow-up of participants included in the analysis are described in Supplemental Table III. Baseline mean FBS was 8.9 (SD 2.5) and 8.5 (SD 2.7) in the intervention and control group, respectively ($P = .077$). At one-year of follow-up, the overall FBS was significantly different between the peer group intervention and control groups [9.1 (SD 2.7) vs 8.5 (SD 2.6), $P = .028$, Figure 3 and Supplemental Table III.

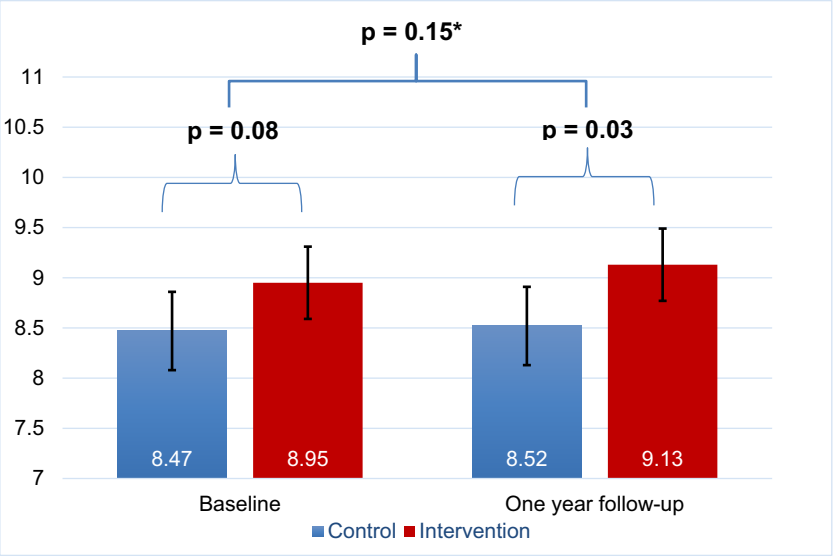
As primary outcome, the difference between groups in the change of FBS from baseline to 1 year was 0.31 points (95% confidence interval −0.12 to 0.75 points; $P = .154$; Figure 3 and Table II). As secondary analyses, the components of the score were examined individually; there were no significant differences in the change of components between the control and intervention group (Table II). There was also no significant difference in the quality of life between the control and intervention groups.

Discussion

The goal of this randomized trial was to assess the effectiveness of a one-year peer group intervention using a composite score to measure cardiovascular health without expensive laboratory or imaging tools. This trial evaluates a novel approach to cardiovascular health in a LMIC. Our results did not demonstrate a significant improvement of the Fuster-BEWAT Score after the peer-group intervention for 1 year. Control individuals maintained their scores throughout the study, suggesting that the education and counseling provided to all participants during the initial enrollment and assessments helped individuals maintain their level of health, but did not significantly change their CV risk factors at the end of the trial.

The Fifty-fifty study in Spain demonstrated a significant improvement in cardiovascular health as assessed by the same composite score. We calculated our sample size and anticipated effect size based on the available data. Notably, the mean baseline FBS was higher in the Grenadian population (higher score indicating better health), making it more challenging to demonstrate a significant 10% change. Therefore, our study could be underpowered to see a difference in FBS. The fact that each cardiovascular health metric has equal weight in calculating the FBS might have limited the ability to find significant differences. However, this approach makes the score easy to understand and use, both for clinicians and for patients to monitor the progress toward health. Comparing these results to the successful peer-group therapy in the Fifty-Fifty trial, we noted that the primary driver of improvement in the FBS in Spain after the intervention was due to smoking cessation.[8] In

Figure 3



Change in Fuster BEWAT Scores at baseline and 1 year.*Comparing change in Fuster-BEWAT Score from baseline to 1 year of the control versus the intervention group.

Grenada, reported tobacco smoking was much less common (only 5% prevalence in this study), leaving little room for improvement. This rate was lower than anticipated given recent data from the WHO indicates that around 11% of the adult population of Grenada smokes cigarettes daily,[22] though it should be noted that two thirds of the study participants were female, and previous studies suggest that less than 5% of females smoke in Grenada.[5,6,22]

These results suggest that there is a high-risk population who participated in peer groups aimed toward lifestyle changes. Nevertheless, these individuals do not have a diagnosis of atherosclerotic heart disease, potentially a critical difference compared to studies on peer group or peer-led interventions for individuals with chronic diseases. Individuals with chronic disease may be more motivated in order to reduce symptoms or complications, whereas the individuals in our study have not necessarily experienced any sequelae of disease.

Peer group interventions have demonstrated varying results.[8,23-25] Best et al. systematically reviewed the effectiveness of peer-led programs to increase physical activity, and found that there were modest improvements in the physical activity of the participants,[23] yet they were short interventions, and more research is needed regarding retention and sustainability. Peer support groups have also been attempted for cardiac disease, with some positive results, though it remains difficult to make conclusions based on the heterogeneity of studies.[26-28] Another critical difference between our study and others is that we focused on comprehensive lifestyle changes rather than just smoking cessation or physical activity alone. Typically, poor health habits tend to cluster together, but it remains unclear whether targeting multiple health behaviors is superior to targeting a single habit.[29-32]

As with other lifestyle interventions, participation in this trial was voluntary, which may lead to selection bias. Participants willing to enroll in the study may be more likely to change their habits, regardless of their group assignment. A participant's readiness to change in the "stages of change" model prior to the study might play a prominent role in their success.[33] The blood pressure and anthropometric measures were recorded by research staff, but the survey data are self-reported, which may underestimate the true incidence of vascular risk factors due to a lack of health literacy or access to primary/preventive care. Additionally, in a close-knit community like that of Grenada, there is a possibility of cross-over in the study, biasing the results toward the null. The peer-led group intervention took place on a monthly basis, at the convenience of the participants. Anecdotal feedback from participants suggested more frequent meetings could reinforce their positive lifestyle changes. Nevertheless, we were not able to quantitatively assess the adherence or fidelity to the intervention, which may be important factors influencing the intervention effects.[8] The ideal duration for a lifestyle intervention remains unclear. To derive the maximum benefit, behavior changes made during any lifestyle intervention should ideally continue throughout life.[34-36] Peer-support strategies have been shown to be cost-effective in specific situations, such as the control of type 2 diabetes[37-39]; however, additional studies are needed to determine their cost-effectiveness in other settings.

Table II. Change from baseline to 1 year in the overall Fuster-BEWAT score, and its components

		Within-group differences		*Between-group difference*	
	Scale range	Control (95% CI)	Intervention (95% CI)	Difference (95% CI)	*P*
Fuster-BEWAT overall*	0–15	0.05 (–0.31 to 0.41)	0.19 (–0.12 to 0.49)	0.31 (–0.12 to 0.75)	.154
B-Blood pressure	0–3	0.07 (–0.08 to 0.22)	–0.02 (–0.17 to 0.13)	–0.03 (–0.23 to 0.16)	.735
E-Exercise	0–3	–0.10 (–0.32 to 0.13)	0.05 (–0.15 to 0.25)	0.19 (–0.07 to 0.45)	.157
W-Weight	0–3	–0.07 (–0.20 to 0.07)	–0.06 (–0.18 to 0.06)	0.09 (–0.07 to 0.25)	.283
A-Alimentation	0–3	0.09 (–0.05 to 0.24)	0.20 (0.07 to 0.32)	0.08 (–0.07 to 0.23)	.289
T-Tobacco	0–3	0.04 (0.00 to 0.08)	0.02 (–0.02 to 0.06)	–0.02 (–0.06 to 0.02)	.393
Quality of life†	0–3	0.31 (0.17 to 0.45)	0.18 (0.04 to 0.32)	–0.03 (–0.18 to 0.11)	.649

Data are presented as mean differences and 95% confidence intervals (CI) as derived from linear mixed-effects models. Fixed effects were the corresponding baseline score and treatment group. Between-group differences calculated as intervention vs. control.
* Overall Fuster-BEWAT Score (FBS) is a composite score ranging from 0 to 15. It consists of Blood pressure (0–3), Exercise (0–3), Weight (0–3), Alimentation (0–3), and Tobacco (0–3). A higher score implies better health.
† Quality of life is based on the SF-36 question score. An SF 36 score of >80 translated to a QOL score of 3, 71–80 translated to a score of 2, 51–70 translated to a score of 1, and <=50 translated to a score of 0.

Furthermore, conducting comprehensive peer-support preventative efforts in LMICs may be particularly challenging. The main cost of a peer group intervention such as GHP-CHANGE is the human capital required to organized and execute the intervention. Healthcare providers are required to conduct periodic assessments, interpret results and counsel participants on their progress and goals. Specialized multidisciplinary teams (eg, physicians, nurses, community health workers, etc) may be required to oversee and deliver the intervention successfully.[40] Particularly relevant is how peer leaders can be supported outside research studies; although they are generally volunteers, peer leaders need training and some level of supervision.[41] Therefore, for a successful peer group intervention, there needs to be a structural framework for oversight. As with all lifestyle interventions, individuals might prioritize other issues limiting the participation in peer-group sessions such as work commitments, lack of time, health issues, location and timing issues, and family issues or commitments.[42] Finally, peer-support programs require consideration of organizational issues, local needs and resources, as well as community engagement and the involvement of stakeholders.[43]

This intervention demonstrated that a low-cost, peer-group-based intervention to promote heart healthy behaviors is feasible in a LMIC. The baseline prevalence of obesity, physical inactivity, and poor nutritional habits, particularly in middle-aged women, suggest that this is a critical target population. Given the prevalence of obesity, hypertension, diabetes, and physical inactivity, this data suggests that in the future there could be a sharp rise in the incidence of cardiovascular disease.[44] For a small middle-income country such as Grenada, battling chronic cardiovascular disease could be devastating for their resource-poor healthcare system.

Previous data from our group has demonstrated that group dynamics seem to maintain the initial increase in score whereas the effect of education alone fades over time.[8] We are currently conducting a trial called FAMILIA (Family-based Approach in a Minority Community Integrating Systems-Biology for Promotion of Health) in Harlem, New York, which also utilizes the peer-group model for health promotion (NCT02481401).[45,46] We believe that a holistic approach to heart health and peer support are critical to successful behavior change.

Conclusions

In the GHP-CHANGE community-based trial, a monthly peer group-based cardiovascular health promotion intervention did not demonstrate a significant improvement in the Fuster-BEWAT Score of participants at 1 year as compared to the control group. Further studies should assess the effects of low-cost lifestyle interventions in LMICs.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ahj.2019.08.022.

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