The Effect of a Community-Based Multi-Lifestyle Intervention on Cardiovascular Health in Rural Populations: A Community-Based Participatory Research Approach

Kyuwan Lee

Follow this and additional works at: https://researchrepository.wvu.edu/etd

Recommended Citation
https://researchrepository.wvu.edu/etd/6049

This Thesis is protected by copyright and/or related rights. It has been brought to you by the The Research Repository @ WVU with permission from the rights-holder(s). You are free to use this Thesis in any way that is permitted by the copyright and related rights legislation that applies to your use. For other uses you must obtain permission from the rights-holder(s) directly, unless additional rights are indicated by a Creative Commons license in the record and/or on the work itself. This Thesis has been accepted for inclusion in WVU Graduate Theses, Dissertations, and Problem Reports collection by an authorized administrator of The Research Repository @ WVU. For more information, please contact researchrepository@mail.wvu.edu.
The Effect of a Community-Based Multi-Lifestyle Intervention on Cardiovascular Health in Rural Populations: A Community-Based Participatory Research Approach

Kyuwan Lee

Thesis submitted to the School of Medicine at West Virginia University in partial fulfillment of the requirements for the degree of Masters of Science in the Department of Exercise Physiology

Paul Chantler, Ph.D., Chair
Randall Bryner, Ed.D.
Mark Olfert, Ph.D.

Department of Exercise Physiology

Morgantown, West Virginia
2015

Keywords: Cardiovascular Diseases (CVD), Community-Based Participatory Research (CBPR), Multi-Lifestyle intervention

Copyright 2015 Kyuwan Lee
Abstract
The Effect of a Community-Based Multi-Lifestyle Intervention on Cardiovascular Health in Rural Populations: A Community-Based Participatory Research Approach

Kyuwan Lee

Background: The overall rate of cardiovascular diseases (CVD) mortality has decreased in the US over the last few years. However, in rural areas, this reduction in CVD mortality is less substantial compared to urban areas despite the effort to translate lifestyle intervention which was successful in urban areas. An effective approach to translating a lifestyle intervention into a rural setting would be to consider their rural characteristics, resources, and to engage the local community directly. This may be accomplished by using community-based participatory research (CBPR), which is an approach that involves equitable partnerships between researchers and community stakeholders.

Aims: Aim 1: Use CBPR principles to conduct a pilot study to test the feasibility and acceptability of a rural multicomponent lifestyle intervention in CVD patients and their partners. We will determine feasibility by examining study participant recruitment and retention, implementation fidelity, and acceptability by assessing provider and patient satisfaction. Aim 2: Examine the effect of CBPR-developed lifestyle intervention on CV health and other traditional CVD risk factors in rural populations. We hypothesize the pulse wave velocity and endothelial function will be enhanced with improved Framingham risk score and 6-min walk distance after 10 weeks of intervention.

Methods: We assessed the feasibility and acceptability using satisfaction questionnaires, retention and recruitment rate along with cardiovascular parameters i.e., Framingham risk score, 6-min walk test, reactive hyperemia index, carotid thickness, and pulse wave velocity, pre and post 10 week lifestyle intervention.

Results: 10 patients with CVD were screened with their family member, yielding 20 individuals screened (recruitment rate 59%). 17 patients were enrolled and retained (retention rate 100%). The 6-minute walk distance significantly ($p=0.01$) increased (466±17m to 503±17m) with a tendency of improved heart rates and diastolic function represented by sub-endocardial viability ratio after 10 weeks intervention, although these parameters did not quite reach statistical significance. In contrast, there were no significant changes in the other CVD parameters. These findings provide valuable evidence to conduct lifestyle intervention for CVD patients in rural areas.

Conclusion: This study suggests that the multi-lifestyle intervention using the principle of CBPR is feasible and acceptable to improve CV health in rural CVD populations. Because this study was conducted as a pilot study which consists of smaller populations and shorter periods than the full intervention, we expect that phase 2 will show more significant outcomes which determine if an educational lifestyle intervention is beneficial to reduce the incidence of CVD in rural areas. These findings will also provide an important evidence to implement a larger trial targeted at CVD patients and their family member.
ACKNOWLEDGEMENTS

The time I spent in the Masters program was the most challenging period in my life. The only reason I was able to accomplish my degree on time is I met wonderful people and received great help and support from them. I am very happy to express my appreciation for all of you.

First of all, I would give special thanks to my advisor Dr. Paul Chantler for his encouragement and constructive advice. As a mentor, he showed endless patience and supports every time I had problems with my student life. His enthusiasm in his work always influences my motivation. I know I would not move to the next step of my research career without his encouragement and understanding.

I also want to thank my thesis committee members Dr. Randy Bryner and Dr. Mark Olfert for insightful comments and warm greetings every time we met in Health Science building. Their advice led me to the right way. I also appreciate the Chair of the Exercise Physiology department Dr. Alway for his valuable suggestion and guidance during the Masters program. I was very honored to be taught by their knowledgeable and influential thoughts.

I cannot express enough gratitude to all my friends. I am grateful my everlasting friendship with Sunkoo Rhee. I was so lucky to have him as my friend in my life. I thank Kent Lemaster for everything he has done for me. I would not forget his teaching abilities, consideration, patience, and sense of humor. I also thank my colleagues Sara Fournier, Evan Devallance, Kayla Brayan, and Corey Moore for their helpful instructions and sincere supports. I hope we can collaborate research projects in near future.

I highly appreciate people at Roane County who spent time and efforts for our research project. They were excellent research teams and collaborator. I would also like to acknowledge funding from the National Institutes of General Medical Sciences of the NIH (U54GM104942) and the Bendum Foundation which enabled us to do this research.

Last but not least, I would like to express my deepest gratitude to my family. I thank my wonderful parents, sister, and brother in law for supporting me in all my decisions. My wife and daughter, Nari and Jenny, for their endless love and support. I cannot express how grateful I am for their supports in a few words but I would like to tell you that I love you all and thank you for putting your trust in me as I progress through my education. The best thing in my life is having them as my family. I will do my best to make you all happy every single day.
Introduction

1.1. Purpose

1.2. Specific Aims and Hypothesis

1.3. Background and Significance

Review of Literature

2.1. Cardiovascular Disease in Rural Areas

2.1.1. Normal Cardiac and Arterial Function

2.1.2. Cardiac and Arterial Function with Cardiovascular Disease

2.1.3. Obesity in Rural Areas

2.1.4. Hypertension in Rural Areas

2.1.5. Type 2 Diabetes Mellitus in Rural Areas

2.2. Characteristics of Rural Areas
2.2.1. Geographical Disparity .................................................................12
2.2.2. Socioeconomic Disparity ..............................................................13
2.2.3. Educational Disparity .................................................................14
2.2.4. Racial Disparity .....................................................................15
2.2.5. Natural Environment Disparities ..................................................16

2.3. Lifestyle Intervention for Cardiovascular Disease

2.3.1. Physical Activity Focused Intervention ...........................................18
2.3.2. Nutrition Focused Intervention ......................................................19
2.3.3. Smoking Cessation Focused Intervention .......................................21
2.3.4. Stress Management Focused Intervention .......................................22

2.4. Community-Based Participatory Research for Cardiovascular Diseases ..... 23

METHODS ........................................................................................................25

3.1. Ethics and Medical Screening ............................................................25
3.2. Study Design ....................................................................................25
   3.2.1. Community Barriers Assessment ...............................................27
   3.2.2. Barriers to Recruitment and Retention ...........................................28
   3.2.3. Target Community and Subjects ..................................................28
   3.2.4. Intervention Procedures .............................................................31
3.3. Feasibility and Acceptability Assessment .............................................35
3.4. CV Physiological Measures ...............................................................36
3.4.1. Body Composition ................................................................. 36
3.4.2. Arterial Geometry ................................................................. 36
3.4.3. CV Function ........................................................................... 37
3.4.4. Endothelial Function ............................................................. 39
3.4.5. Biomarker and Framingham Risk Score ................................. 41
3.4.6. Physical Performance ............................................................. 42
3.4.7. PA Measures ......................................................................... 43

3.5. Psychometric Properties .......................................................... 43
3.7.1. Health-Related Quality of Life-14 (CDC HRQOL-14) .............. 43
3.7.2. Depression Anxiety Stress Scales-21 (DASS-21) .................... 44
3.7.3. Mindful Attention Awareness Scale (MAAS) ......................... 44

3.6. Statistical Analyses ................................................................... 45

RESULTS ......................................................................................... 46

4.1. Feasibility and Acceptability Measures ..................................... 46
4.1.1. Recruitment and Retention Rates ........................................... 46
4.1.2. Participants’ Satisfaction Measures ......................................... 46
4.1.3. Providers’ Satisfaction Measures ............................................ 47

4.2. Characteristics of Study Participants ....................................... 48

4.3. Clinical Characteristics of CVD patients and family members .... 51

4.4 Level of PA .............................................................................. 54
List of Figures

Figure 2.1. Geographic Variation in the Prevalence of Obesity .......................... 9
Figure 2.2. Geographic Variation in the Prevalence of HTN ............................. 10
Figure 2.3. Geographic Variation in the Prevalence of T2DM ............................ 12
Figure 3.1. Schematic Diagram of rHeART ................................................... 27
Figure 3.2. Intervention at RCFHC ............................................................... 32
Figure 3.3. Carotid Intima-Media Thickness .................................................. 37
Figure 3.4. PWA and PWV at RCFHC ......................................................... 38
Figure 3.5. CV Indices Derived From Arterial Pulse Wave .............................. 39
Figure 3.6. Endothelial Function Measurement at RCFHC .............................. 40
Figure 3.7. Normal Endothelial Function Derived From EndoPAT ................. 40
Figure 3.8. EndoPAT Device ................................................................. 41
Figure 3.9. 6-minute Walk Test at RCFHC .................................................. 42
Figure 4.1. Recruitment Rate and Retention Rate ........................................... 46
Figure 4.2. CVD Risk Factors of Participants ................................................ 50
Figure 4.3. Subjects’ Perception of Health .................................................... 50
Figure 4.4. Family Medical History ............................................................. 51
Figure 4.5. Mean Comparison of BMI between Pre and Post Measurements in Participants with Full Attendance ................................................................. 52
Figure 4.6. Mean comparison of total level of PA between pre and post measurements in CVD patients and their family member combined ................................. 55
Figure 4.7. Mean comparison of total level of PA between pre and post measurements in CVD patients separately ................................................................. 56
Figure 4.8. Mean Comparison of Sitting Time on a Weekday between Pre and Post Measurements in Family Member ................................................................. 56
Figure 4.9. Mean Comparison of 6MWT between Pre and Post Measurements in CVD Patients and Their Family Member ................................................................. 57
Figure 4.10. Mean Comparison of PTId between Pre and Post Measurements ...... 58
Figure 4.11. Mean Comparison of SEVR% between Pre and Post Measurements ..... 59
Figure 4.12. Mean Comparison of RHI between Pre and Post Measurements ........ 59
Figure 4.13. Mean Comparison of FRS between Pre and Post Measurements .......... 60
Figure 4.14. Mean Comparison of MAAS between Pre and Post Measurements ..... 61
Figure 4.15. Mean Comparison of DASS-21 between pre and post Measurements .... 61
List of Tables

Table 3.1. Inclusion and Exclusion Criteria ......................................................... 30
Table 3.2. rHeART 10 Session Core Curriculum .................................................. 33
Table 4.1. Clinical Characteristics of All Participants before and after Intervention .... 53
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACSM</td>
<td>American College of Sports Medicine</td>
</tr>
<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>ATDM</td>
<td>Automated Telephone Disease Management</td>
</tr>
<tr>
<td>AI</td>
<td>Augmentation Index</td>
</tr>
<tr>
<td>AP</td>
<td>Augmentation Pressure</td>
</tr>
<tr>
<td>CBPR</td>
<td>Community-Based Participatory Research</td>
</tr>
<tr>
<td>CCA</td>
<td>Common Carotid Artery</td>
</tr>
<tr>
<td>CHD</td>
<td>Coronary Heart Disease</td>
</tr>
<tr>
<td>CHF</td>
<td>Congestive Heart Failure</td>
</tr>
<tr>
<td>cIMT</td>
<td>Carotid Intima Media Thickness</td>
</tr>
<tr>
<td>CV</td>
<td>Cardio Vascular</td>
</tr>
<tr>
<td>CVD</td>
<td>Cardio Vascular Disease</td>
</tr>
<tr>
<td>DASH</td>
<td>Dietary Approaches to Stop Hypertension</td>
</tr>
<tr>
<td>DASS-21</td>
<td>Depression Anxiety Stress Scales-21</td>
</tr>
<tr>
<td>DPP</td>
<td>Diabetes Prevention Program</td>
</tr>
<tr>
<td>ED</td>
<td>Ejection Duration</td>
</tr>
<tr>
<td>EXPH</td>
<td>Exercise Physiology Department</td>
</tr>
<tr>
<td>FMD</td>
<td>Flow-Mediated Dilation</td>
</tr>
<tr>
<td>FRS</td>
<td>Framingham Risk Score</td>
</tr>
<tr>
<td>HDL</td>
<td>High-Density Lipoprotein</td>
</tr>
<tr>
<td>HF</td>
<td>Heart Failure</td>
</tr>
<tr>
<td>HRQOL-14</td>
<td>Health-Related Quality of Life-14</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>HTN</td>
<td>Hypertension</td>
</tr>
<tr>
<td>IPAQ</td>
<td>International Physical Activity Questionnaire</td>
</tr>
<tr>
<td>Look AHEAD</td>
<td>Look Action for Health in Diabetes</td>
</tr>
<tr>
<td>MASS</td>
<td>Mindful Attention Awareness Scale</td>
</tr>
<tr>
<td>METs</td>
<td>Metabolic Equivalents</td>
</tr>
<tr>
<td>MetS</td>
<td>Metabolic Syndrome</td>
</tr>
<tr>
<td>MI</td>
<td>Myocardial Infarction</td>
</tr>
<tr>
<td>MOVHD</td>
<td>Mid-Ohio Valley Health Department</td>
</tr>
<tr>
<td>PA</td>
<td>Physical Activity</td>
</tr>
<tr>
<td>PAT</td>
<td>Peripheral Arterial Tone</td>
</tr>
<tr>
<td>PRC</td>
<td>Prevention Research Center</td>
</tr>
<tr>
<td>PWA</td>
<td>Pulse Wave Analysis</td>
</tr>
<tr>
<td>PWVcf</td>
<td>Carotid to Femoral Pulse Wave Velocity</td>
</tr>
<tr>
<td>RCFHC</td>
<td>Roane County Family Health Care</td>
</tr>
<tr>
<td>rHeART</td>
<td>Rural Health/Heart Accelerating Research Transition</td>
</tr>
<tr>
<td>RHI</td>
<td>Reactive Hyperemia Index</td>
</tr>
<tr>
<td>SEVR%</td>
<td>Sub-Endocardial Viability Ratio</td>
</tr>
<tr>
<td>SOM</td>
<td>School of Osteopathic Medicine</td>
</tr>
<tr>
<td>Tg</td>
<td>Triglycerides</td>
</tr>
<tr>
<td>TM</td>
<td>Transcendental Meditation</td>
</tr>
<tr>
<td>T2DM</td>
<td>Type 2 Diabetes Mellitus</td>
</tr>
<tr>
<td>WVU</td>
<td>West Virginia University</td>
</tr>
</tbody>
</table>
Abbreviations continued

6MWT  6-Minute Walk Test
Chapter 1

Introduction
1.1. Purpose

The overall rate of cardiovascular diseases (CVD) mortality in the US has decreased by 30.8% over the last decade [1]. However, in rural areas, this reduction in CVD mortality is substantially less in relation to urban areas [2]. Rural areas have a higher risk of CVD mortality due to the higher prevalence of CVD risk factors such as diabetes, obesity, and hypertension compared to urban areas [3]. Further, CVD burdens are exacerbated by obesity, tobacco use, and malnutrition which are directly associated with arterial dysfunction such as atherosclerosis, arteriosclerosis, and endothelial dysfunction [4]. In turn, arterial dysfunction directly contributes to an increase in CVD mortality [2]. There has been increasing geographic variation in cardiovascular (CV) health which results in a two-fold increase of risk for CVD in rural populations [5]. Previous interventional studies have been performed to address possible risk factors of residents living in rural areas, but the prevalence of CVD in rural areas remain relatively unchanged. An effective approach to introduce a lifestyle intervention to a rural population would be to take into account the rural characteristics, resources, and to engage the local community [6]. This can be accomplished by using community-based participatory research (CBPR). CBPR is an approach that involves equitable partnerships between researchers and community stakeholders who are directly affected by and knowledgeable about factors which may impact health. Although there have been previous attempts to apply CBPR approaches to a lifestyle intervention in a rural setting, they do not address the combined CVD risk factors associated with tobacco use, and they have not involved the participant’s family to modify their home environment.
The purpose of this study is to employ the principles of CBPR to develop a multi-lifestyle intervention in a rural population to improve CV health. Health care expenses are forecasted to increase to 818 billion dollars by 2030 which is a three-fold growth compared to the 2010 medical costs [7]. Our intervention may be an effective way to reduce the disease burden of individuals as well as decrease overall health care costs.

1.2. Specific Aims & Hypothesis

Aim 1: Use CBPR principles to conduct a pilot study to test the feasibility and acceptability of a rural multicomponent lifestyle intervention in CVD patients and their partners. We will determine feasibility by examining study participant recruitment and retention, implementation fidelity, and acceptability by assessing provider and patient satisfaction.

Aim 2: Examine the effect of CBPR-developed lifestyle intervention on CV health and other traditional CVD risk factors in rural populations. We hypothesize the pulse wave velocity and endothelial function will be enhanced with improved Framingham risk score and 6-min walk distance after 10 weeks of intervention.
1.3. Background and Significance

Since the mid-1960s, the overall mortality rate of CVD has decreased, and it has positively contributed to the reduction of overall mortality in the United States [1]. However, there has been increasing geographic variation in CV health that results in a two-fold increase of risk for CVD in rural populations [5]. According to the data presented by National Health and Nutrition Examination Survey, rural areas have approximately 6% higher prevalence of obesity with concentrations of African Americans (2.1%) who tend to have a prevalence of obesity (47.3%), diabetes (8.6%) and coronary heart disease (CHD) (38.8%) [1]. The increased prevalence of CVD in rural areas may be attributed to their different lifestyle behaviors compared to urban areas. Mensah and colleagues [7] demonstrated that physical inactivity, tobacco use, unmanaged stress, and unbalanced nutrition are correlated with lower educational attainment and socioeconomic status. Additionally, environmental characteristics such as lack of local health facilities and a shortage of health care resources, low presence of sidewalks, and streetlights have been significantly associated with rural health behaviors [8]. Further, mental illness is another prominent issue found in rural populations that may contribute to CVD [9]. Although previous attempts have been made to implement health lifestyle interventions in rural areas, they lack substantial amounts of beneficial outcomes.

Lifestyle interventions which target CVD risk factors (physical inactivity and unbalanced nutrition) are known to improve CV health outcomes including, but not limited to arterial function [10]. For example, the Dietary Approaches to Stop Hypertension (DASH) and Diabetes Prevention Program (DPP) have been shown to
improve CV health through mechanisms such as reducing blood pressure or maintaining a proper weight [11]. Importantly, these lifestyle interventions are designed to be conducted in carefully-controlled efficacy focused trials performed in academic and large clinical centers, located in non-rural settings. The highly-controlled nature of these studies drastically reduces their “real world” application, relevance, and generalizability to rural populations. To date, only one study has attempted to adapt a multi-lifestyle intervention from an urban to a rural area with some success [6]. A possible reason for the limited success of other studies is that rural areas have their own culture, faith, physical and social environment, which create limitations for implementing lifestyle interventions in rural areas. Considering the complexity and interaction of these factors with the research participants should be the first step in integrating a multi-lifestyle intervention in rural populations.

CBPR is an approach that involves equitable partnerships between researchers and community stakeholders which reflects a philosophy and practice of shared power and decision making among researchers and communities; conceptualizes the conduct of research with a community, rather than on, in, or for a community, and has a goal of social interaction to reduce health disparities by engaging local experts to aid in the identification of the problem and solution. There is evidence that both the delivery of the core curriculum and the adherence to that content by the participants are enhanced by family engagement which can increase the efficacy of the interventions [12]. Since families tend to have similar lifestyle patterns which increases CV risk, inclusion of the partner in this study can improve the CV health of the family. For example, if participants
in the study are inclined to revert back to their previous lifestyle, the disinclination of another family member may prevent the participant from reverting back to their unhealthy habits. These findings will provide valuable evidence to conduct lifestyle interventions for CVD patients and their family members in rural areas.
Chapter 2

Review of Literature
2.1. Cardiovascular Disease in Rural Areas

CVD is the leading cause of death in the United States, accounting for more than 2,150 death of American each day, an average of 1 death every 40 seconds [1]. It is estimated that 116 million Americans will have some form of CVD and will amount to $149 billion of the nation’s health expenditures by 2030 [13]. While CVD has a strong prevalence in the United States as a whole, there is evidence rural populations have a greater prevalence of CVD compared to urban areas [14]. Also, rural areas have a higher rate of disease which are strongly correlated with CVD such as hypertension (HTN), type 2 diabetes mellitus (T2DM) and obesity, and other risk factors which may influence CVD [15].

2.1.1. Normal Cardiac and Arterial Function

The primary function of heart is to eject a large percentage of the ventricle’s blood volume into the systemic and pulmonary circulation during systole and to receive blood via venous return during diastole [16]. Under normal hemodynamic conditions, the left ventricle pumps blood into large conduit arteries, which then flow into smaller vessels, arterioles then capillaries, due to the pressure gradient created by the heart and passive vessel tension of the conduit arteries [17]. The large central arteries not only act as a passageways for blood, but also function as a pressure reservoir which is created by the arteries elastic nature to provide a steady flow of blood through the arterioles and capillaries during diastole [18]. When the heart pumps blood through the vessels, a pressure wave is generated and propagates down the arterial system, (i.e. the forward wave) until it encounters high-resistant arteriole bifurcations causing it to reflect back.
toward the heart (i.e. the reflected wave) [19]. This is determined by high elastic components contributing to arterial compliance, particularly the aorta and its major branches (radial and femoral arteries) [20]. Arteries progressively branch into smaller vessels to supply blood to different organs and tissues. As a small artery enters the tissues, it branches into arterioles and further into capillaries to where it can exchange oxygenated for deoxygenated blood. Capillaries form small venules and merge to form small veins which leave the organs and return to the heart. During diastole, heart is not pumping and no blood is pumped into arteries. Instead, the elastic recoil of arteries drives the blood forward in order to supply a consistent blood flow to the various tissues [21].

2.1.2. Cardiac and Arterial Dysfunction with Cardiovascular Disease

Cardiac and arterial functioning undergo structural and functional changes with various CVD including hypertension, obesity, and T2DM [22]. As individuals develop CVD, the arterial systems, the aorta and carotid in particular, gradually lose some of their elasticity and compliance. In turn, it reduces the ability of the arteries to supply a steady blood flow during diastole. This is explained by the mechanism which is induced by lumen enlargement with wall thickening resulting in higher velocity of the pulse wave across an artery and the faster arrival of reflected wave at the heart earlier than normal pressure wave [23]. Due to the resistance caused by the less compliant arteries, left ventricular afterload increases which can lead to ventricular hypertrophy and result in a decreased coronary artery perfusion pressure and may increase the risk of other pathological conditions such as congestive heart failure and myocardial infarction [24].
Patients with CVD present various alterations in the vasculature which may increase CV events. Recent studies confirmed that the remodeling of the carotid intima media thickness (cIMT) increases, along with increased pulse wave velocity (PWV) and flow-mediated shear stress which is induced by changes in stiffness of blood vessels and arterial wall thickness [25].

2.1.3. Obesity in Rural Areas

It is estimated that the number of people with overweight and obesity defined as body mass index of 30.0 kg/m\(^2\) or greater (weight in kilograms divided by height in meters squared) is 154.7 million in 2010 [1]. The consequences of being obesity increases risks for comorbidities such as HTN, T2DM and stroke, and the current epidemic of obesity in the United States manifests the long-term risks on CVD and shorter life expectancy. It has been shown that these factors are significantly influenced by geographic/socioeconomic, sex, race and age disparities, and exacerbated by physical inactivity, excessive caloric intake, and psychological stress which are prevalent in rural areas. For example, women are more likely to have a higher prevalence of obesity, especially Hispanic Black women and Mexican American women in rural communities have a higher obesity rate than urban counterparts, whereas men in rural areas present similar rates of obesity in urban areas [26]. It is also important to note that the overall rate of obesity in Black and Hispanic children, who are significantly affected by their parent’s behaviors, is higher compared to urban White children [27]. Although there have been a variety of efforts to ameliorate obesity-related metabolic abnormalities such as bariatric surgery and drugs treatment, these are only viable options for severe
obesity, not applied for general obesity populations [28]. Further, it is not cost effective to deliver large obese populations in the rural areas. Few studies have examined the effective means for long-term weight loss in rural areas, but patients with obesity still fail to obtain recommended amounts of physical activity and diets, suggesting that lifestyle interventions have not been successful in rural areas.

Figure 2.1. Geographic Variation in the Prevalence of Obesity

2.1.4. Hypertension in Rural Areas

Hypertension (HTN) is a common and disabling chronic disease, affecting more than 50 million people in the United States [29]. A recent study suggested that HTN is more prevalent in rural than urban areas, and rural women are especially susceptible to developing HTN [29]. Among women residing in rural areas, African Americans reported worse diastolic blood pressure than rural Whites (11% of rural whites and 23% of rural African) suggesting that there are possible factors influencing CV disparities, and the
greater needs of the rural minority populations will be important to reduce CV health problems [30]. Rural populations have limited access to health care services resulting in lower rates of optimal health outcomes and increased CVD disparities. In addition, the National Institutes of Health suggests that genetic factors combine with their lifestyle such as physical inactivity, unbalanced diet can contribute to high blood pressure making them the most prevalent population for CVD [31]. Given the relationship between nutrition and HTN, DASH diet, which increases potassium intake and decreases sodium intake, has been suggested to lower blood pressure and CVD. Since DASH diet recommends high protein, calcium, low fat products, red meat, and refined carbohydrates, it can be applied to the general population as well as severe clinical populations. It has been shown that it results in more beneficial effects in combination with other non-pharmacologic treatments such as physical activity and stress management [32].

Figure 2.2. Geographic Variation in the Prevalence of HTN
2.1.5. Type 2 Diabetes Mellitus in Rural Areas

Type 2 diabetes mellitus (T2DM) is one of the enormous health concerns which disproportionately impacts rural areas. It is a metabolic disorder associated with severe complications including retinopathy, liver dysfunction and ketoacidosis, as well as vascular alterations leading to CVD. The prevalence of 382 million individuals worldwide have diabetes in 2013, and the number is expected to rise up to 592 million by 2035 according to recent estimates [31].

T2DM care appears to be challenging; however, it is manageable if routing physician visits, Hemoglobin A1C (HBA1C) testing, foot examinations are provided. However, patients with T2DM in rural areas have significant barriers to meet these recommendations due to the lack of the health infrastructure [33].

The American Diabetes Association (ADA) recommends that all diabetic patients participate in Diabetes Self-Management Education which has been effective in urban areas. However, rural residents were less likely to participate in the program due to the rural characteristics such as lower levels of income, educational attainment, location and health insurance. Also, DPP, which is an intensive physical activity and a nutrition intervention, has been translated into rural areas [34]. However, it has not been successful to improve rural CV health although it took into account racial and ethnic minorities in the project. Further, patients with T2DM have a higher prevalence of hypertension compared to subjects without diabetes [35]. Without considering real rural characteristics, delivering lifestyle interventions in rural areas may not be successful, and will contribute to the health disparity between rural and urban populations.
2.2. Characteristics of Rural Areas

2.2.1. Geographical Disparity

It has been known that rural areas are medically underserved regions and have less access to health care despite the improved availability of rural health services. Rural residents have limited opportunities for health promotion and disease prevention services and few links with the health care system [36]. They are more likely to have to travel greater distances to receive health care. For instance, intravenous thrombolytic treatment, which is time-sensitive treatment for CVD such as ischemic stroke and myocardial infarction, should be provided within 180 minutes of the onset of symptoms. However, rural populations experienced delayed arrival to an appropriate care facility.

Figure 2.3. Geographic Variation in the Prevalence of T2DM
According to the Center for Studying Health System Change, the disparity in the availability of health facilities is a serious problem based on results showing the number of 53 primary care physicians per 100,000 rural residents versus 78 primary care physicians per 100,000 urban residents. More seriously, this geographical disparity is greater when the number of health specialists (54 and 134 per 100,000 residents in rural and urban areas, respectively) is compared [37]. Another geographical disparity is lack of availability of healthy and fresh foods. It is ironic that rural populations, who live in the communities where produce fruits and vegetables are less likely to consume fruits. However, the availability of healthy food entirely depends on the size, number and distance of food stores. Since they have fewer geographic access to supermarkets or large grocery stores that carry a wide selection of healthy, rural individuals have to shop at convenience store or small grocery store with low-cost and unhealthy food which significantly influences the consumption of daily fruits, vegetables, low-fat dairy products, and grains in rural populations [38].

2.2.2. Socioeconomic Disparity

Rural populations experience a lower rate of annual income due to the limited job opportunities compared to urban counterparts. Although the education level in rural Americans has been slightly increased, their poverty rates are still higher and affected by low-wage labor without health insurance benefits. Rural populations are more likely to work in lower skilled jobs such as agriculture and construction that does not require college degrees, and the high level of poverty have reduced the ability of rural residents to obtain health care services due to the increasing health care costs. Also, they barely
participate in physical activity (PA) including programmed exercise and lifestyle PA, which is directly correlated with decreased obesity rates. In a study which analyzed the correlations of PA among United States adults and income levels, the lower income level was significantly correlated with physical inactivity [39]. It has been reported that 34% of rural African Americans, 25% of rural Hispanic populations, and 34% of rural Native American populations are living in poverty, and 71% of rural African Americans are living in areas that lack health care facilities [40]. As a result, rural residents are less likely to visit physician services due to their insurance status. According to data from National Health Interview Survey, it is reported that insurance status, which is significantly associated with economic status, is the most influencing factor to healthcare services visits [41]. In accordance with the survey, there was a 3 year evaluation in Japan showing that high monthly salary is significantly correlated with increased outpatient rates [42]. Also, there was a correlation between individuals who live within 30 min of cardiac care, highest household income, and median housing income. These studies suggest that individuals with lower income tend to live further away from cardiac centers, thus causing lower rates of health services visit. Similarly, median household income and median housing value tend to be lower in neighborhoods which have longer travel times to a stroke center [43].

2.2.3. Educational Disparity

It is obvious that educational disparities are closely related to socio-economic disparities, that is, low income populations are less likely to be educated (high school or less). However, there is another point of view for educational issues to be highlighted because
of its new characteristics [40]. Low level of knowledge about CV health is associated with a high rate of CVD mortality. In other words, abundant knowledge can decrease CV events. For example, heart failure (HF) is associated with the level of knowledge about HF as they are confused about specific symptoms that may exacerbate HF with other diseases. However, individuals in rural areas encounter many challenges to receiving professional education such as nutrition, diabetes and PA education provided by health professions. It has been suggested that this problem originates from the difference of educational attainment between rural and urban areas such as high school completion or college enrollment. According to data from American Community Survey, rural residents were less likely to receive a bachelor’s degree (21%), compared with those in urban areas (34%). Additionally, there is strong evidence that high school students who have parents with professional degrees are ten times more likely to complete college than those who have parents with non-professional degrees which cause intergenerational transfer of education. It appears that there is a correlation between low educational status and CVD risk factors. A recent publication has shown that a high proportion of rural residents who did not receive CPR training is significantly correlated with a lower rate of educational status [44].

2.2.4. Racial/Ethnic Disparity

Rural areas tend to have less ethnic diversity which may contribute to prolonged chronic health disparities—that is, certain races are densely populated in rural areas which have significantly influenced on the prevalence of CVD [45]. In the general U.S. population, minority populations in rural areas tend to have greater risk for CVD. The reason for the
presence of rural-urban racial disparity is unclear. However, possible factors which influence the disparity have been suggested. First, Hispanic populations have increased from 1.4 to 2.7 million in rural America. There is a report showing that Hispanic populations increased approximately 1,000 percent in seven Iowa rural counties between 1990 and 2000 [46]. Another data have also shown that populations of Latin Americans who are more susceptible to become diabetic have rapidly increased since the year 2000 in the state of Iowa due to the availability of employment without health insurance benefits [46]. Hispanic populations in Kansas, Nebraska, and Minnesota have also risen in rural areas. In addition to Hispanic, African American who are more likely to have T2DM, are also prevalent in rural America [30]. The rate of severe CVD related to deaths for African Americans in the United States has continued to rise, which is over 46% higher than Caucasian Americans. The prevalence of hypertension is also 12% higher in rural African American, and a 7% higher rate was reported for urban African Americans compared to Caucasian Americans. Further, the rate of individuals who received diabetic education provided by American Diabetes Association can possibly influence the health disparity. The rate is significantly higher in urban populations, and African Americans living in urban locations have a much higher diabetic education programs compared to individuals living in rural regions. According to recent estimates, Hispanic and African American will become the largest minority group in rural America by 2025 and significantly affect CV health in many rural areas [47].

2.2.5. Natural Environments Disparity

Since the general picture of rural areas is clean air, water and soil environments, natural
factors in rural areas have been easily disregarded. However, air pollution is a critical cause of CV events, and there are potential factors of CVD which negatively influences rural CV health outcomes such as coal mining facilities, agricultural facilities and livestock operations in rural areas. Epidemiological studies suggest that fine particulate matter from combustion processes such as coal fired power plant (< 2.5 μm in diameter) can increase CV health risks [48]. It has been recently reported that exposure to concentrated ambient coarse particles (10-2.5μm in diameter) in rural locations is associated with a rapid elevation in blood pressure and heart rates suggesting that coarse particles may contribute to triggering acute CV events [49]. According to data reported by Environmental Protection Agency, there are 931 fossil fuel burning power plants and 16,574 toxic release inventory sites. As agricultural practices shift from small business generated by family unit to large scale corporate, environmental health issues are being magnified as a new controversy, although it provides rural residents with an economic base. In a study which estimated daily measures of particulate matter air pollution, the rate of hospital admission for patients with congestive heart failure (CHF) were significantly correlated with ambient particulate air pollution suggesting that ambient particles, which can be caused by agriculture-related pollution, may lead to hospitalization for CHF by altering cardiac hemodynamics [50].

2.3. Lifestyle Intervention for Cardiovascular Disease

Lifestyle interventions have been promoting behavior changes in patients with CVD and reducing weight and other CVD risk factors. Since it has generally been implemented in urban research settings, the feasible and sustainable evidence for rural CVD can only
be found in previous interventional studies.

2.3.1. Physical Activity Focused Intervention

PA has been demonstrated to improve CV health in various aspects. American College of Sports Medicine (ACSM) recommendations call for adults to participate in PA for 30 minutes per day, 3 to 5 days per week with moderate intensity (3-6 METs) to improve health-related benefits including CV health [51]. In particular, aerobic exercise is inversely correlated with HTN, T2DM, stroke, and obesity by preventing arterial dysfunction as well as other factors which influence CVD [52]. Despite the benefits, physical inactivity is the biggest problem in rural areas such as Appalachian regions, Southern and Western parts of United States in particular [53]. In contrast, PA interventions for urban areas have improved public health and human well-being by preventing CVD. One successful attempt was found in DPP, which is a goal-based intensive behavioral intervention for diabetes patients with a 16-session core curriculum [54]. Every exercise session was supervised by exercise physiologists and focused on achieving 7% weight loss from initial body weight. PA was described to meet 150 min of moderate PA (e.g. brisk walking and bicycling) to consume 700 kcal/week. Although it has successfully prevented or T2DM and metabolic syndrome (MetS), cost-effectiveness of its implementation and sustainability of behavior change have not been demonstrated [55]. Another PA focused intervention has been found in school-based interventions. Findings from urban school-based PA interventions have shown that PA is effective in decreasing an obesity rate which is a major contributor to chronic CVD [56]. A school-based PA intervention has suggested that playground sports in urban school
are more effective in increasing moderate-to-vigorous PA than nature-based orienteering in rural areas showing that there is a positive correlation between fitness and exercise intensity in urban areas, whereas no association was found between nature-based orienteering and physical fitness in rural areas [57]. ParentCorps designed to promote foundational parenting and parent knowledge has increased PA in early obesity childhood living in low-income communities in urban areas suggesting that parent overweight and parenting practices may affect young childhood obesity [58].

Early prevention is critical to prevent obesity, especially in Hispanic preschool children, who lead to one of the highest rates of obesity. In southwestern United States, Vada Saludable was conducted to improve maternal PA for low-income Hispanic mothers with preschool children at a large urban health center [59]. The problem is, however, half of individuals who initiate PA do not maintain their increased PA levels and return to sedentary lifestyle within six months. The Booster intervention recommended by United Kingdom National Institute of Health and Clinical Excellence suggested that a face-face intervention is necessary for sustaining the effect of intervention for a long period of time [60]. The study evaluating the impact of a comprehensive community-based PA intervention in urban communities found the level of PA was significantly increased after a two-year community-based intervention on PA.

2.3.2. Nutrition Focused Intervention

Unhealthy diets directly influence CV disorders [61]; however, it is also a key modifiable factor to improve CV health. Some studies suggest that CVD risk factors has increased due to the westernized diet and urbanization [62]; whereas other evidence revealed that
urbanization play an important role in the decrease of CVD risks [63]. Although previous studies are controversial, there have generally been positive results of nutrition focused intervention in urban areas [64]. Nutrition interventional studies have generally been conducted with PA interventions. Similar to DPP, Look Action for Health in Diabetes (Look AHEAD) has been conducted for CVD patients, especially for patients with diabetes [65]. The difference is, however, the primary method of weight loss is to restrict caloric intake to achieve weight loss (at least 7% of weight loss and encouraged to lose 10% or more of initial body weight) rather than focusing on PA interventions. Look AHEAD project also includes PA, but it is an unsupervised-PA intervention with a goal of 175 minutes of moderate intensity per week. Also, occupational activities are not counted towards the PA goal in the study. Another successful nutritional intervention with PA for African American women in the Boston area found that weight and CV risk factors decreased after culturally tailored weight management program in an urban community [66]. A 6-week program which met weekly to provide 45 min of structured PA and 45 min nutrition education for girl students increases in daily PA and decreases in body mass index from baseline to the 12 month follow-up period in urban school. Few studies have elucidated nutritional effects itself on CVD without PA interventions. One study which suggested the effects of medical nutrition therapy without PA interventions in preventing urban African American with T2DM revealed that it has beneficial impact on glycemic control, weight, lipids, and blood pressure in urban African Americans with T2DM [64].
2.3.3. Smoking Cessation Focused Intervention

Although smoking rates have declined over the past several decades, it is still the leading cause of CVD in both rural and urban areas [67]. Approximately 12 million smokers live in rural communities in the United States; however, few studies have examined smoking in rural areas. It has been reported that smoking cessation is associated with reduction in relative risk of CHD mortality by 36% compared with those who do not quit smoke, and myocardial infarction (MI) has also decreased after smoking cessation [68]. There have been studies addressing effective interventions to quit smoking for reducing CVD mortality in patients who smoke in urban areas. A number of studies have documented that physician-delivered counseling interventions are effective [69]. Generally 10% to 20% of cessation rates have been yielded after physician-based primary care interventions [70]. Another successful intervention was conducted by tobacco cessation counselor to educate behavior modification, stimulus control and nicotine fading. The study showed that smoking cessation interventions with a duration of 3 months reduces smoking in patients with CVD, in turn, clinical cardiac event rates and death [71]. Recent attempts have found an automated telephone disease management (ATDM) used to monitor and manage smoking cessation, as well as other chronic diseases, showed it has beneficial effects on smoking cessation in patients with CHD [72]. Ninety-nine smokers with CHD were randomized to either usual care with counseling and nicotine replacement therapy or an ATDM group which consists of automated telephone follow-up calls at 3, 14, and 30 days after discharge with usual care. The rates of quitting in the ATDM group were greater compared with the usual care group suggesting that an AVR system may be an effective strategy for decreasing
tobacco rates. It has also been reported that the satisfaction rate of ATDM in patients with diabetes from diabetes care was approximately 85% suggesting that ATDM has positive impacts on diabetes care outcomes [73]. Similar results were found in another study focusing on patients with hypertension who used a computer-controlled telephone system [74]. However, aging factor should be considered when ATDM is used. Smokers recruited from urban communities in underserved locations showed that older participants aged over 40 years were particularly interested in the cessation products and resources, and their attitudes on phone contacts and social media usage were lower than participants aged 18-39 years who preferred mobile phones health messages [70]. Recent studies focus on web-based or internet-based smoking cessation interventions, and it appear to be possible strategies to reduce the CVD mortality [75, 76].

2.3.4. Stress Management Focused Intervention

Recent evidence indicate that psychosocial stress contributes to CV health [77]. Previous studies revealed that several CV events were associated with chronic psychosocial stress, and long-term chronic stress can induce high blood pressure [78] [79]. Patients with ischemic heart disease who participated in the stress management with aerobic exercise training had greater improvement in flow-mediated dilation (FMD), baro-reflex sensitivity and heart rate variability after a 16 weeks of intervention [80]. Patients were educated about therapeutic techniques which includes monitoring irrational automatic thoughts, developing alternative interpretation of situations, progressive muscle relaxation, and problem solving. It has been suggested that the
transcendental meditation (TM) program, which is one of the relaxation therapies, reduce CVD risk factors such as HTN, myocardial ischemia and atherosclerosis by reducing physiologic arousal. Patients with CHD who carried out TM for 20 minutes twice a day while sitting with eyes closed showed a 48% reduction in the risk for clinical CV events by decreasing blood pressure and anger scores [81]. Further, a recent study evaluated the long term effects of TM in older subjects with hypertension by decreasing hypertension by 30% compared with other usual care implying that TM is a useful approach for hypertension [82].

2.4. Community-Based Participatory Research for CVD

CBPR is a collaborative approach of research translation that incorporates researchers with local community by taking into account the context and dynamics of communities [83]. In order for CBPR to be successful, community leaders and other community organizations should participate in the research with a consideration of local infrastructure and health resources. Religious or civic organizations can also contribute to the success of CBPR [84]. It has been suggested that CBPR can be a better approach when it includes community-based screening to determine eligibility in churches, worksites, and local hospitals since social cohesion is established with local organization in rural areas. Also, community health workers are important position to conduct a community-based intervention since they can engage patients with shared language, culture and value of local resources and health issues [85]. A successful case of CBPR was found in a community-based modified Diabetes Prevention Program group lifestyle balance intervention that has been carried out in an urban area [86].
Participants who enrolled in urban medically underserved community reduced at least 5% of their body weight with reduction in waist circumference, blood pressure, triglycerides, and HDL cholesterol levels and improve metabolic syndrome parameters in a community setting. This study suggested that translating a diabetic intervention into the community needs to consider diverse populations, local health resources, and selected nonclinical screening sites. Although previous translational lifestyle interventions have been successfully conducted in a variety of urban settings, few studies have shown that CBPR can be effective in enhancing rural CV health. The PILI Ohana Project (POP) which includes in Native Hawaiians and Pacific Islanders, who have a higher prevalence of obesity, engaged a family member to conduct a community-focused weight loss maintenance intervention, delivered in six sessions over 6 months [34]. It was a successful approach to decrease obesity; however there were several limitations. Subjects were required to volunteer in morning screenings, therefore influencing the small sample size of the cohort. In particular, the participation rate in males was 26%, which suggests that recruiting the same percentage of male and female in subjects is another limitation in CBPR. They also suggested that the effective translation of a lifestyle intervention in rural areas should be conducted with local community members who have a specific consideration about characteristics of population and health resources in their community.
Chapter 3

Methods
3.1. Ethics and Medical Screening

Prior to participation, all subjects were informed about the purpose of the study, discomforts, benefits, compensation, and various changes or symptoms that may occur during the procedures. A written informed consent was approved by West Virginia University Institutional Review Board (IRB# 1406327034 H-24120) and administered to subject before participation in the study. All participants were able to ask questions related to the research and ensured that all subjects understand the information. The potential subject signed the written informed consent form. The identity of the subject was kept confidential by assigning each subject a specified identification number for use throughout the study. The CVD patients and their family members were recruited through a community health worker who served as a patient navigator at Roane County Family Health Care (RCFHC). Individuals were included in the study if they had CVD including T2DM, HTN, and obesity; and their partner are willing to be a part of the project. Subjects with neurological impairment, cancer, diabetic complications, pregnancy, and uncontrolled hypertension (SBP >190mmHg) were excluded.

3.2. Study Design

The rural multi-lifestyle intervention, entitled “rHeART (rural Health/Heart Accelerating Research Transition)”, was developed by multiple research teams including West Virginia University (WVU) School of Medicine Division of Exercise Physiology (WVU EXPH), WVU School of Osteopathic Medicine (WVSOM), WVU Prevention Research Center (WVU PRC), and Mid-Ohio Valley Health Department (MOVHD) in close collaboration with a local community resident and a patient navigator who is a registered
nurse at RCFHC. RCFHC was used as a practice-based research network which identifies the problems that arise in daily practice and applies new practice in actual care. We discussed together to identify barriers to local facilities, resources, intervention materials, and successful approaches to change the research subjects’ lifestyle behaviors based on the principle of CBPR. Among a variety of lifestyle interventions which have been successful in urban areas, the DASH diet was selected to be administered because it is appropriate for diverse CVD patients. The DASH diet intervention is not only focusing on weight loss, but also takes into account the intake of sodium and potassium as well as the intake of healthy vegetables and fruits [87]. Due to the high prevalence of smoking and stress in rural areas and their strong correlation to CVD, we also added a smoking cessation intervention and a stress management [88]. WVSOM provided instructions to local health workers from MOVHD on how to properly intervene with the subject’s lifestyle, how to continue to monitor the patients, and how to sustain the projects. MOVHD delivered this multi-lifestyle intervention to the participants. By allowing the local health workers from MOVHD in their community to deliver the lifestyle intervention, it is more cost-effective, sustainable and expandable. The first implementation of this pilot study, “Phase 1” included a smaller population and a shorter period of time compared to the full intervention which will include a larger population and a longer period of time. All CVD patients and one of their family members underwent 10-weeks of multi-lifestyle interventions based on the DASH diet. The key feature of the rHeART study was to involve the patients’ family members into the study which will promote healthy lifestyle changes in their home environment. Before and after the intervention, subjects completed several health-related surveys which included
questions regarding nutritional habits, PA, tobacco use, and level of stress. Also, we measured patients' body composition and administered a venous blood draw for lipid panels and blood glucose levels, followed by several non-invasive CV measurements before and after the intervention. The diagram of rHeART are outlined in Figure 3.1.

![Figure 3.1. Schematic Diagram of rHeART Study](image)

**3.2.1. Community Barriers Assessment**

Rural health researchers frequently encounter barriers related to the lack of participant accessibility to local health care facilities. Previous rural health research has reported problems with accessibility to public transportation and healthcare infrastructure [89]. In particular, the distance to community health centers is the biggest challenge to rural medical research [90]. This implies that potential subjects may not be included in the
study because of lack of transportation, even if they are eligible to participate in the study. To prevent eligible participants from discontinuing the study, we identified barriers and assets to implementing this project and identification of these barriers was used to adapt the intervention. For example, a free local bus which operates Monday-Friday was assessed and information about public transportation was provided if the subject does not have their own vehicle. The best walking pathways were also evaluated to provide patients who live in walking distance to reach RCFHC by foot to increase their transportation-related PA.

3.2.2. Barriers to Recruitment and Retention

Recruiting participants is a fundamental element of clinical research; however, it is also a main barrier to rural CV health studies since rural populations have their own perceptions, social/cultural values, attitudes and behavioral patterns [91]. Rural residents generally assume that they are healthier than their actual health status. As a result, they are less likely to participate in interventional studies [92]. It has also been found that rural populations do not fully trust the research team or the confidentiality of the research [93]. In order to recruit rural populations, our study engaged a culturally-sensitive community health care worker who could provide guidance as a patient navigator, and minimize cultural differences between the research team and subjects.

3.2.3. Target Community and Subjects

The target community was selected to represent rural America. The MOVHD covers ten counties including Calhoun, Pleasants, Roane, Jackson, Gilmer and Mason counties.
Among those counties, Roane County was defined as a rural area because of the population of ≈14,000 people and a high prevalence of diabetics (14.7%), HTN (40.2%), obesity (34%), and hypercholesteremia (44%) with older populations below average socio-economic status and physical inactivity. Also, the local farmers market was well established in Roane County, so it was targeted to improve participants’ nutritional status.

Both a reactive approach and a proactive approach were used to recruit subjects to the intervention. Both a reactive approach which informed subjects of intervention about the intervention program via brochures, flyers or advertisements, and a proactive approach which contact potential subjects directly was used to recruit CVD patients [94]. Flyers were put in a community health care, a pharmacy, a grocery store, and a patient navigator received calls inquiring about the study. The patient navigator also directly contacted CVD patients and offered the lifestyle intervention to them. After participants were engaged in the study, a patient navigator provided support to maintain their voluntary participation throughout the intervention by building partnerships between the patient and the health care group. Ten CVD patients and their family member were screened, yielding 20 individuals screened. Specific inclusion / exclusion criteria are outlined in Table 3.1.

Table 3.1. Inclusion and Exclusion Criteria
**Specify inclusion criteria:**
Diagnosed with CVD as defined by one of the following:

a) Prior MI (> 2 months)
b) Revascularization procedure for coronary disease (> 2 months)
c) Ischemic heart disease
d) Stroke (> 2 months)
e) Type2 diabetes
f) High BP >140/90 or on HTN therapy
g) Obesity

**Specify exclusion criteria:**
1) Uncontrolled HTN SBP>190 mmHg
2) A serious life-threatening non-cardiac co morbidity with a life expectancy <5 yrs
3) Neurological impairment
4) A change of cardiac/vascular medications in the past 2 months.
5) Pregnancy
6) Cancer requiring treatment or recently completed treatment (last 2 months)
7) Diabetic complications
   a) Diabetic ketoacidosis
   b) Retinopathy
   c) Liver dysfunction
   d) Peripheral neuropathy
8) Illicit drug abuse
9) They do not speak English and are not capable of understanding the study risks

3.2.4. Intervention Procedures
Participants and their family member performed a 10-week multi-lifestyle educational intervention. From MOVHD, local community health providers who were trained by the WVSOM to deliver the core curriculum to achieve the lifestyle goals educated participants. All participants were instructed to increase PA, to apply new dietary skills, and manage stress by taking educational sessions, 1 day per week, lasting for 1 hour. The first 5 sessions included education about CVD, nutrition, PA, tobacco issues, and how to self-monitor food intake. The last 5 weeks focused on how to manage psychological and motivational challenges to maintain improved lifestyle behaviors for a long period of time. All participants were encouraged to achieve their PA 150 minutes/week of moderate exercise as recommended by ACSM and instructed to perform PA 10 minutes short bouts at least so that they increase the total amount of PA [95]. Subjects were able to choose the type of exercise so they could utilize local health facilities that were available to them in their area. However, information about the type of PA and local community health facilities (free or charged) such as free Zumba classes and free membership to RCFHC gym were provided. The dietary intervention increased subjects’ knowledge of dietary information so that they could make better food choices. Subjects were guided to reduce intake of fat, red meats, sweets, sugared beverages and sodium (<1500mg/day) and increase whole grains, poultry, fish, and nuts with food knowledge and food items in grocery shopping. Community health educators accompanied the participants to the local grocery stores and educated them how to obtain healthy food during their grocery shopping. Healthy cooking classes were demonstrated to provide health food recipe. Smoking cessation intervention was conducted using the 5’A principle (Ask, Assess, Advise, Assist, and Arrange) principle to
promote smoking cessation [96]. Subjects were able to enroll in a local tobacco prevention program if they were interested in giving up tobacco products. Stress management education was delivered by local health educators, and was used to educate participants on common signs of stress, how to improve sleep quality, and relaxation techniques. For example, common signs of stress, how to have good sleep, and ways to get relaxation were delivered by local health educators.

Figure 3.2. Intervention at RCFHC

Table 3.2. rHeART 10 session Core Curriculum
**Session 1. Introduction to the CV health**

Help the patients have a better understanding of CVD including hypertension and obesity. Patients complete the form of health history assessment and self-evaluation of CV risk.

**Session 2. Healthy lifestyle behaviors**

Introduce the information of DASH diet, advantages of exercise, and self-monitoring of PA. Patients evaluate their regular meal patterns and the amount of PA, and build their own PA goals.

**Session 3. Modify a Recipe**

Teach how to modify their recipe to lower the intake of fat, calories, sugar and sodium. Share a specific healthy recipe and demonstrate the patients on a virtual tour of a local grocery store in selecting the best choices from those foods.

**Session 4. Start PA plan**

Introduce the basic concepts of PA and help the patients learn to overcome local barriers to exercise in the community. e.g. free membership of local exercise facilities and exercise classes in Roane County.

**Session 5. Smoking Cessation and Prevention**

Highlight harmful effects of smoking on the body and the benefits to quit smoking. Explain how to build a quit plan and share with the patients free tobacco quit program in West Virginia and a federal government site available.

**Session 6. Managing Your Blood Pressure**

Introduce the basic principle of HTN medicine (e.g. how it works for your BP), herbal/supplement treatment of HTN. Patients evaluate their current medication for
HTN and are aware of how to self-manage their BP.

**Session 7. Stress Management**

Present strategies for managing stress including how your body’s response to stress for hypertension or CVD and tips for a good night sleep. Practice the relaxation exercises and breathing with the repetition of a word, sound, phrase or muscular activity.

**Session 8. Problem Solving**

Provide potential community barriers/solution to diet and PA plan. Patients write a list of their individual DASH assets/barriers. These can be supportive equipment, knowledge, and people characteristics which are supportive or negative.

**Session 9. My Health Goals**

Enhance motivation for patients to be active on their personal health goals and refine their goals so that they maintain their new lifestyle even after the intervention is completed. Each goal meets the IMPACT (Improve, Measurable, Positively, Achievable, Call forth actions, and Time limited) criteria.

**Session 10. Review**

Brief review and answer the question regarding PA, nutrition, tobacco cessation, and stress management. Perform self-evaluation on how much the participants change their lifestyle and set a long term goal to maintain their new lifestyle.
3.3. Feasibility and Acceptability Assessment

This section describes the assessment of the feasibility and acceptability of this pilot study. Feasibility was judged based upon the overall recruitment strategies, the retention rate, and willingness of participants to engage in the studies with their family members. Acceptability was estimated on the basis of participants’ perception/feedback about the intervention using questionnaire which scales satisfaction of participants and instructors [97].

As a part of the pilot study, the satisfaction of participants was evaluated using a questionnaire developed by using key questions of validated job satisfaction index. Patients’ satisfaction was evaluated to identify issues about the intervention environment and general services such as quality of curriculum and educators. Principal components of the participants’ questionnaires identified several factors related to the core curriculums, content, information, difficulty, and usefulness. Open-ended questions were used to identify feedback and recommendations. The questionnaire participants’ satisfaction comprises of 11 statements which asked the participants to rate on a five-point scale from strongly agree to strongly disagree, and three open-ended questions which asked the participants to state whether there were anything about they liked or disliked about the interventional study, and their opinion and recommendations. The questionnaire for health educators was developed to measure effectiveness of the intervention using 17 multiple choice questions and 3 open-ended questions. This questionnaire discussed the interaction between participants and educators, barriers of delivering the educational intervention, and the development of the core curriculum.
3.4. CV Physiological Measures

All CV assessments including Endopat, carotid intima media thickness (cIMT), carotid-femoral pulse wave velocity (PWVcf), blood pressure, and pulse wave analysis (PWA) were obtained using a non-invasive technique for assessing CV function after a minimum of 15 minutes of quiet rest, with dimmed lights, except for 6 min-walk test. Central aortic pressure and hemodynamic indices i.e. augmentation index (AI), augmentation pressure (AP), sub-endocardial viability ratio (SEVR%), systolic/diastolic pressure time index (PTIs/PTId), and ejection duration index (ED%) were derived from PWA of the right radial artery with the SphygmoCor System (AtCor Medical Pty Ltd, Sydney, Australia). Participants were asked to abstain from alcohol, caffeine, vitamins, and any other supplements 24 hours prior to assessments. All post-training measurements were conducted after 10 weeks of life-style intervention at the same time of day for each subject.

3.4.1. Body Composition

Anthropometric assessments including height, weight, along with hip and waist circumferences were measured to identify body mass index and obesity. Body fat percentages were obtained using a bio-electrical impedance system (Life measurement, Concord, CA, USA).

3.4.2. Arterial Geometry

CIMT of the right common carotid artery (CCA) was measured using B-mode ultrasound (GE Vivid I; GE Healthcare, Chalfont St Giles, UK) which directly scans carotid arteries
in the supine position. The ultrasound scan of cIMT provides lumen diameter, intima-media thickness, and presence and extent of plaques. Large interventional studies have shown that a reduced cross-sectional cIMT is significantly correlated with decreased CVD risk factors. To measure cIMT, carotid bifurcation should be detected as a reference (Figure 3.3). Digitally stored images were manually analyzed from 10mm proximal to the bifurcation point for the start of the measurement using ultrasonic calipers. The calculation of cross-sectional area of right carotid artery was \[\left[\frac{\text{maximal lumen diameter}}{2}\right]^2 \times \pi - \left(\frac{\text{maximal lumen diameter}}{2} - \text{cIMT}\right)^2 \times \pi\] [98].

![Figure 3.3. Carotid intima-media thickness](image)

**3.4.3. CV Function**

Blood pressure was measured by a trained exercise physiologist in supine position. PWA was non-invasively evaluated using applanation tonometry over the right radial artery. AP, the increasing part of pulse waveform that contributes to systolic blood pressure, and AI calculating AP divided by pulse pressure were measured in triplicate, and the mean values was used for analysis. SEVR% indicating myocardial perfusion and contraction (supply to demand ratio) was calculated by the diastolic area under
pulse wave curve divided by the systolic area of under pulse wave curve. The reliability of the PWA signal was measured by the operator index which reflects wave form variability and the acceptable range was set between 80% and 100%.

PWVcf were obtained to measure the degree of arterial stiffness using applanation tonometry that generates the aortic pressure waveform by converting the peripheral waveform to a central waveform (Figure 3.4, 3.5) [99]. SphygmoCor system synthesizes ascending aortic pressure waveform from the radial pressure waveform that does not differ from that of an intra-arterially recorded wave using a validated generalized transfer function that has reproducibility under major hemodynamic changes. It has been generally shown that patients who have problems with arterial function present increased PWVcf and abnormality in AP, and AI.

![Figure 3.4. PWA and PWV at RCFHC](image)
3.4.4. Endothelial Function

Endothelial function was non-invasively measured using EndoPAT device (Itamar Medical, U.S.) which detects plethymographic pressure changes (vaso-reactivity) in the finger tips with pneumatic probes (Figure 3.6, 3.7, 3.8) [100]. Using the same mechanisms of shear stress traditionally measured by flow mediated dilation (FMD), reactive hyperemia index (RHI), which translates arterial pulse to peripheral arterial tone (PAT) after 5 min occlusion of brachial artery, was obtained to determine endothelial dysfunction. Right side arm is occluded because of experimental convenience and left arm is control for changes in vascular tone. Each recording has total 16 minutes including 6 minutes of baseline measurement, 5 minutes of occlusion with 250mmHg of blood pressure, and 5 minutes post-occlusion measurement. All subjects were asked to stay their arm as much as possible after deflation of blood pressure cuff An RHI below 1.67 is generally thought to be endothelial dysfunction [101].
Figure 3.6. Endothelial function measurement at RCFHC

Figure 3.7. Results of endothelial (dys)function derived from EndoPAT™
3.4.5. Biomarker and Framingham Risk Score

Venous blood was drawn to identify total cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides (Tg), Hemoglobin, glucose, and insulin using standard techniques after a 12-hour overnight fast. Framingham risk score (FRS) was calculated for each subject to predict 10-year risk of CVD using age, sex, history of smoking, presence of diabetes, blood pressure, fasting serum total cholesterol, and HDL cholesterol. Based on the Framingham study population, the web-based calculator uses an algorithm that calculates the score assigned for each risk factor ranging from the lowest for the least risk to the highest for the greatest risk [102].
3.4.6. Physical Performance

The 6-minute walk test (6MWT, Figure 3.9) was used to compare functional capacities before and after the intervention. 6MWT has previously been used to indicate functional status of HF and peripheral vascular diseases, as well as chronic obstructive pulmonary disease and pulmonary hypertension. It has been shown that 6MWT is significantly correlated with peak oxygen uptake via cardiopulmonary exercise test. Also it is easy to perform, cost-effective, and reproducible. All participants were asked to walk back and forth over the distance of 30 meters as far as they can during 6 minutes [103]. During the test, subjects were instructed to wear comfortable footwear and stop walking as necessary. The total walking distance was recorded after 6 minutes.

Figure 3.9. 6-minute walk test at RCFHC
3.4.7. PA Measures

The amount of PA was measured using the long version of the International Physical Activity Questionnaire (IPAQ) which has been valid to measure total level of PA for adults in previous studies [104]. It includes four different domains including occupational PA, transport-related PA, housework-related PA, and recreational PA. The estimate of total PA per week was calculated as duration x frequency per week x metabolic equivalents (METs), expressed as MET-minutes per week (MET·min·wk⁻¹). IPAQ was designed to collect weekly PA levels in populations among 15 to 69 year old adults in diverse settings with appropriate categories of intensity such as low, moderate (3-6 METs), and vigorous (> 6 METs) PA. Depending on the domain, energy expenditures were transformed using METs, which was calculated based on previously published values [105]. For example, vigorous PA in work domain is 8 METs, whereas vigorous PA in housework is 5.5 METs. The questionnaire also included questions about time spent sitting at a work, at home and during leisure time to indicate their sedentary behavior.

3.5. Psychometric Properties

3.5.1. Health-Related Quality of Life-14 (CDC HRQOL-14)

The generalized assessment of well-being was measured using the Center for Disease Control and Prevention Health-Related Quality of Life-14 (CDC HRQOL-14), which measures physical, functional, psychological, and social well-being (See Appendix A). Previous studies have shown that lower self-esteem and adverse psychosocial consequences were found in patients with depression, obesity, and aging [106].
3.5.2. Depression Anxiety Stress Scales-21 (DASS-21)

Psychometric properties were measured using the Depression Anxiety Stress Scale 21 (DASS-21). DASS-21 is a shorter version of DASS, which has 42 items self-report measure of depression (See Appendix B). Therefore, DASS-21 is more acceptable for populations who have limited time and concentration. DASS-21 has widely been used to identify the symptoms and diagnosis of both anxiety and depression as well as a tension/stress using 21 items, ranging from 0 to 3 scales. It has been demonstrated that DASS-21 can reliably measure depression, anxiety and stress in clinical and non-clinical populations older than 18 years of age. High score on DASS-21 are significantly correlated with a diagnosis of anxiety disorder and panic disorder [107].

3.5.3. Mindful Attention Awareness Scale (MAAS)

The Mindful Attention Awareness Scale (MAAS) is one of the promising psychometric measures designed to assess a receptive awareness and attention to present events (See Appendix C). MAAS is consisted of both general and situation-specific statements referenced by a 6-point Likert scale. MAAS score is calculated by a mean of the 15 items. A higher score is a predictive of greater mindfulness, and the average score is derived from a large sample of US adults is 4.22 [108].
3.6. Statistical Analyses

Feasibility of this study was assessed using descriptive statistics. Responses to the multiple items on the participant's/educator's satisfaction on the questionnaire were coded from one to five. A higher score indicated greater satisfaction. Mean and standard errors were given as descriptive statistics. A paired t-test was used to identify the improvements in PA, nutritional status, and stress as well as the effects of lifestyle intervention on CV parameters in CVD patients and their family member. The analysis was done in three categories; CVD patients separately, their family member separately and then both combined. Further analysis was completed to investigate the lifestyle intervention depending on their attendance; full attendance, 1 class missed, 2 classes missed using a paired t-test. Statistical analysis was performed with SPSS statistical package version 22 (SPSS, Chicago, IL). Significance level was $P<0.05$. 
Chapter 4

Results
4.1. Feasibility and Acceptability Measures

4.1.1. Recruitment and Retention Rates

To evaluate the feasibility of this pilot study, recruitment and retention rates were calculated. Recruitment rate is shown in figure 4.1 which refers to the number the number of people contacted divided by the number of people screened. Retention rate which represents the number of interventions sessions attended were obtained. Seventeen potential subjects contacted our patient navigator in this study and 10 patients with CVD were screened with their family member, yielding 20 individuals screened (recruitment rate 59%). Of 20 individuals screened, 17 patients were enrolled, 2 individuals dropped out, and 1 patient was excluded due to the severe diabetic complications. Seventeen participants retained through the intervention, achieving 100% of the retention rate.

![Recruitment Rate and Retention Rate](image)

Figure 4.1. Recruitment Rate and Retention Rate

4.1.2. Participants Satisfaction Measures

Following the 10 weeks of lifestyle intervention, all 17 participants responded to the satisfaction questionnaire (100% responded). The first section of the questionnaire
consisted of six items including overall rate of satisfaction, PA and nutrition information, difficulties, and the length of the course. The data showed that mean scores was 4.3 out of 5. On the training methods section which includes the training manual, handouts, the group sessions, exercise portion, slide presentations, instructional activities, and other materials, the average score was 30 of 35. A total of 94% participants responded that they would like to maintain their ‘new’ lifestyle behaviors even if they would not receive compensation from the research team. Eighty four percent of participants reported that 10 weeks was right length, 11.8% reported that it needs to be 1-2 weeks longer, and 5.8% who reported 3-4 weeks longer. On the open-ended questions which asked participants the best factor in the rHeART project, over half of the participants (59%) responded that they were able to change their eating habits due to the information provided by health educators. Thirty five percent of participants reported that group interaction during the intervention was the best factor and 6% were satisfied with the politeness and helpfulness of our research team. When participants were asked if they could change rHeART project, three individuals recommended to make the project with longer period of time, 12% reported that more group interactions may be needed.

4.1.3. Providers’ Satisfaction Measures

Three providers returned questionnaires to the research team for evaluation. The first section of questionnaire consisted of 4 items asking about overall satisfaction with the intervention, our research team, difficulty, planning, and recruitment showed that mean scores were 13 out of 15. The mean score for the evaluation and implementation sections was 37 out of 40. These sections included the importance of the study,
classroom size, an appropriate number of participants, the intervention facilities. All providers strongly agreed (full score) with the classroom size and the number of participants in the study. All providers participated in this project because of their interest in lifestyle intervention. None of the providers experienced cultural differences with participants when asked via questionnaire. Two providers responded that there was no difficulty in referring patients to the course. One reported patient work obligations as a difficulty. On the open-ended questions, all providers would more than likely to refer patients in the future, and they evaluated rHeART program was a well-planned intervention. All providers also suggested that the most important factor in the success of the project was interaction between participants and participants, participants and providers, and providers and providers.

4.2. Characteristics of Study Participants
Seventeen individuals (15 females, 2 males) participated in this study. The mean age of participants was 49.5. Forty seven percent were between 40 and 49 years, 41% of individuals who were aged > 50 years, and 12% of participants were 35-40. The study population included 100% Caucasian individuals with a mean BF% of 47.4% and a higher BMI (37.2 ± 1.9). Eighty eight percent of participants had obesity estimated by waist circumference defined by the National Cholesterol Education Program: Adult Treatment Panel III (NCEP APT III). At enrollment, 10 subjects (59%) out of the 17 individuals were considered to have metabolic syndrome (MetS) defined by NCEP APT III, with 88% of obesity, 47% of dyslipidemia, 35% of hyperglycemia, 35% of hypertension, 47% of low HDL cholesterol, and 35% of hyperglycemia (Figure 4.2).
Of participants, 29% were divorced/separated and 18% did not have access to the Internet at their home. In terms of their job distribution, 88% were currently in the workforce and 12% were retired. Of the working participants, 47% were health professionals, 13% were homemakers, 13% were managers or educators, 8% were working for services, and 19% of individuals responded “other” but did not specify their occupation. When participants came to the RCFHC to participate in the study, 76% were able to arrive within 20 minutes from their home, 18% were living within 20-40 minutes away, and 6% were taking 40-60 minutes to travel to the clinic.

Based on HRQOL-14, 41% of participants believed that their general health was good (3) (ranging from excellent (5) to poor (1), 41% thought their health was fair (2), 6% were excellent (5), 6% were very good (4), and 6% were poor (Figure 4.3.). On the questions related to mental health status, the mean of depression was 2 days and anxious was 6 days per month on average. On average, all participants were having 4.6 of 13 chronic disease risk factors such as aging, family history, high BP, cholesterol, T2DM, sedentary lifestyle, eating habits, and alcohol intake. All participants had their family medical history for CVD including CHD, high blood pressure, cancer, stroke, chronic obstructive pulmonary disease, T2DM, and gallbladder disease (Figure 4.4.). The current status of nutrition prior to participation in the study was quantified, and it showed that subjects ate 1 cup of fruit (e.g. 1 medium apple, banana, orange) and 2 cups of vegetables (e.g. 1 cup of vegetable juice), 2.5 ounces of bread and cereal, 1.8 ounces of red meat, 1.7 ounces of fish and poultry, and 1.7 cups of dairy products per day.
Figure 4.2. CVD Risk Factors of Participants

Figure 4.3. Subjects’ Perception of Health
4.3. Clinical Characteristics of CVD patients and family members

The changes in traditional CV parameters between pre and post are displayed in table 4.1. Our data showed that there is no significant difference in clinical parameters when the analysis was performed in CVD patients and family members combined or separately. However, when we analyzed the participants’ characteristics depending on their attendance (e.g. full attendance, 1 class missed, and 2 classes missed) the weight (110.9 ± 26.2 to 109.5 ± 25.3) and BMI (38.6 to 38.2) were significantly (p<0.05) decreased with a tendency of improved HR (p=0.08) in the participants with full attendance (Figure 4.5). However, there was no significant difference in participants who missed 1 or 2 classes.

Figure 4.4. Family Medical History
Figure 4.5. Mean comparison of BMI between pre and post measurements in participants with full attendance. Data are expressed as mean ± SE. Significant difference between the two measurements at p<0.05.
Table 4.1. Clinical Characteristics of All Participants (CVD patients and family member combined) before and after intervention

<table>
<thead>
<tr>
<th>Variables</th>
<th>Pre</th>
<th>Post</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>49.5 ± 2.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (% female)</td>
<td>71 %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>Caucasian (100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>12.5 ± 0.8 years (12 – 15 years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height (cm)</td>
<td>167 ± 6.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>105.4 ± 5.9</td>
<td>104.6 ± 5.7</td>
<td>0.06</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>37.2 ± 1.9</td>
<td>36.9 ± 1.9</td>
<td>0.09</td>
</tr>
<tr>
<td>HbA1C (%)</td>
<td>6.19 ± 0.2</td>
<td>6.15 ± 0.4</td>
<td>0.36</td>
</tr>
<tr>
<td>HDL (mg/dl)</td>
<td>46 ± 3</td>
<td>46 ± 3</td>
<td>0.45</td>
</tr>
<tr>
<td>TCL (mg/dl)</td>
<td>207 ± 14</td>
<td>202 ± 9</td>
<td>0.25</td>
</tr>
<tr>
<td>HR (bpm)</td>
<td>68 ± 2.3</td>
<td>65 ± 2.4</td>
<td>0.07</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>127 ± 2.7</td>
<td>128 ± 3.0</td>
<td>0.33</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>78 ± 6.1</td>
<td>81 ± 1.8</td>
<td>0.06</td>
</tr>
<tr>
<td>MAP (mmHg)</td>
<td>96 ± 1.9</td>
<td>98 ± 2.2</td>
<td>0.12</td>
</tr>
<tr>
<td>cPP (mmHg)</td>
<td>38 ± 2.6</td>
<td>38 ± 2.2</td>
<td>0.49</td>
</tr>
<tr>
<td>AP (mmHg)</td>
<td>11 ± 1.7</td>
<td>11 ± 1.2</td>
<td>0.39</td>
</tr>
<tr>
<td>AGI (%)</td>
<td>27 ± 2.8</td>
<td>29 ± 2</td>
<td>0.12</td>
</tr>
<tr>
<td>PWV (m/s)</td>
<td>7.7 ± 0.4</td>
<td>7.5 ± 0.4</td>
<td>0.17</td>
</tr>
<tr>
<td>RHI (%)</td>
<td>2.4 ± 0.1</td>
<td>2.3 ± 0.1</td>
<td>0.25</td>
</tr>
</tbody>
</table>

Data are expressed as mean ±SE for n=17. No significant change was found in clinical characteristics after 10 weeks.
4.4. Level of PA

As shown in the Figure 4.6, the total amount of PA was significantly (p<0.05) increased in the analysis of CVD patients and their family member combined as compared to baseline (2865 ± 536 to 4673 ± 918). In particular, occupational PA and recreational PA were significantly improved, whereas housework-related PA transportation-related PA were not increased compared to baseline. When the analysis was conducted in CVD patients separately (Figure 4.7.), job-related PA and recreational PA were significantly (p<0.05) increased after the intervention with a tendency of the improved total amount of PA (p=0.06). In the analysis of separate effect of family member, recreational PA was significantly (p=0.05) improved after the intervention (3660 ± 634 to 3998 ± 771), whereas the improvements in other PA were not statistically significant.

The time spent sitting while at work, at home, and leisure time during a weekday was significantly decreased in the analysis of CVD patients and family members combined (375 ± 41 to 293 ± 32 min), whereas the time spent sitting during weekend was not significantly decreased (Figure 4.8.). In the analysis of CVD patients separately, no significant sitting time changes on a weekday was found after the intervention, but there was a trend to decrease the sitting time on weekend. In contrast, no significant sitting time changes was found during weekend in the analysis of family member separately whereas the sitting time on a weekday was significantly decreased after the intervention (381 ± 35 to 259 ±27).
Figure 4.6. Mean comparison of total level of PA between pre and post measurements in CVD patients and their family member combined. Data are expressed as mean ± SE. Significant difference between the two measurements at p<0.05.

Figure 4.7. Mean comparison of total level of PA between pre and post measurements in CVD patients separately. Data are expressed as mean ± SE. Significant difference between the two measurements at p=0.06.
Figure 4.8. Mean comparison of sitting time on a weekday between pre and post measurements in family members separately. Data are expressed as mean ± SE. Significant difference between the two measurements at p<0.05
4.5. Physical Performance

Following the 10 weeks of lifestyle intervention, both CVD participants and their family member showed a significant improvement in physical performance represented by 6MWT. The distance in 6MWT compared to pre-measurements ($p<0.05$) was increased after the intervention from $466.4 \pm 17$ to $503.1 \pm 17$m. Participants showed an average of 37% increase in the total distance.

When the analysis was conducted in CVD patients separately, the distance was significantly ($p=0.05$) improved after the intervention ($461 \pm 15$ to $498 \pm 18$m). However, no significant change was found when the analysis was carried out in family members separately. Also, there was no significant improvement in 6MWT in participants with full attendance.

Figure 4.9. Mean comparison of 6MWT between pre and post measurements in CVD patients and their family member combined. Data are expressed as mean ± SE. Significant difference between the two measurements at $p<0.05$. 
4.6. CV Measures

Our data also showed that PTId was significantly (p<0.05) improved after 10 weeks of lifestyle intervention (Figure 4.10) along with a tendency of improved SEVR% (p=0.07), HR (p=0.07), and diastolic BP (p=0.06) (Figure 4.11). In contrast, no significant differences in other CV parameters related to arterial stiffness were found after 10 weeks of lifestyle intervention compared to baseline values.

When the analysis was conducted in CVD patients and family members separately, no significant changes were found in PTId and SEVR%. However, HR was significantly decreased in family members with a tendency of SEVR (p=0.06). Further, the RHI was not improved in CVD patients and family members combined or separately. Also, carotid IMT was not improved in CVD patients and family members (Figure 4.12).

Figure 4.10. Mean comparison of PTId between pre and post measurements. Data are expressed as mean ± SEM. Significant difference between the two at p<0.05.
Figure 4.11. Mean comparison of SEVR% between pre and post measurements. Data are expressed as mean ± SEM. P-value was 0.07.

Figure 4.12. Mean comparison of RHI between pre and post measurements. Data are expressed as mean ± SE. No significant improvement was found after 10 weeks.
4.7. Framingham Risk Score

Following 10 weeks of intervention, participants had a slight decrease in FRS, which was not statistically significant. When FRS was calculated by lipid levels, there was a bigger trend to decrease in FRS (8.48 ± 1.44 to 8.23 ± 1.48) than the value calculated by BMI (10.15 ± 1.95 to 10.13 ± 1.87) but not statistically significant. When the analysis was performed to investigate the separate effect on CVD patients and their family members FRS was not significantly different. Also, there was no significant change when the analysis was carried out in participants with full attendance, 1 class missed and 2 classes missed.

Figure 4.13. Mean comparison of FRS between pre and post measurements. Data are expressed as mean ± SE. No significant improvement was found after 10 weeks.
4.8. Psychometric Measures

The results show that the state of mindfulness was not significantly affected by the lifestyle intervention. The mean of MAAS was 4.1 ± 0.3 before intervention and changed to 4.3 ± 0.3 after the intervention, but it did not reach statistical significance in both CVD patients and family members. Further, the state of depression, anxiety, and stress measured by DASS-21 did not change statistically compared to baseline measurements in participants with full attendance (0.6 ± 0.1 to 0.5 ±0.1).

Figure 4.14. Mean comparison of MAAS between pre and post measurements. Data are expressed as mean ± SE. No significant change was found after the intervention.

Figure 4.15. Mean comparison of DASS-21 between pre and post measurements. Data are expressed as mean ± SE. No significant change was found after the intervention.
Chapter 5

Discussion
5.1. Feasibility of CBPR-based lifestyle intervention

The results of this pilot study suggest that the implementation of a multi-lifestyle intervention is a feasible approach to improve CV health in a rural area. Reports from previous studies suggest that recruiting rural populations to participate in multi-lifestyle interventions is challenging due to a variety of factors influencing the recruitment and retention in rural areas such as overcoming the significant challenge of earning the trust of the local community members [109]. The specific approach to recruitment and retention we proposed in this study was based on the premise that there are cultural differences between research teams and rural participants. Therefore, we used a patient navigator who is a culturally-sensitive registered nurse from the same community who could act as a neutral intermediate between the rural population and the ‘outsider researchers’. Further, our patient navigator ensured that all participants were satisfied with the research study throughout the 10 weeks of participation in the intervention by communicating with the participants to sustain acceptable adherence rates throughout this study. With that said, we retained 100 % of the participants throughout the 10 week intervention. Consistent with previous studies, the present study demonstrated a successful patient navigator must be interested in local health care, be willing to learn, and have experience with the community which will be considered as necessary criteria for community health workers in next phase of this study. Findings from this study also support that community health workers such as a registered nurse or a dietitian can be used as a patient navigator and an effective recruiter in rural health studies [6].

Accessibility to the intervention center also plays a critical role for a successful
lifestyle intervention in a rural area. In other words, if the location of the intervention center is not convenient for the patient or the research team, it may negatively affect the study outcome. Findings from a previous rural study in central Tennessee revealed that most rural communities had no access to cardiac or stroke centers within a 30 minute drive, and the quantity of those centers did not increase between 1999 and 2010 [110].

To improve the participation of rural populations in preventative interventions, previous rural researchers provided them with compensation for the expenses related to their participation (e.g. parking, mass-transit passes, cab-vouchers, actual transportation to the research site, monetary incentives, and gift cards). These strategies improved subject recruitment and subject retention rates in rural populations, but it is costly [111] [112]. By using a principle of CBPR, a community resident was included into the research team whose key role was to assess and develop a convenient and cost effective means of transportation for the research participants and the research team to the intervention site.

Overall, satisfaction questionnaires of participants revealed that the patients were very satisfied with rHeART lifestyle education sessions based on both qualitative and quantitative analyses. Specifically, the qualitative data revealed that the participants were particularly satisfied with nutritional information and interacting with other participants during the intervention. For example, one participant stated that rHeART was not only a good resources to manage a healthier lifestyle but also a good opportunity for them to interact with other people who were making similar changes. In accordance with this idea, a systematic review suggested that enhancing the interaction
between study participants can also improve the participants’ understanding of intervention through peer support as well as increase retention rates [113]. In addition to the positive responses, some of the negative responses were also helpful and will provide valuable insights when conducting phase 2 of the intervention (e.g. what they disliked and how it could be improved). However, most negative response were about interaction activities among the participants and the short duration of the intervention. Although we were aware of the short duration, phase 1 was a pilot study and phase 2 will consist of a 16 week period. These data will be used to improve the quality of next phase of research which consists of larger populations and longer period of interventions.

Understanding the health care providers’ preferences and dislikes is important for planning the core curriculum, facilities, classroom size, and number of participants [114]. Overall, all of the health care providers who assisted in the study were satisfied. The majority of positive responses were about planning and implementation of this intervention such as the timeline of the project, the support of the RCFHC staffs, and patients’ involvements. Another positive response was that all providers did not have any cultural differences on the questionnaire. This may be due to the cultural appropriateness of the courses and teaching properties because all of the health care providers were from the same community as the participants. Also, the providers’ participation in this study was voluntary and they were interested in providing healthy lifestyle interventions to their community member, which may have contributed to the success of this lifestyle intervention. Although negative responses were rarely observed
on the questionnaires, some of the negative responses were about patient obligations and the lack of interaction activities between patients and providers. Suggestions for what researchers would add to the intervention were to include additional interacting activities between participants themselves and providers/participants and providers themselves. These should be considered prior to the next phase of intervention. For instance, healthy potluck lunch or meeting to share experiences of living with CVD can be included to improve the satisfaction of the participants and providers [115].

5.2. Summary of Study Participants and Intervention Area
Prior to developing the aims of this study, we analyzed the baseline characteristics of participants and the intervention area to determine if the study can represent the general characteristics of rural America. Although there is no clear definition of rurality, the US federal government uses the definition of a rural location as a city comprised of fewer than 2,500 people. The city of Spencer in Roane County consisted of approximately 2,300 people, therefore it can be classified as a rural area. In addition to the population number, we added other important criteria to define rural America such as a high percentage of older individuals, a variety of race/ethnicity, a median household income, median education level, as well as a high prevalence of CVD. The median age in Roane County was 44.4 years old with a higher prevalence of CVD, and median household income was $27,772. Although Caucasians comprise of the majority of the population (98.3%) in Roane County, this does not represent rural areas in America as a whole, but it can represent rural Appalachian regions.
In the current study, the subjects were Caucasian (100%) with a lower educational attainment rate (64.7% had less than a high school education) compared to the average of rural Appalachian education level (23.2% had less than a high school education) [116]. A higher median age (49.5 years) which revealed in the demographic analyses of the participant, and this age is consistent with the characteristics of rural American as a whole. In this study, men were less likely to participate in the study than women (71% of female) which was also the limitation in a previous study. These results suggest that the sample was relatively representative of rural Americans with the exception of tobacco use. All of the participants are non-smokers and only 2 participants were previous smokers.

5.3. Effects of a Multi-lifestyle intervention in rural populations

The data from this pilot study suggests that a multi-lifestyle intervention has beneficial impacts on increasing the amount of overall PA, thereby improving physical performances in rural populations. These results are in line with previous studies which revealed the efficacy of PA interventions on weight loss and cardiorespiratory fitness [117]. However, our results show a significant impact on weight loss, but only in patients with full attendance, suggesting that attendance to the educational sessions may contribute to better outcomes. Although attendance was not correlated with physical performance in this populations, previous studies suggested that self-motivation were highly associated with attendance, therefore affecting greater knowledge gains and CV health [118].
Previous studies reported that physical performance is improved by significant weight loss in patients with obesity [119]. However, it is still controversial whether weight loss itself, independent of other factors, can directly improve physical performance in CVD patients. A recent study suggested that weight loss induced by caloric restriction alone (without exercise) is not associated with improvements in physical performance [120], whereas weight loss induced by an exercise intervention, independent of other factors, can improve physical performance in obese patients. Our study revealed weight loss was induced by multiple factors including exercise, nutrition and stress management which were correlated to the amount of PA, but did not determine if the association between weight loss and physical performance were due to the exercise intervention itself, nutrition intervention itself or combination effects of multiple lifestyle intervention. Also, our study revealed that there was no change in clinical blood markers despite the significant weight loss in the participants with full attendance. While the populations showed a significant weight loss in the patients with full attendance, the average percentage of clinical blood markers was not significantly improved in fully-attended populations. Interestingly, several CV parameters were significantly improved despite the lack of changes in the clinical blood markers such as plasma lipids and blood glucose. Traditionally, it was believed that the effects of exercise were primarily due to critical role of improving clinical blood markers. However, recent evidence suggest that clinical blood markers can improve in less than 50% of CVD patients in an exercise intervention study [121]. Our study also supports the beneficial effects of lifestyle intervention on weight loss, independent of clinical blood markers, in the majority of our study participants.
In this study, the improvements related to CV health were reflected by the increased myocardial efficiency which is represented by PTId (p=0.04) and SEVR% (p=0.07). Previous studies which investigate the coronary circulation and myocardial perfusion in CVD patients have shown that myocardial ischemia (an increase in PTIs and a decrease in PTId) was a well-recognized consequence of severe obesity by the mechanism of oxygen demand and supply [122]. Hollekim-Strand et al. [123] suggested the reduction in myocardial blood flow may be a result of functional and structural derangements induced by fibrosis, apoptosis, and inflammation in the heart and/or the coronary artery. Further, Hafstad et al. [124] suggested that myocardial ischemia eventually leads to an energetically compromised heart with reduced working capacity, thereby preceding the development of ventricular dysfunction. Also, it has been suggested that arterial stiffness is another important independent determinant of myocardial ischemia, because arterial stiffness increases pulse wave velocity (PWV) which augments systolic pressure by increasing myocardial demand and decreasing myocardial supply. Although our patients did not have myocardial ischemia (SEVR 50%-100%) prior to participation in this study, our data revealed that myocardial blood supply which increases coronary arteries blood irrigation can be improved by a 10 week multi-lifestyle intervention [125]. Also, our study suggests that myocardial blood supply is reversible even in the absence of a significant weight loss among CVD patients. Although the underlying mechanisms leading to myocardial ischemia in obesity patients are unclear, several possible mechanisms have been reported. In animal models, acute elevations of fatty acids in a healthy heart may induce cardiac oxygen wasting [126]. Fatty acid is a less efficient substrate compared to glucose, and increases oxidative
stress due to the impaired antioxidant capacity in the heart [127].

Exercise has been shown to increase the antioxidant capacity in animal models, but the beneficial effects on cardiomyocytes following exercise training in patients with obesity have not been reported in human models [128]. A recent animal study demonstrated that exercise training improves myocardial efficiency due to reduced oxygen wasting associated with EC-coupling [129]. Also, obesity-induced left ventricular remodeling was improved by exercise because of a reduced wall stress that decreased ventricular efficiency [130]. In relation to the previous studies, our study also shows that obesity-related myocardial efficiency can improve using a multi-lifestyle intervention. Although the extent to which exercise can improve myocardial efficiency, arterial and endothelial function (type, frequency, intensity, and duration) has not been documented, a recent study revealed that aerobic exercise training improved arterial stiffness after 8 weeks of supervised aerobic exercise training; starting at 60% of heart rate reserve and increased by 10% every 2 weeks until 85% of intensity is achieved [131]. In contrast to the previous findings on arterial stiffness with an exercise intervention, our study demonstrated that arterial stiffness did not improve following a 10 week multi-lifestyle intervention, despite the improvement in myocardial efficiency. Perhaps in hindsight, this was to be expected because this pilot study only lasted 10 weeks, and during this time the subjects began to learn new information on how to change their lifestyle. However, it would be important to establish if after phase 2 of the study reducing arterial stiffness would occur i.e. after a longer interventional stimulus.
Limitations

This pilot study used the novel approach of translating a multi-lifestyle intervention into a rural setting, but it has several limitations which should be taken into account for the next step of the study.

Similar to the limitations found in previous pilot studies, this study was limited by a shorter intervention period, a small population and no control groups. We believe the lack of benefits observed in this study was primarily due to the short duration of the intervention. However, this study was designed and conducted as a pilot study to estimate the feasibility of key features such as participant recruitment and retention strategies. The next phase of the study will include a larger sample size, a longer intervention, and control groups. Also, we intend to add more patient navigators to accommodate the increase in the sample size to ensure quality recruitment and retention among our participants in the larger trial.

All of our participants were 100% Caucasian which represents a narrow range of ethnicity, so our findings may not be generalized to the characteristics of rural Americans as a whole. However, given the level of education, age, and demographic data among participants, the results may be applied to CVD patients in rural areas. Also, our participants were not current smokers, so we were unable to identify the effects of a smoking cessation intervention in this study. Future research will need to recruit a more ethnically diverse population which includes both smokers and non-smokers.

Since patients’ nutritional status was not evaluated, the nutritional parameters of
our participants were not monitored, therefore we were unable to conclude whether or not their nutritional knowledge improved following a lifestyle intervention or if nutritional factors were directly correlated to myocardial efficiency which may explain why the CV parameters did not change as much as we expected. To understand the effects of a nutritional intervention on CV health, we will track their eating habits using a questionnaire containing a list of questions about daily food consumption, eating habits related to fat intake, cooking practices, and the number of meals consumed or skipped. Dietary counseling will also be encouraged to promote a better understanding of nutrition and healthy food consumption.

**Future Directions**

To fully understand the effects of multi-lifestyle intervention in rural areas, a 16-session education curriculum originally conducted in DASH interventions will be incorporated into phase 2 of this study. Using the data obtained from our pilot study, we will conduct the next step of this study with at least 54 participants and the goal of improving arterial stiffness by a minimum of 10% by 16 weeks of a multi-lifestyle intervention. If a participant is absent from a core curriculum session, a brief individual session or a video tutorial could be provided to make up the missed group session. To objectively monitor the PA level, an accelerometer could be used as well as IPAQ. Additionally, we intend to implement continuous, monthly counseling for 5 years following phase 2. By translating and applying this study’s interventional methods into other rural community practices, we may expand these healthy lifestyle changes to other rural communities.

Using proactive and reactive recruitment methods, a patient navigator at each
clinic will attempt to recruit approximately 500 CVD patients (equal numbers of men and women) and their family member with a variety of ethnicities including African American, Hispanic Americans, and Asian Americans from different rural health clinics over a 1 year span. Follow up counseling could be implemented to maintain healthy lifestyle habits for the following 5 years. Although it may difficult to administer procedures such as a standard maximal cycle ergometer or a treadmill exercise test in rural areas, clinicians can use a 6 minute walk test to measure heart rates and blood pressures of their participants to estimate functional capacity and heart rate recovery to compare the long-term effects of two study conditions: a multi-lifestyle intervention group versus a control condition of CVD patients. Therefore, we intend to compare the long-term effects of a multi-lifestyle intervention (versus a control group) on patients with CVD with the ultimate goal of applying these lifestyle modifications to rural areas in the need of health improvements.
Conclusions

In conclusion, this study suggests that the multi-lifestyle intervention using the principle of CBPR is feasible and acceptable to improve CV health in rural CVD populations. In particular, the amount of PA was significantly improved following a 10 week lifestyle
intervention with a significant improvement in 6 min-walk test after 10 weeks of lifestyle intervention. However, there were no significant changes in other CV parameters except for the myocardial efficiency. Because this study was conducted as a pilot study which consists of smaller populations and shorter periods than the full intervention, we expect that the next step of this study will show more significant outcomes which determine if an educational lifestyle intervention is beneficial to reduce the incidence of CVD in rural areas. These findings will also provide an important evidence to implement a larger trial targeted at CVD patients and their family member.
Chapter 7

References


70. Piette, J.D., et al., Use of automated telephone disease management calls in an ethnically diverse sample


119. Fenk, S., et al., Successful weight reduction improves left ventricular diastolic function and physical


Appendix A. Health-Related Quality of Life-14 Questionnaire
rHeART Health Behavior Questionnaire

Personal Information
Today’s Date ____________ subject ID number ________________
How old are you? ______ years Sex: □ Male; □ Female

Please circle the highest grade in school you have completed:

Elementary School  1  2  3  4  5  6  7  8
High School  9  10  11  12
College/Postgrad  13  14  15  16  17  18  19  20+

What is your marital status? □ Single; □ Married; □ Widowed; □ Divorced/Separated

Race or ethnic background:
□ White, not of Hispanic origin  □ American Indian/Alaskan native  □ Asian
□ Black, not of Hispanic origin  □ Pacific Islander  □ Hispanic

What is your job or occupation? Check the one that applies to the greatest percent of your time.
□ Health professional  □ Disabled, unable to work  □ Service
□ Manager, educator, professional  □ Operator, fabricator, laborer  □ Unemployed
□ Skilled crafts  □ Homemaker  □ Student
□ Technical, sales, support  □ Retired  □ Other

Do you have a computer with Internet access at home? □ yes; □ no

How long did it take you to get to clinic today? □ Less than 20 min; □ 20-40 min; □ 40-60 min; □ more than 60 min

CDC Health-Related Quality of Life-14 (CDC HRQOL-14)
The CDC HRQOL-14 instrument assesses health-related quality of life. This is a 14-item, 3 module (Healthy Days Core [items 1 to 4], Activity Limitation [items 5 to 9], Healthy Days Symptoms [items 10 to 14]) instrument. A summary index of unhealthy days is calculated by summing the number of days from responses to items 2 and 3, with a logical maximum of 30 unhealthy days. Healthy days index is calculated by subtracting the number of unhealthy days from 30 days. The items in Activity Limitation and Healthy Days Symptoms modules are typically not summed together but scored separately.

Healthy Days Core Module
1. Would you say that in general your health is:
a) Excellent
b) Very good
c) Good
d) Fair
e) Poor
f) Don’t know/Not sure
2. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?
   a) Number of days: _____
   b) None
   c) Don’t know/Not sure

3. Not thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?
   a) Number of days: _____
   b) None
   c) Don’t know/Not sure

4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work or recreation?
   a) Number of days: _____
   b) None
   c) Don’t know/Not sure

Activity Limitation Module
5. Are you LIMITED in any way in any activities because of any impairment or health problem?
   a) Yes
   b) No
   c) Don’t know/Not sure

*If answered to #5 B or C, skip to question #10

6. What is the MAJOR impairment or health problem that limits your activities?
   a) Arthritis
   b) Back or neck problem
   c) Fractures, bone/joint injury
   d) Walking problems
   e) Lung/breathing problem
   f) Hearing problem
   g) Eye/vision problem
   h) Heart problem
   i) Stroke problem
   j) Hypertension/high blood pressure
   k) Diabetes
   l) Cancer
   m) Depression/anxiety/emotional problem
   n) Other impairment/problem
   o) Don’t know/Not sure

7. For HOW LONG have your activities been limited because of your major impairment or health problem?
a) Days  
b) Weeks  
c) Months  
d) Years  
e) Don’t know/Not sure

8. Because of any impairment or health problem, do you need the help of other persons with your PERSONAL CARE needs, such as eating, bathing, dressing, or getting around the house?
   a) Yes  
   b) No  
   c) Don’t know/Not sure

9. Because of any impairment or health problem, do you need the help of other persons in handling your ROUTINE needs, such as everyday household chores, doing necessary business, shopping, or getting around for other purposes?
   a) Yes  
   b) No  
   c) Don’t know/Not sure

Healthy Days Symptoms Module
10. During the past 30 days, for about how many days did PAIN make it hard for you to do your usual activities, such as self-care, work, or recreation?
    a) Number of days: _____  
    b) None  
    c) Don’t know/Not sure

11. During the past 30 days, for about how many days have you felt sad, blue or depressed?
    a) Number of days: _____  
    b) None  
    c) Don’t know/Not sure

12. During the past 30 days, for about how many days have you felt worried, tense or anxious?
    a) Number of days: _____  
    b) None  
    c) Don’t know/Not sure

13. During the past 30 days, for about how many days have you felt you did not get enough rest or sleep?
    a) Number of days: _____  
    b) None  
    c) Don’t know/Not sure

14. During the past 30 days, for about how many days have you felt very health and full of energy?
    a) Number of days: _____  
    b) None
c) Don’t know/Not sure

**Symptoms or Signs Suggestive of Disease**
*Place a check in the box if your answer is “yes.”*

- 1. Have you experienced unusual pain or discomfort in your chest, neck, jaw, arms, or other areas that may be due to heart problems?

- 2. Have you experienced unusual fatigue and/or shortness of breath at rest, during usual activities, or during mild-to-moderate exercise (e.g., climbing stairs, carrying groceries, brisk walking, cycling, etc.)?

- 3. Have you had any problems with dizziness or fainting?

- 4. When you stand up, or sometimes during the night while you are sleeping, do you have difficulty breathing?

- 5. Do you suffer from swelling of the ankles (ankle edema)?

- 6. Have you experienced an unusual and rapid throbbing or fluttering of the heart?

- 7. Have you experienced severe pain in your leg muscles during walking?

- 8. Has a doctor told you that you have a heart murmur?

**Chronic Disease Risk Factors**
*Place a check in the box if your answer is “yes.”*

- 9. Are you a male over age 45 years, or a female over age 55 years, or a female who has experienced premature menopause and is not on estrogen replacement therapy?

- 10. Has your father or brother had a heart attack or died suddenly of heart disease before age 55 years; has your mother or sister experienced these heart problems before age 65 years?

- 11. Has anyone in your family died suddenly before the age of 40, excluding accidental death

- 12. Are you a current cigarette smoker?

- 13. Has a doctor told you that you have high blood pressure (more than 130/80 mm Hg), or are you on medication to control your blood pressure?

- 14. Is your total serum cholesterol greater than 200 mg/dl, or has a doctor told you that your cholesterol is at a high risk level?
15. Do you have diabetes mellitus?

16. Are you physically inactive and sedentary (little physical activity on the job or during leisure time)?

17. During the past year, would you say that you experienced enough stress, strain, and pressure to have a significant effect on your health?

18. Do you eat foods nearly every day that are high in fat and cholesterol such as fatty meats, cheese, fried foods, butter, whole milk, or eggs?

19. Do you tend to avoid foods that are high in fiber such as whole grain breads and cereals, fresh fruits or vegetables?

20. Do you weigh 30 or more pounds than you should?

21. Do you average more than two alcoholic drinks each day?

Medical History

22. Please check which of the following conditions you have had or now have. Also check medical conditions in your family (father, mother, brother(s), or sister(s)). Check as many as apply.

<table>
<thead>
<tr>
<th>Personal</th>
<th>Family</th>
<th>Offspring</th>
<th>Medical Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Coronary heart disease, heart attack, coronary artery surgery</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Angina</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>High blood pressure</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Peripheral vascular disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Phlebitis or emboli</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Other heart problems (specify: _________)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lung cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Breast cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Prostate cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Colorectal cancer (bowel cancer)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Other cancer (specify: ____________)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Stroke</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Chronic obstructive pulmonary disease (emphysema)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pneumonia</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Asthma</td>
</tr>
</tbody>
</table>
23. Please check any of the following medications you currently take regularly. Also give the name of the medication. This section will be taken from the subject’s medical record along with a 10 year weight history, date of diagnosis, and the dates of cardiovascular events.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Name of Medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart medicine</td>
<td></td>
</tr>
<tr>
<td>Blood pressure medicine</td>
<td></td>
</tr>
<tr>
<td>Blood cholesterol medicine</td>
<td></td>
</tr>
<tr>
<td>Hormones</td>
<td></td>
</tr>
<tr>
<td>Birth control pills</td>
<td></td>
</tr>
</tbody>
</table>
Diet

28. On average, how many cups of fruit do you eat per day? (One cup = 1 medium apple, banana, orange, etc., ½ cup of chopped, cooked, or canned fruit, counts as 1 cup as well as 1/2 cup of fruit juice).

☐ none  ☐ 1  ☐ 2  ☐ 3  ☐ 4 or more

29. On average, how many cups of vegetables do you eat per day? (One cup = ½ cup cooked or chopped raw, 1 cup raw leafy, 1/2 cup of vegetable juice).

☐ none  ☐ 1-2  ☐ 3  ☐ 4  ☐ 5 or more

30. On average, how many ounces of bread, cereal, rice, or pasta do you eat per day? (One ounce (oz.) = 1 slice of bread, 1 ounce of ready-to-eat cereal, ½ cup of cooked cereal, rice, or pasta).

☐ none  ☐ 1-3  ☐ 4-6  ☐ 7-9  ☐ 10 or more

31. When you use grain and cereal products, do you emphasize:

☐ whole grain, high fiber  ☐ mixture of whole grain and refined
☐ refined, low fiber

32. On average, how many ounces of red meat (not lean) do you eat per day? (Three ounces (oz.) = a small hamburger or steak of beef, roast beef, lamb, pork chops, ham, etc.).

☐ none  ☐ 1  ☐ 2  ☐ 3  ☐ 4 or more
33. On average, how many ounces of fish, poultry, lean meat, cooked dry beans, peanut butter, or nuts do you eat per day? (Three ounces = one small chicken breast, ¼ cup of cooked dry beans, one tablespoon of peanut butter, or ½ ounce of nuts (e.g., 7 walnut halves, 12 almonds, or 24 pistachios)).

- none
- 1
- 2
- 3
- 4 or more

34. On average, how many cups of dairy products do you eat per day? (One cup = 1 half-pint of milk or yogurt, 1.5 ounces of hard cheese (cheddar, mozzarella, Swiss, parmesan), or 2 ounces of processed cheese (American)).

- none
- 1
- 2
- 3
- 4 or more

35. When you use dairy products, do you emphasize:

- regular
- low-fat
- non-fat

36. How would you characterize your intake of fats and oils (e.g., regular salad dressings, butter or margarine, mayonnaise, vegetable oils).

- High
- Moderate
- Low

Body Weight

37. How tall are you (without shoes)? _____ feet _____ inches

38. How much do you weigh (minimal clothing and without shoes)? _____ pounds

39. What is the most you have ever weighed? _______ pounds

40. Are you NOW trying to:

- Lose weight
- Gain weight
- Stay about the same
- Not trying to do anything

Psychological Health

41. How have you been feeling in general during the past month?

- In excellent spirits
- In very good spirits
- In good spirits mostly
- I’ve been up and down in spirits a lot
- In low spirits mostly
- In very low spirits
42. During the past month, would you say that you experienced __________ stress?
   □ a lot of    □ moderate    □ relatively little    □ almost none

43. In the past year, how much effect has stress had on your health:
   □ a lot      □ some        □ hardly any or none

44. On average, how many hours of sleep do you get in a 24-hour period?
   □ Less than 5 □ 5 to 6.9 □ 7 to 9 □ More than 9

Substance Use

45. Have you smoked at least 100 cigarettes in your entire life?
   □ Yes    □ No

46. How would you describe your cigarette smoking habits?
   □ Never smoked
   □ Used to smoke
      How many years has it been since you smoked? _______ years
   □ Still smoke
      How many cigarettes a day do you smoke on average? _______ cigarettes/day

Do you currently use smokeless tobacco on a daily basis, less than daily, or not at all?
   □ Daily
   □ Less than daily
   □ Not at all
   □ Don’t know

Have you used smokeless tobacco daily in the past?
   □ Yes
   □ No
   □ Don’t know

In the past, have you used smokeless tobacco on a daily basis, less than daily, or not at all?
   □ Daily
   □ Less than daily
   □ Not at all
   □ Don’t know
How often does anyone smoke inside your home? Would you say daily, weekly, monthly, less than monthly, or never?

☐ Daily
☐ Weekly
☐ Monthly
☐ Less than monthly
☐ Never
☐ Don’t know

47. How often do you have a drink containing alcohol? (A “drink” is a glass of wine, a wine cooler, a bottle/can of beer, a shot glass of liquor, or a mixed drink).

☐ Never
☐ 2-3 times per week
☐ Monthly or less
☐ 2-4 times a month
☐ 4 or more times a week

How many drinks containing alcohol do you have on a typical day when you are drinking?

☐ 1-2
☐ 3-4
☐ 5-6
☐ 7-9
☐ 10 or more

How often do you have six or more drink on one occasion?

☐ Never
☐ 2-3 times per week
☐ Less than monthly
☐ Monthly
☐ 4 or more times a week

Environmental Supports for Physical Activity

In general, would you say that the people in your neighborhood are...

☐ Very physically active
☐ Somewhat physically active
☐ Not very physically active
☐ Not at all physically active
☐ Don’t know/Not sure
☐ Refuse to answer

Overall, how would you rate your neighborhood as a place to walk? Would you say...

☐ Very pleasant
☐ Somewhat pleasant
☐ Not very pleasant
☐ Not at all pleasant
☐ Don’t know/Not sure
☐ Refuse to answer
For walking at night, would you describe the street lighting in your neighborhood as…

☐ Very good
☐ Good
☐ Fair
☐ Poor
☐ Very poor
☐ Don’t know/Not sure
☐ Refuse to answer

How safe from crime do you consider your neighborhood to be? Would you say…

☐ Extremely safe
☐ Quite safe
☐ Slightly safe
☐ Not at all safe
☐ Don’t know/Not sure
☐ Refuse to answer

Generally speaking, would you say most people in your neighborhood can be trusted?

☐ Yes
☐ No
☐ Don’t know/Not sure
☐ Refuse to answer

Does your neighborhood have any sidewalks?

☐ Yes
☐ No
☐ Don’t know/Not sure
☐ Refuse to answer

Do you use any private or membership only recreation facilities in your community for physical activity?

☐ Yes
☐ No
☐ My community does not have these facilities
☐ Don’t know/Not sure
☐ Refuse to answer

Do you use walking trails, parks, playgrounds, sports fields in your community for physical activity?

☐ Yes
☐ No
☐ My community does not have these facilities
☐ Don’t know/Not sure
☐ Refuse to answer
Do you use shopping malls in your community for physical activity and/or walking programs?

☐ Yes
☐ No
☐ My community does not have these facilities
☐ Don’t know/Not sure
☐ Refuse to answer

Do you use any public recreation centers in your community for physical activity?

☐ Yes
☐ No
☐ My community does not have these facilities
☐ Don’t know/Not sure
☐ Refuse to answer

Do you use schools that are open in your community for public recreation activities?

☐ Yes
☐ No
☐ Schools in my community are not open for the public to use
☐ Don’t know/Not sure
☐ Refuse to answer

Access to food in neighborhoods or communities

In my neighborhood, it is easy to buy fresh fruits and vegetables?

☐ Strongly agree
☐ Agree
☐ Undecided
☐ Disagree
☐ Strongly disagree

In my neighborhood, it is easy to buy tobacco products.

☐ Strongly agree
☐ Agree
☐ Undecided
☐ Disagree
☐ Strongly disagree

My neighborhood, has the best food stores in town.

☐ Strongly agree
☐ Agree
☐ Undecided
☐ Disagree
☐ Strongly disagree

I prefer to shop for food at the local convenience store or corner store.
☐ Strongly agree
☐ Agree
☐ Undecided
☐ Disagree
☐ Strongly disagree

In my neighborhood, it is easy to buy alcohol.
☐ Strongly agree
☐ Agree
☐ Undecided
☐ Disagree
☐ Strongly disagree

The food stores in my neighborhood sell outdated or rotten products.
☐ Strongly agree
☐ Agree
☐ Undecided
☐ Disagree
☐ Strongly disagree

The local convenience store or corner store is expensive.
☐ Strongly agree
☐ Agree
☐ Undecided
☐ Disagree
☐ Strongly disagree

In my neighborhood, it is easy to buy healthy foods
☐ Strongly agree
☐ Agree
☐ Undecided
☐ Disagree
☐ Strongly disagree
Appendix B. Depression Anxiety Stress Scales-21 Questionnaire

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I found it hard to wind down</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>I was aware of dryness of my mouth</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>I couldn't seem to experience any positive feeling at all</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>I experienced breathing difficulty (e.g., excessively rapid breathing, breathlessness in the absence of physical exertion)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>I found it difficult to work up the initiative to do things</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>I tended to over-react to situations</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>I experienced trembling (e.g., in the hands)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>I felt that I was using a lot of nervous energy</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>9</td>
<td>I was worried about situations in which I might panic and make a fool of myself</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>I felt that I had nothing to look forward to</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>11</td>
<td>I found myself getting agitated</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>12</td>
<td>I found it difficult to relax</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>13</td>
<td>I felt down-hearted and blue</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>14</td>
<td>I was intolerant of anything that kept me from getting on with what I was doing</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>15</td>
<td>I felt I was close to panic</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>16</td>
<td>I was unable to become enthusiastic about anything</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>17</td>
<td>I felt I wasn't worth much as a person</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>18</td>
<td>I felt that I was rather touchy</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>19</td>
<td>I was aware of the action of my heart in the absence of physical exertion (e.g., sense of heart rate increase, heart missing a beat)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>20</td>
<td>I felt scared without any good reason</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>21</td>
<td>I felt that life was meaningless</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>
Appendix C. Mindful Attention Awareness Scale Questionnaire

Mindful Attention Awareness Scale

Description:

The MAAS is a 15-item scale designed to assess a core characteristic of dispositional mindfulness, namely, open or receptive awareness of and attention to what is taking place in the present. The scale shows strong psychometric properties and has been validated with college, community, and cancer patient samples. Correlational, quasi-experimental, and laboratory studies have shown that the MAAS taps a unique quality of consciousness that is related to, and predictive of, a variety of self-regulation and well-being constructs. The measure takes 10 minutes or less to complete.

Day-to-Day Experiences

Instructions: Below is a collection of statements about your everyday experience. Using the 1-6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what really reflects your experience rather than what you think your experience should be. Please treat each item separately from every other item.

<table>
<thead>
<tr>
<th></th>
<th>Almost Always</th>
<th>Very Frequently</th>
<th>Somewhat Frequently</th>
<th>Somewhat Infrequently</th>
<th>Very Infrequently</th>
<th>Almost Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I could be experiencing some emotion and not be conscious of it until some time later.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>I break or spill things because of carelessness, not paying attention, or thinking of something else.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>I find it difficult to stay focused on what's happening in the present.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>I tend not to notice feelings of physical tension or discomfort until they really grab my attention.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>I forget a person's name almost as soon as I've been told it for the first time.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
It seems I am "running on automatic," without much awareness of what I'm doing.

I rush through activities without being really attentive to them.

I get so focused on the goal I want to achieve that I lose touch with what I'm doing right now to get there.

I do jobs or tasks automatically, without being aware of what I'm doing. I find myself listening to someone with one ear, doing something else at the same time.

I drive places on "automatic pilot" and then wonder why I went there.

I find myself preoccupied with the future or the past.

I find myself doing things without paying attention.

I snack without being aware that I'm eating.

Scoring information:
To score the scale, simply compute a mean of the 15 items. Higher scores reflect higher levels of dispositional mindfulness.

Reference: