Lifestyle Intervention for Cardiovascular Disease Risk Factors among Female Residents of the National Guard Residential City, Jeddah, Saudi Arabia: A Randomized Controlled Trial

8th of June 2017

Authored by:

Jumana Khouja, Badr Al Jasir, Amina Bargawi and Mohammed Kutbi

Community and Preventive Medicine Department,
King Abdullah International Medical Research Center.
Ministry of National Guard Health Affairs, Jeddah, Saudi Arabia

Abbreviations

BMI body mass index

BP blood pressure

CHD coronary heart disease

CRP Coronary Risk Profile

CVD cardiovascular disease

FRS Framingham risk score

HDL high-density lipoprotein

LDL low-density lipoprotein

Lifestyle Intervention for Cardiovascular Disease Risk Factors among Female Residents of the National Guard Residential City, Jeddah, Saudi Arabia: A Randomized Controlled Trial

Jumana Khouja, Badr Al Jasir, Amina Bargawi and Mohammed Kutbi

Abstract

Cardiovascular disease (CVD) remains the major cause of mortality globally. Applying a comprehensive interventional program based on the individual's risk may reduce the incidence and complications of CVD; thus, helping to decrease the burden on the healthcare system. This study compared the effects of a 3-month intervention involving lifestyle modification and physical activity with standard care in women ≥30 years having a moderate-to-high risk of CVD, with respect to improving physical activity and cardiovascular disease risk factors at the National Guard Residential City in Jeddah, Saudi Arabia, in 2015. The effects of this community-based lifestyle program were assessed through a randomized controlled trial. Women in the intervention group (n=31) received health education, exercise training, and diet counselling as individuals and in groups according to the participant's risk. Women in the control group (n=28) received one health education session at the screening site. The Framingham risk score (FRS) was calculated at baseline and at 3 months for both groups. The mean participant age was 42±8 years. At the 3-months' follow-up, reductions were greater in the intervention group and the difference between groups was statistically significant ($p < 0.05$). Lifestyle intervention program reduced systolic blood pressure (-9.2 mmHg); blood glucose (-45mg/dL) and Framingham risk score (-13.6). Linear regression analysis revealed a significant improvement in the Framingham risk score ($p<0.001$). In previously sedentary adults, a community-based lifestyle modification program is effective in improving the 10-year cardiovascular Framingham risk score in at least up to 3 months among women with moderate-to-high risk of CVD.

Key Words: Cardiovascular Diseases, Framingham risk score, Life style modification, Randomized Controlled Trial

1. Introduction

Cardiovascular disease (CVD) includes various conditions such as hypertension, coronary heart disease (CHD), myocardial infarction, angina pectoris, heart failure, and stroke (Rambo, 2012). Although CVD incidence and mortality have markedly declined in recent decades (Eriksson, 2010), CVD remains the leading cause of death worldwide (Cox et al., 2013); being responsible for 17.3 million deaths in 2008 (30% of all mortalities) (Alwan, 2011). According to the World Health Organization statistics for 2008, most of the mortalities in Saudi Arabia were due to non-communicable chronic diseases. Of the 413 deaths per 100,000 individuals in 2009, 144 (35%) were due to CVD (Alwan, 2011). CHD is one of the main health problems in Saudi Arabia, representing the third most common cause of hospital-based mortality after accidents and senility (Kumosani and Madani, 2007).

Women tend to have more CVD in the more developed areas of the world. CVD accounted for approximately 0.3 million deaths in 2009 in the United States, and was responsible for 1 in every 4 female deaths (Kochanek, 2011). Almost two-thirds (64%) of women who die suddenly of CHD have had no previous symptoms (Go et al., 2013). According to the World Heart Federation, CVD is the most serious neglected health problem affecting women worldwide (Schenck-Gustafsson, 2009).

Modifiable risk factors that have been clinically proven to influence cardiovascular health include diabetes, high blood pressure, hypercholesterolemia, being overweight or obese, insufficient physical inactivity (less than 30 minutes of moderate activity 5 times/week or 20 min of vigorous activity 3 times/week, or the equivalent), unhealthy diet, and smoking. Other non-modifiable risk factors include age, gender, family history, and race or ethnicity (Eriksson, 2010; American Diabetes Association, 2010; Mendis et al., 2011).

Many interventions have been developed to prevent and treat CVD. Cardiovascular disease risk factors can act synergistically to increase the risk of developing heart disease; therefore, interventions that focus on modifying multiple risk factors may be more effective in reducing risk than those that focus on only one risk factor at a time (Rambo, 2012; American Diabetes Association, 2010; Al-Nozha, 2004).

A multidisciplinary approach combining diet, exercise, and behavioral change can improve survival, prevent or reduce recurrent events and procedures, and improve quality of life (Rambo, 2012). According to the Centers for Disease Control and Prevention, 6 of 10 deaths from CVD are preventable (Centers for Disease Control and Prevention, 2013). Therefore, it is important to develop more comprehensive approaches for the primary

prevention of CVD (Schenck-Gustafsson, 2009). The public health burden of a sedentary lifestyle necessitates interventions that can reach enough women to make a health impact on a wide scale (Pazoki et al., 2007).

In addition, the Saudi female social culture promotes poor nutritional habits and limits physical activity, increasing the risk of CVD. Applying a comprehensive interventional program according to the individual's risk factors may decrease the prevalence of CVD and its associated complications, and reduce the burden on the healthcare system. However, this concept has not been sufficiently investigated in Saudi Arabia. This study aimed to assess the effects of a community-based lifestyle modification program targeting women ≥30 years at moderate-to-high risk of CVD.

2. Methods

The study was conducted in the National Guard Residential City, Jeddah, which comprises five geographical sections containing 1229 villas each. A randomized controlled trial was conducted from January 1, 2015, to September 6, 2015. All female residents of the National Guard Residential City aged ≥30 years were screened and their Framingham risk scores (FRSs) were calculated. To be included in the study, the participants had to be at moderate-to-high risk of CVD according to FRS. Those with a low CVD risk according to FRS, who were pregnant, or diagnosed with CVD were all excluded.

The sample size was calculated using the formula for superiority trials:

$n = (Z\alpha + Z\beta)^2 \times (p1 \times (1 - p1) + p2\ (1 - p2)/(p2 - p1)^2$

(Where n is the sample size, α is the probability of type I error = 5%, β is the probability of type II error = 80%, p1 is the expected success proportions of sample one and p2 is the expected success proportions of sample two). According to an international study (Cox et al., 2013), the estimated population was as follows:

- For moderate risk:

Sample size required per group (intervention/control)

$= (1.96 + 0.84)^2 \times (0.32 \times 0.68) + (0.22 \times 0.78)/ (0.10)^2 = 188$

Total sample size required = 188 × 2 = 376

- For high risk:

Sample size required per group

$= (1.96 + 0.84)^2 \times (0.38 \times 0.62) + (0.13 \times 0.87)/ (0.25)^2 = 31$

Total sample size required = 31 × 2 = 62

Thus, 438 participants (376 in the moderate-risk group and 62 in the high-risk group) were required to provide a power of 80% with an α of 0.05 to show the study outcome. Each arm included 219 participants who were randomly assigned to the intervention or control arm. At the start of the study, all the households in the residential city were visited and informed about the study by a group of trained research assistants supported by the required documents. Women received basic education about CVD and its associated risk factors. The participants were interviewed and screened by the researcher and two trained nurses, using the validated and widely used Coronary Risk Profile (CRP) questionnaire from Wellsource Inc. (Portland, OR, USA) (Wellsource, 2014). The CRP questionnaire was translated to Arabic and tested for content and face validity to ensure appropriate clarity and fulfillment of the study objectives. Three experts reviewed the final version of the questionnaire and pilot testing was conducted among a group of 10 women. The results were reviewed and modifications were applied. The questionnaire collects data on health history, smoking habits, physical activity, eating practices, and social factors. Data from the CRP questionnaire were used to calculate individualized FRS. The risk estimate and factors that influenced cardiovascular disease risk were explained for each individual. The total sample size was 616. From the total sample, 85 participants were in the moderate- and high-risk groups. The intervention arm included 42 participants; and the control arm, 43 participants.

Eligible participants randomly chose a card that assigned them to the intervention or control group. The researcher was blinded to the participants' group assignment. The participants assigned to the intervention arm of the study underwent a lifestyle modification program, including exercise training sessions and diet counselling. Those assigned to the control arm received one session of health education at the screening site (Figure 1). Eligible participants were recruited in April 2015 and received the intervention in May 2015. The 3-month follow-up was completed at the beginning of September 2015.

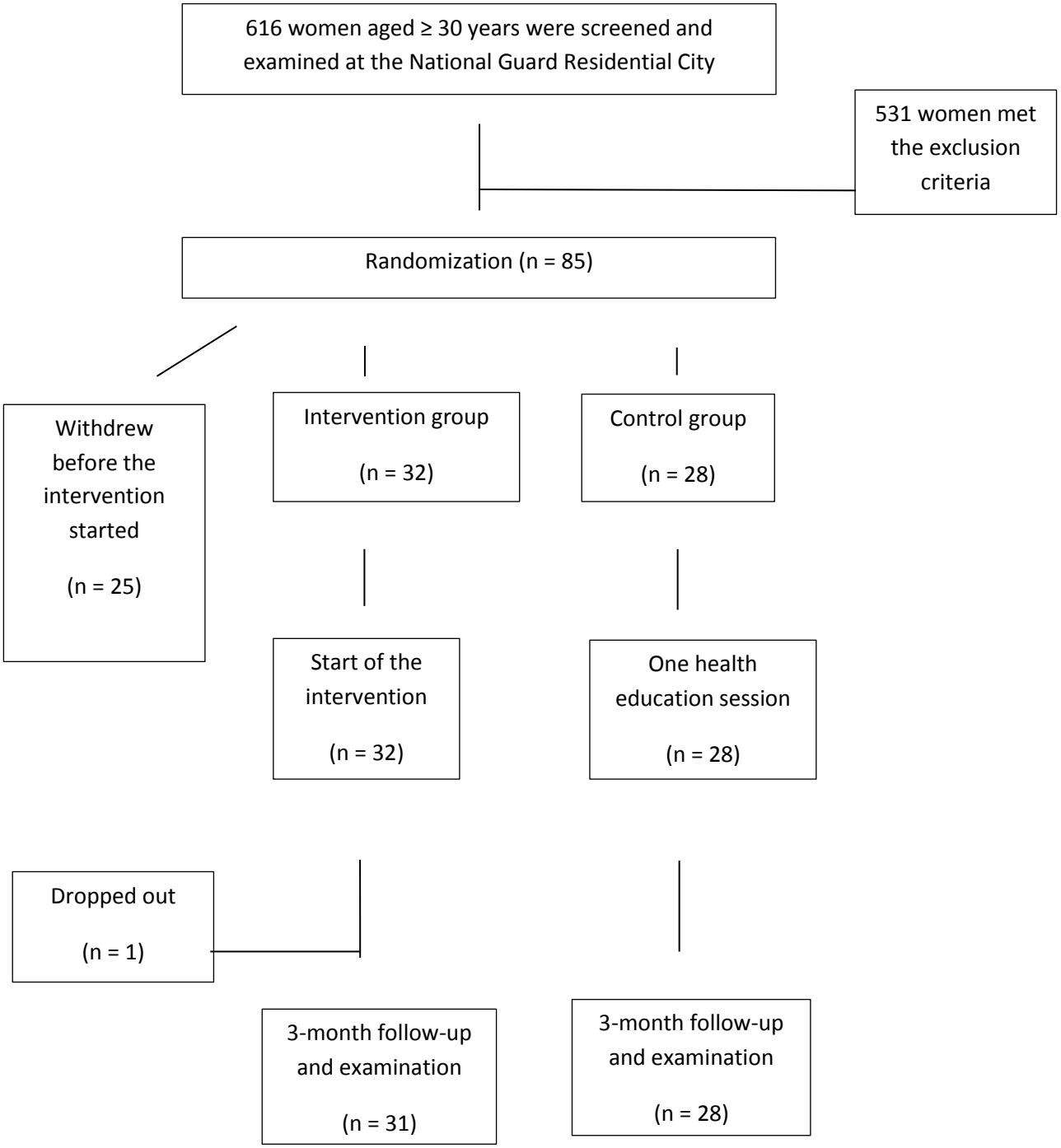

Figure 1: Flowchart from recruitment to completion of the follow-up of the participants at the National Guard Residential City in Jeddah, Saudi Arabia, in 2015

2.1 Clinical measurements

The participant's weight was measured without shoes and the height was measured using a stadiometer. Body mass Index (BMI) was calculated as weight in kilograms divided by height in meters squared. Waist circumference was measured in centimeters from the point midway between the inferior margin of the last rib and the iliac crest. Blood pressure was assessed in the sitting position using a standard mercury sphygmomanometer. A fasting blood sample was obtained using the CardioChek PA System, [Polymer Technology Systems, Inc. Indianapolis, USA] which provides results on cholesterol, high-density lipoprotein (HDL), glucose, and triglyceride levels. The results met the accuracy guidelines established by the National Cholesterol Education Program of the National Institutes of Health (Wellsource, 2014). Blood samples were obtained at baseline and at 3 months. According to the above-mentioned measures, FRS was calculated to estimate the 10-year risk of a major cardiovascular event and for risk categorization into low (<10% FRS), moderate (10%–19% FRS), or high risk ≥20% FRS). Those with moderate and high risks were evaluated for their metabolic syndrome status. They were classified as having metabolic syndrome if they satisfied 3 of the 5 following criteria (based on the criteria established by the National Heart, Lung and Blood Institute for the diagnosis of metabolic syndrome) (Mosca et al., 2004; Yoon et al., 2012): (1) abdominal obesity, determined by increased waist circumference >88 cm in women; (2) increased triglyceride levels ≥1.7 mmol/L (150.6 mg/dL); (3) reduced HDL level of <1.30 mmol/L (50.2 mg/dL); (4) elevated blood pressure ≥130 mmHg systolic or ≥85 mmHg diastolic blood pressure; and (5) increased fasting glucose level ≥6.1 mmol/L (109.8 mg/dL). Individuals with a high fasting blood glucose level ≥126 mg/dL (7.0 mmol/L), high blood pressure ≥140/90 mmHg, or total cholesterol level ≥240 mg/dL (6.2 mmol/L) were referred to the primary health-care center for further assessment by their respective physicians. Nevertheless, they still participated in the study.

2.2. Study intervention

The participants in the intervention arm of the study received a program of lifestyle modification, including health education, exercise training sessions, and diet counselling

delivered by the researcher, health educator, physiotherapist, and nutritionist. Anthropometric measures, blood pressure, blood glucose level, total cholesterol level, triglyceride level, and HDL level were measured at baseline and after 3 months. Those assigned to the control arm received one session of health education at the screening site and underwent the same measurements.

The intervention was a 1-month program based on the 'Be Active your way' (Services, 2008), developed by the United States Department of Health and Human Services and the National Guidelines for Management of Cardio-metabolic Risk Factors (National Guideline, 2011), developed by the Saudi Ministry of Health. The intervention was conducted in the morning and afternoon at the officer's sports club in the residential city. The initial visit included assessment of the participant's cardiovascular disease risk. The intervention was conducted in group and individualized sessions according to the participants' needs and risk status. The lifestyle intervention program was designed to teach women how to incorporate a daily 30-minute physical activity of moderate-intensity into their routine and how to select and eat nutritious foods. The intervention arm included 31 participants and the intervention's duration for the whole group was 4 weeks. About 10 individuals were included daily. Each participant had two visits to undertake the intervention over the period of 4 weeks (once every other week). During each visit, a 2-hour face-to-face educational session was conducted. During the 2 hours, each participant had to rotate through all the sections (researcher, health educator, exercise specialist, and nutritionist) and received different educational materials from trained staff. Various motivational measures were considered to keep meetings interesting and to boost attendance, such as contests and individual rewards. After the active intervention period, the participants were encouraged monthly by phone to maintain at least the 30 minutes of physical activity daily, a healthy diet, and to monitor the effect of these modifications on their health.

The participants in the control (n=28) arm of the study received standard care at their primary health-care centers and one health education session of 30 minutes about CVD and itsrisk factors. They were given information about the prevention of these diseases by adopting healthy behaviors, including diet and exercise.

2.3. Data Analysis

Data entry and statistical analysis were conducted using the Statistical Package for Social Sciences version 22 (IBM, Armonk, NY, USA). Demographic and clinical data were

analyzed using descriptive statistics, including means, standard deviations, and frequencies. Pre- and post-outcome measures were compared using the *t*-test or repeated-measures analysis of variance for continuous data. The effects of the intervention on multiple outcomes were evaluated using multiple linear regression techniques. Linear regression analysis was used for FRS. This research used an alpha level of 0.05 as the threshold for statistical significance.

2.4. Ethical considerations

The study was approved by the Scientific Committee of the Saudi Board Community Medicine Residency Program. The research methods and data collection were approved by the King Abdullah International Medical Research Center (KAIMRC) Ethics and Scientific Committee (Institutional Review Board approval number: RJ13/039/J). All participants received detailed information regarding the purpose and nature of the study and provided written informed consent before enrollment.

3. Results

The mean age of the intervention and control group was 49±6.5 and 48±5.6 years, respectively. The proportion of the employed among the participants in the intervention group (39%) was significantly greater than that in the control group (11%) (p=0.014). Other demographic details are shown in Table 1.

Table 1: Sociodemographic characteristics of the participants (n=59) at the National Guard Residential City in Jeddah, Saudi Arabia, 2015

Sociodemographic characteristic	Intervention group (n = 31)	Control group (n = 28)	p-value
Age (years)			
Mean ± SD	49 ± 6.5	48 ± 5.6	0.315
30-39	1 (3%)	0 (0%)	
40-49	16 (52%)	19 (68%)	
50-59	12 (39%)	9 (32%)	
60-69	2 (7%)	0 (0%)	
70+			
Marital status			
Single			
Married	31 (100%)	26 (93%)	0.318
Separated	0	1 (3.5%)	
Divorced	0	1 (3.5%)	
Education			
Illiterate	7 (22%)	16 (57%)	0.065
Read and write	3 (10%)	2 (7%)	
Primary	3 (10%)	3 (11%)	
Intermediate	4 (13%)	2 (7%)	
High school	5 (16%)	0 (0%)	
University	9 (29%)	5 (18%)	
Occupation			
Housewife	19 (61%)	25 (89%)	0.014*
Employee	12 (39%)	3 (11%)	
Income/month (SR)			
<5000	4 (13%)	9 (32%)	0.031*
5000-10000	12 (39%)	14 (50%)	
>10000	15 (48%)	5 (18%)	

Data are presented as number and percentage (%). * Statistically significant at $p < 0.05$ (Chi square test).

Data on dietary habits and physical activity showed that 62% of participants did not regularly exercise. Approximately 38% habitually missed breakfast. Once-a-day fruit and vegetable intake were satisfactory (42% and 46%, respectively).

Table 2: The effect of a community-based lifestyle modification program in the intervention (n = 31) and control group (n = 28) status for modifiable risk factors (pre-post) at the 3-months' follow-up at the National Guard Residential City in Jeddah, Saudi Arabia, 2015

	Paired t-test					
Measures	Control group			Intervention group		
Risk factor	Mean difference	95% CI of the difference (upper to lower)	p-value	Mean difference	95% CI of the difference (upper to lower)	p-value
BMI (kg/m^2)	-0.1821	-0.3932 to 0.0289	0.088	-0.832	-1.302 to -0.362	0.001*
Waist circumference (cm)	-0.143	-1.898 to 1.613	0.869	1.871	-5.036 to 8.778	0.584
Total cholesterol (mg/dL)	4.625	-10.557 to 19.807	0.537	3.774	-22.270 to 29.818	0.769
HDL (mg/dL)	-1.190	-6.852 to 4.471	0.670	5.968	0.021 to 11.914	0.049*
LDL (mg/dL)	15.821	0.633 to 31.010	0.042*	11.419	-4.428 to 27.267	0.152
Triglycerides (mg/dL)	-23.679	-56.872 to 9.515	0.155	-1.355	-35.058 to 32.348	0.935
Systolic BP (mmHg)	-1.714	-5.943 to 2.515	0.413	-13.355	-19.696 to -7.013	0.001*
Diastolic BP (mmHg)	0.214	-2.367 to 2.796	0.866	-4.516	-8.672 to -0.360	0.034*
Fasting blood glucose (mg/dL)	-10.404	-44.573 to 23.766	0.537	-6.667	-25.526 to 12.193	0.475
FRS	3.04286	0.09271 to 5.99300	0.044*	-4.932	-6.203 to -3.661	0.001*

* Statistically significant at $p < 0.05$.

CI: confidence interval, BMI: body mass index, HDL: high-density lipoprotein; LDL: low-density lipoprotein, BP: blood pressure, FRS: Framingham risk score.

As shown in Table 2, five parameters significantly changed with the application of the intervention. BMI decreased from 33.7±6.6 kg/m^2 to 32.9±6.5 kg/m^2 ($p<0.001$). HDL level increased from 40.6±17.4 mg/dL to 46.5±8.8 mg/dL ($p=0.049$). Systolic blood pressure decreased from 141±18.4 mmHg to 127.6±13.9 mmHg ($p<0.001$), and diastolic blood pressure decreased from 91.9±11.5 mmHg to 87.42±9.7 mmHg ($p=0.034$). In addition, FRS significantly changed, decreasing from 13.02±3.3 to 8.1±5.03 ($p<0.001$).

Table 3: The effects of a community-based lifestyle modification program on the Framingham risk score among the intervention and control groups (n=59) at the National Guard Residential City in Jeddah, Saudi Arabia, 2015

Wilcoxon signed-rank test						
		n	Mean rank	Sum of ranks	Z	p-value
Framingham risk score (control group)	Negative ranks	7	7.36	51.50	-2.226	0.026
	Positive ranks	14	12.82	179.50		
	Ties	7				
Framingham risk score (intervention group)	Negative ranks	27	14.78	399.00	-4.464	0.001
	Positive ranks	1	7.00	7.00		
	Ties	3				

The result of the Wilcoxon signed-rank test ($z= -4.46$, $p<0.001$) showed a significant difference between the pre and post-intervention results. The 10-year CVD risk score was decreased in 27 subjects (87%) but increased in 1 (3%). Three (10%) subjects had the same pre- and post-intervention scores (Table 3).

Table 4: Pre-post shift in Framingham category in the intervention and control group (n=59) at the National Guard Residential City in Jeddah, Saudi Arabia, 2015

Chi-square test					
		Risk category-post			p-value
		Low	Moderate	High	
Risk category-pre (control)	Moderate	2	10	7	0.035
	High	0	1	8	
Risk category-pre (intervention)	Moderate	22	7	0	0.001
	High	0	1	1	

The chi-square correlation test revealed a significant difference ($p<0.001$) in Framingham risk category level (low, moderate, and high) in the intervention and control group before and after the intervention (Table 4). In the intervention group, 22 women (71%) shifted from the moderate to low level, 7 (23%) remained at the moderate level, and 1 (3%) remained at the high level. In addition, 1 woman (3%) shifted from the high to moderate level.

Table 5: The 3-months' effect of the lifestyle modification program on the intervention and control groups, with respect to the metabolic syndrome (n = 59) at the National Guard Residential City in Jeddah, Saudi Arabia, 2015

ANOVA							
Variable		n	Mean	SD	95% Confidence Interval for Mean		p-value
					Lower bound	Upper bound	
Total Cholesterol (mg/dL)	Control group	28	190.71	44.500	173.46	207.97	1.000
	Intervention group	31	190.71	51.436	171.84	209.58	
BMI (kg/m^2)	Control group	28	30.629	8.1393	27.472	33.785	0.236
	Intervention group	31	32.916	6.5225	30.524	35.309	
HDL (mg/dL)	Control group	28	43.93	11.566	39.44	48.41	0.329
	Intervention group	31	46.55	8.820	43.31	49.78	
Triglycerides (mg/dL)	Control group	28	137.36	52.426	117.03	157.69	0.086
	Intervention group	31	169.84	84.887	138.70	200.98	
LDL(mg/dL)	Control group	28	122.79	45.867	105.00	140.57	0.538
	Intervention group	31	115.61	42.943	99.86	131.36	
Waist circumference (cm)	Control group	28	105.68	11.966	101.04	110.32	0.272
	Intervention group	31	102.03	13.144	97.21	106.85	
Systolic BP (mmHg)	Control group	28	136.93	12.332	132.15	141.71	0.009*
	Intervention group	31	127.65	13.956	122.53	132.76	
Blood glucose (mg/dL)	Control group	28	142.36	66.214	116.68	168.03	0.003*
	Intervention group	31	97.61	44.369	81.34	113.89	
FRS	Control group	28	21.6754	8.46476	18.3931	24.957	0.001*
	Intervention group	31	8.0939	5.03199	6.2481	9.939	
Metabolic syndrome	Control group	28	3.393	1.031	2.993	3.792	0.906
	Intervention group	31	3.354	1.379	2.848	3.861	

* Statistically significant at $p < 0.05$.

ANOVA: analysis of variance, BMI: body mass index, HDL: high-density lipoprotein; LDL: low-density lipoprotein, BP: blood pressure, FRS: Framingham risk score.

Table 5 illustrates the effect of the intervention after 3 months. Significant differences were noted in blood pressure (p=0.009) and blood glucose level (p=0.003). However, no significant difference was observed in blood lipids levels, BMI, and waist circumference. FRS differed significantly (p<0.001) between the intervention and control groups. Table 5 shows that metabolic syndrome status did not differ significantly between the intervention and control groups after 3 months of the intervention.

A. Table 6: The 3-months' effect of the interventional program compared to the control in relation to demographics, social factors and co-morbid conditions. Linear regression model for the Framingham risk score difference (n = 59) at the National Guard Residential City in Jeddah, Saudi Arabia, 2015

Coefficients					
Model	Unstandardized Coefficients		Standardized Coefficients	t	p-value
	B	SE	Beta		
(Constant)	1.416	2.047		0.692	0.492
Intervention	8.366	1.621	0.600	5.162	0.000
Married	-6.585	2.384	-0.306	-2.762	0.008
40-49 years	3.361	1.635	0.229	2.056	0.045
R^2: 0.436					
Adjusted R^2:0.405					

Finally, a linear regression revealed that the intervention showed a statistically significant improvement in FRS between the two groups ($p < 0.001$), when all other co-variates were adjusted for. However, being married was a negative predictor of the cardiovascular risk difference (Table 6).

4. Discussion

A randomized controlled trial was conducted to assess the effect of a community-based lifestyle modification program in women with a moderate-to-high risk of CVD. The results demonstrate that this multidisciplinary intervention, tailored to the individual's risk, was effective in reducing some of the CVD risk factors and the overall FRS, compared to standard care in women at moderate-to-high risk of CVD after 3 months.

The current study showed significant favorable changes in some of the cardiac risk factors in the intervention group. BMI reduced by 0.8 kg/m^2 and HDL improved by 5.9 mg/dL. In addition there were improvements in systolic and diastolic blood pressure by 13.3 and 4.5 mmHg, respectively. FRS also decreased by 4.9. This agrees with previous Canadian and American studies, which showed improvements in the same cardiac risk factors (Cox et al., 2013; American Diabetes Association, 2010).

The study also revealed non-favorable changes in some of the cardiac risk factors in the control group. Low-density lipoprotein (LDL) worsened by 15.8 mg/dL and FRS increased by

3.04. Other parameters did not differ significantly. The intervention by the multidisciplinary team could have motivated participants in the intervention group to take better charge of their health habits compared to the controls. This explanation is in congruence with other randomized controlled trials showing the effect of lifestyle intervention on CVD risk (Eriksson, 2010; Goyer et al., 2013).

At 3 months, the lifestyle intervention program had decreased systolic blood pressure and blood glucose levels. Reductions were significantly greater in the intervention group. This result is in accordance with findings from other lifestyle intervention studies (Eriksson, 2010; Cox et al., 2013; Pazoki et al., 2007; Goyer et al., 2013; Sarrafzadegan et al., 2013; Ebrahim et al., 2006). The intervention and control group also differed regarding blood glucose, which was lower in the intervention group by 45 mg/dL, as seen in the ANCHOR study (Cox et al., 2013). Although there was an improvement in HDL levels in the intervention group and the LDL level worsened in the control group, the intervention did not produce any significant difference in the overall blood lipid profile between both groups. These results compare favorably with the lifestyle intervention studies conducted by Eriksson et al. (2010), Pazoki et al. (2007), and Ebrahim et al. (2006) BMI decreased in the intervention group, but overall, reductions in BMI and waist circumference were not significant. The same findings were noted in another community-based healthy heart program study conducted in Iran (Pazoki et al., 2007). Rates of metabolic syndrome did not differ significantly between the intervention and control groups; however, other pre-post interventional studies showed an improvement in the status of metabolic syndrome. This could have been achieved through the effect of the behavioral counseling which is the cornerstone approach in the literature (Cox et al., 2013).

Despite this, a significant reduction in FRS was demonstrated at 3 months. It is notable that in the intervention group, 71% of women shifted from the moderate to the low risk category and 3% of the participants shifted from the high to moderate risk category, thus, underpinning the intervention's effectiveness. This improvement was shown in the pre- and post-intervention ANCHOR study (Cox et al., 2013). Moreover, FRS differed significantly between the intervention and control groups, decreasing in the intervention group and increasing in the control group. This was expected since most of the modifiable risk factors that are included in the calculation of FRS improved in the intervention group. This result is consistent with another randomized controlled trial on the efficacy of lifestyle intervention in reducing cardiovascular disease risk (Goyer et al., 2013).

The positive predictors that improved outcomes in the intervention group included health education, diet counselling, exercise training sessions, and the younger age group. This

could be due to their enthusiasm to improve their lifestyle and family health in general. However, being married was a negative predictor of the cardiovascular disease risk difference. The responsibilities of marriage might have made them less interested in improving their lifestyle. In agreement with this, some studies which assessed the motives for participating in a lifestyle intervention trial showed that participants were younger, single, had a higher level of education, and were employed (Lakerveld et al., 2008; Al-Baghli et al., 2010; Tanuseputro et al., 2003). Thus, the intervention itself represents a major change for the success of the program and for FRS reduction. These results could be helpful for identifying subjects with greater chances of successful lifestyle intervention in the development of future programs.

4.1. Limitations of the study

The follow-up duration could have been longer to examine the long-term effects of the intervention and of participants' adherence to any acquired lifestyle changes.

5. Conclusion

This study suggests that a community-based intervention is effective for cardiovascular disease risk reduction. The 10-year CVD risk was successfully reduced among participants with moderate-to-high cardiovascular risk and without established CVD, by applying a comprehensive program tailored to the individual's risk. The overall FRS was improved by the intervention. These results highlight the importance of multifaceted and comprehensive interdisciplinary programs that improve cardiovascular disease risk reduction, encourage healthy behaviors, and promote active lifestyles in persons at risk of CVD.

Acknowledgements

This work was supported by the National Guard Health Affairs, represented by the fund committee of the King Abdullah International Medical Research Center (KAIMRC).

Conflicts of Interest

None

References

Al-Baghli, N.A., Al-Ghamdi, A.J., Al-Turki, K.A., El-Zubaier, A.G., Al-Mostafa, B.A., Al-Baghli, F.A., et al., 2010. Awareness of Cardiovascular Disease in Eastern Saudi Arabia. J. Family Community Med. 17 (1), 15. https://doi.org/10.4103/1319-1683.68784.

Al-Nozha, M.M., Arafah, M.R., Al-Mazrou, Y.Y., Al-Maatouq, M.A., Khan, N.B., Khalil, M.Z., et al., 2004. Coronary Artery Disease in Saudia Arabia. Saudi Med. J. 25 (9), 1165–1171.

Alwan, A., 2011. Global status report on noncommunicable diseases 2010: World Health Organization. http://www.who.int/nmh/publications/ncd_report_full_en.pdf [accessed]

American Diabetes Association, 2010. Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 33 (Suppl 1), S62–9. https://doi.org/10.2337/dc10-S062.

Centers for Disease Control and Prevention, 2013. Preventable Deaths from Heart Disease & Stroke. http://www.cdc.gov/vitalsigns/heartdisease-stroke/index.html. [accessed]

Cox, J.L., Vallis, T.M., Pfammatter, A., Szpilfogel, C., Carr, B., O'Neill, B.J., 2013. A Novel Approach to Cardiovascular Health By Optimizing Risk Management (ANCHOR): Behavioural Modification in Primary Care Effectively Reduces Global Risk. Can. J. Cardiol. 29 (11), 1400–1407. http://dx.doi.org/10.1016/j.cjca.2013.03.007.

Ebrahim, S., Beswick, A., Burke, M., Davey Smith, G., 2006. Multiple Risk Factor Interventions for Primary Prevention of Coronary Heart Disease. Cochrane Database Syst. Rev. (4), CD001561. https://doi.org/10.1002/14651858.CD001561.pub2.

Eriksson, K.M., 2010. A 3-Year Lifestyle Intervention in Primary Health Care: Effects on Physical Activity, Cardiovascular Risk Factors, Quality of Life and Cost-Effectiveness (Doctoral thesis). Umea University, Umea, Sweden. https://www.diva-portal.org/smash/get/diva2:305718/FULLTEXT01.pdf

Go, A.S., Mozaffarian, D., Roger, V.L., Benjamin, E.J., Berry, J.D., Borden, W.B., et al., 2013. AHA Statistical Update. Heart Disease and Stroke Statistics—2013 Update. Circulation 127, e6–e245. https://doi.org/10.1161/CIR.0b013e31828124ad.

Goyer, L., Dufour, R., Janelle, C., Blais, C., L'Abbé, C., Raymond, É., et al., 2013. Randomized Controlled Trial on The Long-Term Efficacy of A Multifaceted, Interdisciplinary Lifestyle Intervention in Reducing Cardiovascular Risk and

Improving Lifestyle in Patients at Risk of Cardiovascular Disease. J. Behav. Med. 36 (2), 212–224. https://doi.org/10.1007/s10865-012-9407-3.

Kochanek, K.D., Xu, J., Murphy, S.L., Miniño, A.M., Kung, H-C., 2011. National Vital Statistics Reports. National Vital Statistics Report 59 (4), 1.

Kumosani, T.A., Madani, K., 2007. Cardiovascular Diseases in Saudi Arabia. Forthcoming .

Lakerveld, J., IJzelenberg, W., Van Tulder, M.W., Hellemans, I.M., Rauwerda, J.A., Van Rossum, A.C., et al., 2008. Motives for (Not) Participating in A Lifestyle Intervention Trial. BMC Med. Res. Methodol. 8 (1), 17. https://doi.org/10.1186/1471-2288-8-17.

Mendis, S., Puska, P., Norrving, B., 2011. Global Atlas on Cardiovascular Disease Prevention and Control. World Health Organization, Geneva.

Mosca, L., Appel, L.J., Benjamin, E.J., Berra, K., Chandra-Strobos, N., Fabunmi, R.P., et al., 2004. Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women. American Heart Association Scientific Statement. Arterioscler. Thromb. Vasc. Biol. 24 (3), e29–50. https://doi.org/10.1161/01.ATV.0000114834.85476.81.

National Guideline C., 2011. Cardiometabolic Risk Management Guidelines in Primary Care Rockville MD: Agency for Healthcare Research and Quality (AHRQ). http://www.guideline.gov/content.aspx?id=34113. [accessed]

Pazoki, R., Nabipour, I., Seyednezami, N., Imami, S.R., 2007. Effects of A Community-Based Healthy Heart Program on Increasing Healthy Women's Physical Activity: A Randomized Controlled Trial Guided By Community-Based Participatory Research (CBPR). BMC Public Health 7 (1), 216. https://doi.org/10.1186/1471-2458-7-216.

Rambo, C.N., 2012. Effects of a One-Year Comprehensive Lifestyle Intervention Program on Cardiovascular Disease Risk in At-Risk Adults (Master's dissertation). Ohio University, Athens, OH. http://rave.ohiolink.edu/etdc/view?acc_num=ohiou1338330328

Sarrafzadegan, N., Kelishadi, R., Sadri, G., Malekafzali, H., Pourmoghaddas, M., Heidari, K., et al., 2013. Outcomes of a Comprehensive Healthy Lifestyle Program on Cardiometabolic Risk Factors in a Developing Country: The Isfahan Healthy Heart Program. Arch. Iran Med. 16 (1), 4–11. https://doi.org/013161/AIM.004.

Schenck-Gustafsson, K., 2009. Risk Factors for Cardiovascular Disease in Women. Maturitas 63 (3), 186–190. https://doi.org/10.1016/j.maturitas.2009.02.014.

Services H., 2008. Be Active Your Way: A Guide for Adults: Based on the 2008 Physical Activity Guidelines for Americans: Be Active, Healthy, and Happy! US Government Printing Office.

Tanuseputro, P., Manuel, D.G., Leung, M., Nguyen, K., Johansen, H., 2003. Risk Factors for Cardiovascular Disease in Canada. Can. J. Cardiol. 19 (11), 1249–1260.

Wellsource, 2014. Health Risk Assessments and Wellness Programs. http://www.wellsource.com/home.html. [accessed]

Yoon, P.W., Gillespie, C.D., George, M.G., Wall, H.K., 2012. Control of Hypertension Among Adults-National Health and Nutrition Examination Survey, United States, 2005-2008. MMWR Morb. Mortal Wkly. Rep. 61 (Suppl), 19–25.