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Rationale and design of the Rockford CHIP, a community-based coronary risk reduction program: results of a pilot phase

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Abstract

Purpose. While residential lifestyle intervention programs have demonstrated coronary risk reduction through education, diet, and exercise, this pilot study was designed to assess the feasibility of a community-based lifestyle intervention program that is both affordable and effective in facilitating better lifestyle choices and health habits and thus effecting indicators of better clinical outcomes.

Materials and methods. A 40-h educational curriculum, delivered over a 30-day period with clinical and nutritional assessments before and after, was offered through the SwedishAmerican Center for Complementary Medicine to the general public. The participants were instructed to exercise 30 min/day and to embrace a more optimal diet (ad libitum) of largely unrefined plant foods high in complex carbohydrates and fiber, yet quite low in fat (<15%), animal protein, sugar, and salt, and virtually free of cholesterol.

Results. Of the 250 enrollees, 242 "graduated" (78 men and 164 women; almost all Caucasian; mean age 54 ± 12 years). They had coronary artery disease (CAD) (12%), diabetes (16%), hypertension (55%), most were overweight (88%), and the majority (79%) had low-density lipoprotein (LDL) levels ≥100 mg%. At 4 weeks, stratified analyses of total cholesterol (TC), LDL, triglycerides (TG), blood glucose, blood pressure, and weight showed that those at highest risk also had the greatest improvements. Depending on baseline levels, TC means dropped 10–23% in men and 6–13% in women. At the same time, LDL means declined 5–30% in men and 6–14% in women. In TG, the biggest drop (48%) was found in men who at baseline were in the highest risk category (in women, the biggest TG drop was 32%).

Conclusion. Community-based intervention strategies can be successfully and affordably utilized to lower coronary risk factor levels in a self-selected, free-living population. The true test, however, will be to what extent social infrastructures can be modified and alumni activities sustained to facilitate long-term adherence and sustained benefits.

Keywords: Cholesterol; Community-based health intervention strategies; Coronary risk reduction; Diabetes; Diet; Healthy communities; Hypertension; Lifestyle medicine; Obesity; Public health; Self-care

> "The greatest challenge in medicine today is to be found in motivating people to assume more responsibility for a health-affirming lifestyle." —C. Everett Koop, MD, former US Surgeon General

Introduction

Every second person in North America dies from occlusive vascular disease related to atherosclerosis. Starting in childhood and largely asymptomatic, the disease is both insidious and progressive. These atherosclerotic processes express themselves clinically most frequently as coronary artery disease (angina pectoris and myocardial infarctions) and cerebral infarctions [1].

Traditionally, atherosclerosis has been viewed and understood largely as an *obstructive* and *focal* process. More recent research, however, has suggested that atherosclerosis is rarely a focal process. To the contrary, more commonly, it is a *diffuse* and *systemic* process [2]. It is now established that obstructive plaques may only be responsible for 10–20% of all myocardial infarctions [3]. The majority of myocardial infarctions (MI) are related more commonly to soft, *nonobstructive*, *unstable* plaques with relatively modest luminal stenoses of usually 40–60% [4,5]. Soft, lipid-rich plaques have now emerged as being considerably more

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vulnerable and prone to rupture than hard, collagen-rich plaques; and they are responsible for 80–90% of all MIs [6].

In this context, and when viewed from international, epidemiological perspectives, hyperlipidemia is increasingly being recognized as the primary, essential, and necessary cause of the current epidemic of occlusive vascular disease [7–10], and new definitions for optimal values (LDL-cholesterol < 100 mg%) have been set [11,12].

Concurrently, vigorous reduction of these blood lipids, primarily with diet and lifestyle changes [13–15] and, if necessary, with the addition of hypolipidemic drugs, can lead to anatomic regression of atherosclerotic plaques [9,16–23]. In addition, reductions in blood lipids have been shown to play a major role in reversing endothelial vasomotor dysfunction, improving myocardial perfusion, lowering the frequency and intensity of angina, and in decreasing the risk of acute coronary events as well as the need for surgical interventions [9,22–25]. Vigorous cholesterol lowering, therefore, should more fully emerge as a goal of therapy and as a foundation for preventing, arresting, and reversing coronary artery disease (CAD) [26,27].

Residential lifestyle intervention programs, such as the McDougall Program and those offered at the Pritikin Longevity Center, have demonstrated their remarkable success in substantially lowering not only cholesterol levels but also other coronary risk factors, such as high blood pressure, excess weight, smoking, diabetes, and elevated triglycerides through a strict regimen of largely diet and exercise. At the same time, they reported substantial reductions in the requirements for medications to control diabetes, hypertension, hyperlipidemia, and angina [13–15].

These residential lifestyle intervention programs, however, are quite cost-intensive and the ability of their graduates to maintain their newly acquired health behaviors over time without adequate social and cultural support is in doubt. A different approach may be needed.

Carefully planned community-based demonstration programs may form an important effort to help solve the problem. The long-term results of the North Karelia Project, using the community as the intervention site of choice, are auspicious [28–30]. These community-based lifestyle intervention programs, when compared to the metabolic ward-type residential programs, have the potential to effect behavioral changes and clinical outcomes at much lower cost and to facilitate better long-term adherence through cultural transformation.

C. Everett Koop, MD, the former US Surgeon General, felt that the greatest challenge in medicine today was to be found in motivating people to assume more responsibility for a health-affirming lifestyle. In response to this challenge, namely, to motivate and empower people to adopt healthier lifestyles while using the community as public domain, a 30-day, educationally intensive, community-based lifestyle intervention program was started. This pilot project tested the concept of the Coronary Health Improvement Program (CHIP) as a viable template for an intended 7-year lifestyle intervention program that aims to substantially reduce coronary risk factor levels simultaneously through the adoption of better health habits and appropriate lifestyle changes.

Rationale and design

The SwedishAmerican Health System through its Center for Complementary Medicine and the California-based Lifestyle Medicine Institute envisioned the Rockford CHIP project as a template for affordable, community-based coronary health improvement strategies. These lifestyle interventions are aimed at primary and secondary prevention with possible disease arrest and reversal.

Endorsed by two Washington, DC-based national consumer advocacy groups, namely, the Center for Science in the Public Interest (CSPI) and the Physicians Committee for Responsible Medicine (PCRM), the Rockford CHIP project is committed to enroll a "critical mass" of 7,000 residents (10% of the Rockford population >40 years of age) over a period of 7 years. Using a comprehensive and educationally intensive (40 h) lifestyle intervention program, delivered each spring and fall to groups of about 500 residents at a time, the CHIP project is designed to measure behavioral change and clinical improvement in the participants. To what extent, however, will a self-selected population be able to substantially reduce coronary risk patterns and facilitate possible reductions in the medication requirements for the treatment of essential hypertension, diabetes (type 2), and CAD through the adoption of better lifestyle choices and health habits? And can this project succeed over time through educational, behavioral, social, and cultural enhancement strategies to reach its overarching goal of being able to create a health-supportive "subculture" within the larger community that may facilitate some cultural transformation?

The 7-year Rockford CHIP project is divided into four phases:

Phase 1–Year 1: Pilot Phase-enrolment of 250 participants.
Phase 2–Years 1–3: Consolidation Phase—enrolment of 2,000 more participants plus another 1,500 enrollees attending facilitator-driven videotaped CHIP programs for community and corporate work sites.
Phase 3–Year 4: Randomized Clinical Trial Phase—enrolment of 500 more.
Phase 4–Years 5–7: Government-Funded Expansion Phase—community-based culture transformational health improvement program enrolling 2,500 more participants.

For the Pilot Phase, CHIP will target people 40 years and older, those who are either at elevated risk for atherosclerosis-related diseases, or those who already have experienced coronary artery disease (CAD) and its clinical

cognates. Because social support is critical in achieving and adhering to the recommended lifestyle, CHIP will strongly encourage spouses and family members to enroll as well.

At the same time, CHIP will focus *initially* on enrolling upper-middle-class participants. This class—with many professionals, business and merchant people—is philosophically and attitudinally quite aware of the importance of fitness and a simpler diet, a nicotine-free lifestyle, and better stress management in controlling and reversing hypertension, obesity, hypercholesterolemia, diabetes, angina, and CAD.

This is also the class of people that is generally better equipped with educational and financial wherewithal. Applying strategic culture-transformational models, it is presumed that the members of this class may be more motivated to implement their new CHIP lifestyle. *In turn*, their status in society could make them desirable role models and catalysts for a healthier lifestyle within the larger community as the project moves strategically through successive phases 2–4 with the hope of possibly becoming a viable implementation model for other communities.

To facilitate greater efficiency, CHIP will be integrated into the evolving SwedishAmerican Center for Complementary Medicine. Sharing a similar philosophy will make it easier to develop consensus about strategies and intervention modalities among potential stakeholders.

Integrating the medical and public health models, CHIP will collaborate closely with the medical, public health, and educational communities. Furthermore, to help participants to more fully integrate and maintain their new lifestyle and to promote ''community ownership'' of the program, CHIP will work closely with its graduates, community organizations, and the media to promote coronary health awareness.

CHIP is also strongly committed to develop a vibrant alumni organization, which will hold monthly educational meetings. Moreover, CHIP will work closely with existing providers of lifestyle change programs, such as smoking cessation and physical fitness programs (YMCA) to promote appropriate follow-up services. Influenced by the social–ecological model for behavior change [31] and by social learning theories [32], CHIP will work closely with local merchants, such as restaurants, supermarkets, and bakeries.

During the Consolidation Phase, the general public, work sites, and school systems will be targeted with CHIP programs to be delivered by certified trainers via a set of 16 videos. In addition, the CHIP project will provide exposure, research, and training opportunities for medical students, young physicians, and graduate students in psychology, public health, and dietetics.

Patients and methods

Recruitment

For the Pilot Phase of this 7-year CHIP project, participants were invited through presentations at service clubs and corporations, public service announcements (PSA) on radio and television, public billboards, newspaper articles, and ads. In addition, the hospital provided special flyers that were distributed to its employees and physicians. Some 4 weeks before the study began, daily orientation sessions were held for 2 weeks to provide an overview of the goals, the expected clinical results, and the salient interventions.

The course admission fee of US$395 per person (or US$650 per couple) covered tuition, text- and workbooks, a 335-page syllabus with daily reading assignments and learning objectives, three coronary risk assessments and counseling sessions (*HeartScreens*). Some participants, unable to afford the full admission fee, received ''need-based'' subsidies.

Each participant gave informed written consent to the hospital-approved study before the lifestyle intervention study began. This included clinical assessments before and after the intensive 30-day program and a follow-up after 1 year (the follow-up analysis has not been evaluated and will be submitted later). All CHIP participants were advised and encouraged to work closely with their personal physicians to monitor and document clinical changes and to make the necessary adjustments in the type and dosage of medication.

Lifestyle interventions

In this 4-week, 40-h intensive educational program, the participants met daily for 2 1/4 h from Monday through Thursday. The focus was on developing a greater measure of intelligent self-care involving a clearer understanding of the nature and etiology of CAD, its epidemiology and its risk factors, and the potential for prevention, arrest, and reversal through better lifestyle choices in the areas of smoking, sedentary living, diet, and stress management. The CHIP curriculum included the following topics: modern medicine—its accomplishments and limitations, atherosclerosis, coronary risk factors, smoking, exercise, dietary fiber, fat and cholesterol, the optimal diet, overweight, diabetes, hypertension, hyperlipidemia, lifestyle and health, behavioral change, and self-worth.

Participants also had access to CHIP-sponsored *Shopping Tours* at local supermarkets (conducted by dietitians in groups of 10) and to two half-day *Applied Nutrition Workshops* held on consecutive Sundays with sit-down banquet meals and food demonstrations. Furthermore, once a week, special focus groups dealing with medications, diabetes, hypertension, CAD, and obesity were available to deal with clinical questions and concerns.

The recommended lifestyle involved implementing a 30 min/day exercise program of aerobics (walking) and general fitness, and moving towards a more optimal diet.

This *Optimal Diet* emphasizes largely unrefined ''foods-as-grown.'' These foods (like grains, legumes, vegetables, and fresh fruits), usually high in unrefined complex carbohydrates, were encouraged to be used ad libitum. Such a more natural, whole-food diet—very low in fat, animal

protein, sugar, and salt, yet high in fiber, antioxidants, and micronutrients and virtually free of cholesterol—is in stark contrast to the typically rich Western diet (Table 1).

HeartScreen: coronary risk factor assessment

Before the educational intervention began, all participants had to undergo their first *HeartScreen* to establish their baseline levels of modifiable risk factors, such as serum lipids, blood glucose, blood pressure, weight/BMI, smoking, stress, and exercise status (Fig. 1).

Their second *HeartScreen* was administered right after the 30-day intervention was completed. A trained clinical team conducted these biometric assessments and interviews to assure standardized procedures and quality control.

Blood samples for measurement of serum lipids and glucose were drawn after a 12-h fast, just before and at the end of the 4-week intervention program. Total cholesterol (TC), high-density lipoprotein (HDL), and triglyceride (TG) concentrations were measured by enzymatic assays (Hitachi 917 Multi-Task Analyzer). Low-density lipoprotein (LDL) values were calculated as TC − [HDL + 0.2 × TG], where TG had to be below 400 mg%. Fasting blood sugar (FBS) was measured by the hexokinase method (Hitachi 917). The coefficient of variation for TC, LDL, TG, and FG was ±2%; for HDL it was ±3%. Serum aliquots were stored at −20°C as reference values for internal validity checks and to ascertain possible laboratory value drifts over time.

All blood pressures were taken twice in a sitting position on the left arm by trained personnel according to established research protocol with participants resting at least 5 min before blood pressure assessment with standardized sphygmomanometers. The two readings then were averaged.

Reference values

To establish the risk factor profile, U.S. reference values were used. For an optimal LDL value, for instance, <100 mg% was used as the reference value recently recommended by the National Cholesterol Education Program [11]. For TG values, data from the Framingham Heart Study were used [33], and for FBS values the recommendations from the ADA Expert Committee [34]. Based on that definition, those with FBS >125 mg% were presumed to be diabetic. Blood pressures were classified into normal (<140/90), grade 1 (140/90–159/99), grade 2 (160/100–179/109), and grade 3 hypertension (≥180/110) according to WHO criteria [35]. Body mass index (BMI) values fell into the following clinical categories: healthy weight, 18.5–24.9; overweight, 25.0–29.9; obesity (class 1), 30.0–34.9; obesity (class 2), 35.0–39.9; and severe obesity (class 3), ≥40.0.

Table 1
Comparison of diet composition: the typical U.S. diet versus the CHIP Optimal Diet

	U.S. diet	CHIP Optimal Diet
Fats and oils	37%[a]	<15%[a]
Protein	15%[a]	10–15%[a]
Complex carbohydrates	25%[a]	65–70%[a]
Simple carbohydrates	23%[a]	<7%[a]
Cholesterol (mg/day)	400	<50
Sugar (tsp/day)	35	<10
Salt (g/day)	12–15	<5
Fiber (g/day)	12	>40
Water (glasses/day)	minimal	8–10

[a] Percentage of total energy intake.

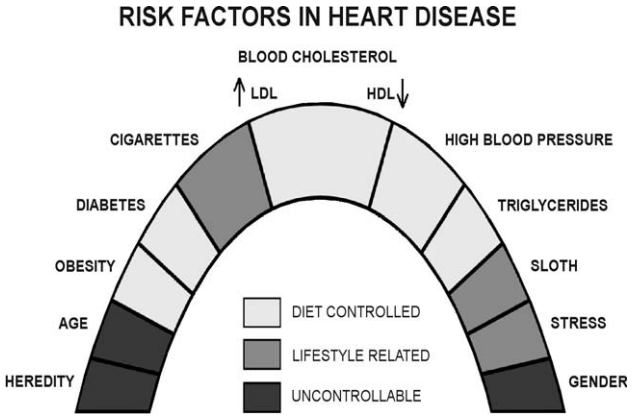

Fig. 1. Coronary risk factors: the higher on the arch, the higher the contribution of the risk factor to heart disease. Five of the eight controllable risk factors are largely under the control of diet.

Questionnaires

In addition to the *HeartScreen*, the participants filled out several questionnaires. This included: (1) medical history, (2) medication use (participants had to present their medication bottles), (3) the Rose Questionnaire to distinguish between primary prevention (no angina pectoris, no previous myocardial infarction) and secondary prevention (angina pectoris and/or previous myocardial infarction), and (4) 3-day food log analyzed by the *Foodopt Diet* (Version 12.56) software [36].

A personal interview helped to collect reasonably good data on the levels of stress, physical activity, and smoking. Based on biometric assessments, questionnaires, and interviews, all participants received written individualized recommendations for suitable lifestyle improvements according to an established protocol.

Data analysis

The data analyses were carried out under the supervision of the Center for Statistical Research at the Justus-Liebig-University at Giessen, Germany. Paired *t* tests were used to detect any differences in continuous variables. To obtain a clearer clinical picture on the response by the participants, stratified analyses in a gender-specific manner were carried out. To examine which factors may have contributed to the

improvements in lipid values, glucose, and blood pressure, multiple regression analyses were performed. The analyses were carried out using the Statistical Analysis System (SAS).

Results

Demographics

A total of 250 people enrolled in the Pilot Phase of the Rockford CHIP project. Of these, 242 (78 men, 164 women) graduated; they attended at least 80% of the educational lectures/sessions and had complete *before* and *after* data sets. Their mean age was 52 (±12) years for women and 57 (±11) for men; almost all of them were Caucasian (235); and 50% attended with spouse. Some 47% of the participants reported an annual income greater than US$60,000 per household, while 23% earned less than US$35,000.

Disease categories and risk factor changes

Of the 242 participants, 29 (12%) had clinically established *CAD*, 39 (16%) had *diabetes*, and 133 (55%) had *hypertension*. According to the body mass index (BMI), 173 (71%) were *above normal weight*. Of these, more than half were in the two highest of four overweight categories (BMI > 25). By using the Metropolitan Life Insurance tables [37] as a standard for overweight (≥10% above ideal weight), the overall number actually increased to 213 (88%). Of the 231 participants not on hypolipidemic medication, 79% did not reach the optimal *LDL* level of <100 mg%.

Table 2
Mean changes, by gender, in coronary risk factors in 30 days in Rockford CHIP participants

	Men (n = 78)			Women (n = 164)		
	Means			Means		
	Before	After	Change	Before	After	Change
Age (years)	57			52		
Weight (lb)	208.2	200.3	−7.9*	176.7	170.3	−6.4*
Body mass index[a]	30.3	29.1	−1.2*	29.6	28.5	−1.1*
Systolic BP[b] (mm Hg)	137.6	133.6	−4.0*	135.6	132.7	−2.9***
Diastolic BP[b] (mm Hg)	85.3	82.2	−3.1*	81.3	79.1	−2.2***
Glucose (mg%)	117.2	107.2	−10.0**	107.4	104.9	−2.5**
Total cholesterol (mg%)	200.4	171.8	−28.6*	209.7	193.0	−16.7*
LDL-cholesterol (mg%)	122.0	102.9	−19.1*	125.4	115.4	−10.0*
HDL-cholesterol (mg%)	45.1	40.5	−4.6**	55.9	50.1	−5.8**
TC/HDL-cholesterol	4.6	4.4	−0.2*	3.9	4.0	+0.1***
Triglycerides (mg%)	184.6	143.3	−41.3*	143.5	136.8	−6.7†

[a] Weight (kg/m^2).
[b] BP = blood pressure.
* $P < 0.001$.
** $P < 0.01$.
*** $P < 0.05$.
† $P > 0.05$.

Table 3
Mean changes in serum lipids in 30 days by entry level and gender in Rockford CHIP participants

	Men			Women		
	Changes			Changes		
	n	mg%	%	n	mg%	%
Total cholesterol (mg%)						
<160	12	−15	−10	21	0	0†
160–179	14	−15	−9	23	−11	−6
180–219	32	−26	−13	57	−14	−7
220–259	12	−48	−20	38	−30	−13
>259	8	−62	−23	22	−36	−13
	78	−29	−14*	161	−17	−8*
LDL-cholesterol (mg%)						
<100	16	−4	−5†	45	+1	+2†
100–129	26	−16	−14	46	−6	−6
130–159	22	−23	−16	43	−11	−8
160–189	7	−54	−30	15	−25	−15
>189	0	0	0	9	−29	−14
	71	−20	−16*	158	−10	−8*
Triglycerides (mg%)						
<100	22	+15	+24	60	+11	+17
100–199	34	−19	−13	75	−7	−5
200–299	12	−71	−29	14	−44	−18
300–399	3	−139	−39	12	−86	−25
400–599	7	−230	−48	3	−132	−32
	78	−41	−22*	164	−7	−5†

All changes in the lipid subcategories are at least at the $p < 0.05$ level of significance, except for those marked †.
The significance levels for the means of the total cohort for TC, LDL and Triglycerides are as follows: *$p < 0.001$ †$p > 0.05$.

After the 4-week program, participants had effected significant changes in their coronary risk factor levels. The reductions in laboratory results, blood pressure, weight, and BMI were *highly* significant ($p < 0.001$), except for women, whose blood glucose and blood pressure changes were only *significant* at the $p < 0.01$ and $p < 0.05$ levels, respectively, and whose TG changes did not reach the significance level (Table 2).

Participants at highest risk showed the greatest improvement (Table 3). Although men in all TC risk categories decreased their levels significantly (at least $P < 0.05$), those with high-risk levels ≥220 mg% achieved much greater reductions (−21%) than participants with levels <180 mg% (−10%). This statistical trend was observed for almost every blood lipid parameter and for both genders. Further data analysis showed that of the 52 men and 117 women with initial TC levels ≥180 mg%, only 2 men and 20 women were not able to lower their cholesterol levels, that is, 4% for men and 17% for women, respectively.

The changes in LDL values were similarly significant. The greatest reductions for both genders were among those with initial LDL levels of ≥160 mg%. Here, men achieved a 30% decrease from an initial mean of 179 to 125 mg%,

while women had an average decrease of 14% from an initial mean of 182 to 155 mg%. Of the 24 women ≥160 mg%, all but three had a marked decrease, while all seven men succeeded in lowering their LDL numbers.

TG levels >200 mg% decreased significantly. The results for women were similarly significant, although of a smaller order. The changes between the genders in lipids across the board were significantly different ($p < 0.001$).

This, however, was not true for FBS values. Since the cross-gender differences were insignificant, the gender-specific data sets were pooled. Table 4 displays the mean changes in FBS levels according to their baseline categories. Of the 39 diagnosed diabetics, the table only includes the 36 diabetics whose medication type and dosage were not changed. Of those, 20 diabetics were on either insulin [5] or on antiglycemic agents [15]. Another 16 were defined as diabetics by clinical history *and* fasting glucose levels >125 mg% but not on medication. Of these, 11 no longer tested in the diabetic range at the end of the 4-week educational phase.

Table 5 displays the mean changes in systolic and diastolic blood pressure levels stratified by risk category. Of the total of 133 hypertensive participants, three were not included in this analysis since their personal physicians discontinued their medication during the 4-week program. Of the remaining 130 hypertensives, 81 were taking antihypertensive medications (which remained unchanged) and another 49 participants were not taking medications but had been classified as hypertensives according to their medical history *and* their repeated baseline blood pressure levels of ≥140 or ≥90 mm Hg for systolic and diastolic values, respectively. Stratified analyses showed significant reductions in all elevated blood pressure categories for both systolic and diastolic values.

The statistically significant trend "the greater the health risk, the greater the improvement," held true not only for blood lipids, blood pressure, and glucose but also for weight. Those in the higher BMI categories lost more weight than those in the lower categories. Expressed in pounds, overweight men lost on the average 9.1 lb, while women with extra weight lost 7.2 lb during the 4-week program.

Table 4
Mean changes in fasting glucose in 30 days by entry level in Rockford CHIP participants

Fasting glucose category (mg%)	Fasting glucose (mg%)			
	Means			
	n	Before	After	Change
Normal (<100)	111	92	92	0
Elevated glucose (100–109)	58	103	102	−1
Impaired glucose tolerance (110–125)	34	116	107	−9*
Diabetes (>125)	36	174	149	−25**

* $P < 0.05$.
** $P < 0.01$.

Table 5
Mean changes in systolic and diastolic blood pressure in 30 days by entry level in Rockford CHIP participants

Blood pressure category (mm Hg)	Blood pressure (mm Hg)			
	Means			
	n	Before	After	Change
Systolic blood pressure				
<140	138	122	122	0
140–159	65	148	141	−7*
≥160	35	175	158	−17*
Diastolic blood				
<90	174	77	76	−1
90–99	48	93	86	−7*
≥100	17	104	94	−10*

* $P < 0.05$.

The participants walked a total of 10,200 miles during the last 3 weeks. This averaged about 2 miles/person per day. Of the nine smokers, three women and two men quit.

The 3-day food log (Foodopt Diet) was completed and returned by a sample of 124 participants (41 men and 83 women). Table 6 depicts significant reductions for both genders in the *absolute amount* of daily energy, protein, and fat (with its fractions), and cholesterol consumed. The amount of total carbohydrate intake, however, remained the same. The table also shows as a function of *percentage of total calories* the decrease in protein and in fat with its different fractions, and the increase in carbohydrates (CHO), where simple (sugars) and complex CHOs (starches) are combined. Simultaneously—according to a special dietary sampling—it was estimated that the average daily consump-

Table 6
Mean changes in diet composition in 30 days in Rockford CHIP participants by gender

	Men (*n* = 41)			Women (*n* = 83)		
	Means			Means		
	Before	After	Change	Before	After	Change
Energy (kcal)	3142	2144	−998	2746	1938	−808
Protein (g)	128	81	−47	114	74	−40
(%)[a]	16.3	15.2	−1.1	16.6	15.2	−1.4
CHO[b] (g)	340	347	+7	306	307	+1
(%)[a]	43.3	64.8	+21.5	44.6	63.4	+18.8
Fat (g)	137	45	−92	117	45	−72
(%)[a]	39.2	19.0	−20.2	38.3	20.8	−17.5
SFA[c] (g)	44	11	−33	38	11	−27
(%)[a]	12.6	4.6	−8.0	12.6	5.3	−7.3
MUFA[d] (g)	51	14	−37	42	14	−28
(%)[a]	14.6	6.0	−8.6	13.7	6.7	−7.0
PUFA[e] (g)	24	11	−13	21	11	−10
(%)[a]	6.9	4.6	−2.3	6.8	4.9	−1.9
Chol[f] (g)	394	85	−309	311	74	−237

[a] Percentage of total energy intake.
[b] Carbohydrates.
[c] Saturated fatty acids.
[d] Mono-unsaturated fatty acids.
[e] Poly-unsaturated fatty acids.
[f] Cholesterol.

tion of fiber for both genders went from 12 to 31 g, an increase of 19 g.

Stepwise regression analysis showed that baseline cholesterol levels were the strongest predictor for cholesterol change ($p < 0.001$), followed by weight loss ($p < 0.01$) and exercise improvement ($P = 0.06$).

Discussion

The Rockford CHIP project is conceptualized as a template for affordable, community-based coronary health improvement strategies aimed at primary and secondary prevention with possible disease reversal by attacking the common causes of this affluent lifestyle-related western disease. Its long-term goal is to enroll 7,000 residents over the next 7 years in the Midwestern city of Rockford (Illinois) and to foster a health supportive "subculture" as a nidus for influencing the level of health in the community-at-large over time and to facilitate cultural transformation.

This pilot phase provides the first short-term results of our initial efforts in Rockford to explore the extent to which a self-selected, free-living population can shift its attitudes and lifestyle practices towards healthier choices and how they, in turn, may affect certain coronary risk factors recognized as major contributors to atherosclerosis-related diseases.

The measurable clinical changes found in this free-living cohort of 242 in response to the recommended ad libitum diet of more foods-as-grown (largely plant-based, low in fat and sugar, yet high in fiber and unrefined complex carbohydrates) coupled with exercise enhancement, smoking cessation, and some stress management showed encouraging results.

In this 4-week pilot study, the total cholesterol means in men came down from 200.4 to 171.8 mg%, that is a reduction of 14%. For women, the means dropped from 209.7 to 193 mg%, a reduction of 8%. Those at highest risk had a decrease of 23% and 13% in men and women, respectively. Simultaneously, the cohort's LDL means dropped by 16% in men and 8% in women (those initially above 159 mg% dropped 30% for men and 14% for women). Table 3 shows the trend: the higher the risk, the larger the drop.

The explanation for these improvements must be sought in the marked dietary changes as assessed by the 3-day food log collected before and after the intervention in the sample of CHIP participants.

The composition of the diet changed profoundly (Table 6) and moved towards the goals of the Optimal Diet (Table 1). The daily total fat intake declined for both men and women. Men's initial 137 g (39% of total calories) and women's 117 g (38%)—both representative of the typical U.S. diet—dropped to 45 g (19% and 21%). During the program, the cohort's average daily intake of saturated fat declined from 12.6% to 5%, while the polyunsaturated fatty acids went from 6.8% to 4.8%. At the same time, the daily cholesterol consumption dropped from 394 and 311 mg to 85 and 74 mg for men and women, respectively.

Keys et al. [38] conducted scores of feeding experiments on human male subjects to measure the dietary effect on serum cholesterol. His findings have been summarized in the Keys' Cholesterol Prediction Equation. When applied to the dietary changes of the current study, the following numbers emerge:

	Before	After	Change (%)
Observed serum cholesterol (mg%) for men	200	172	−14
Predicted serum cholesterol by Keys' equation	205	179	−13

Undoubtedly, the lipid improvements are largely attributable to the dietary changes made. While the percentage of fat intake was cut in half, the cohort's percentage of carbohydrates (CHO) increased from 46% to 64% with the change centering primarily on the *increase* in unrefined complex CHO and the *decrease* in simple CHO (sugars). The shift towards more unprocessed complex CHO foods (grains and legumes) plus more fruits and vegetables is supported by the daily fiber increase of 19 g.

Such a less refined and largely plant food-centered diet typically increases food volume and decreases caloric density; both changes facilitate lower energy intake "without feeling deprived and hungry." The 800–1,000 kcal decrease in daily energy intake combined with a daily walking routine of about 2 miles (during the last 3 weeks) plus the recommended sodium reduction may explain the observed average weight loss of 8 lb in participants with extra weight.

The guidelines of the Optimal Diet were progressively introduced during the educational sessions of week 2 of the program. They were not presented as ideological tenets, but rather as nutritional goals. The participants learned how similar diets have been used successfully with CAD patients in lessening the frequency and intensity of angina [7,15,16,20–24], in regressing atherosclerotic plaques [9,15–22], and in reducing cardiovascular events and revascularization procedures [9,16,17,19,39]. They also became well acquainted with findings from large epidemiological studies.

They learned, for instance, in detail about the massive Cornell-inspired *China Diet Study*, which found very low cholesterol levels (averaging 127 mg%) and CAD mortality in rural China. In contrast, U.S. men <65 years are 16.7 times more likely to die from this disease [10]. As a major finding, the authors reported that CAD risk was inversely related to the consumption of plant-based foods and positively related to the consumption of animal-based foods, which, in turn, were powerfully related to serum cholesterol levels. They concluded, "to fully prevent CAD, serum cholesterol levels must be maintained well under 150 mg%" [10].

Even so, much clinical debate exists of how far dietary change should be pushed to provide effective public health and clinical benefit [40]. A recent Science Advisory by the Nutrition Committee of the American Heart Association acknowledged the value of very low fat diets for coronary risk reduction and regression of CAD. The conclusion, however, was that "numerous unanswered questions remain that make population-wide recommendations of such diets premature" [41]. Two major concerns cited focused on the triglyceride-raising and HDL-lowering effect of a very low fat/high complex carbohydrate diet, especially in the short term.

The results of the present CHIP pilot study do not confirm the AHA concerns about the triglycerides. Triglyceride means significantly dropped 22% and 5% in men and women, respectively. More importantly, upon data stratification, the triglyceride-raising effect was largely limited to the lowest risk group (<100 mg%). While 22 men in this group saw their mean of 62 go up to 77 mg%, the 34 men in the "100–199 mg%" group with a baseline mean of 146 mg% experienced a decrease of 19 mg%. Similarly, while 18 of the 22 men in the lowest risk group had some modest increases, only 13 of the 34 men in the next group up had any increase. While some of these increases—almost exclusively limited to baseline triglyceride levels <200 mg%—were *statistically* significant, they are of little *clinical* significance.

Barnard showed similar results in his study: triglyceride data collected on 4,594 participants at the beginning and end of a 21-day residential intervention program favoring a plant-based diet very low in fat (10%) but very high in unrefined complex CHO (68%) showed a 38% drop among 2,685 men, and a 23% drop among 1,909 women [14].

The results of the present CHIP pilot study regarding the HDL-lowering effect of a diet very low in fat and very high in complex carbohydrates confirm the concerns of the AHA Health Advisory: HDL levels decreased for both men (4.6 mg%) and women (5.8 mg%) (Table 2). In view of the clearly established relationship between low levels of HDL and increased risk of CAD in the United States, it appears that this finding could lessen the overall benefit derived from reducing the levels of other risk factors.

Barnard, however, points out that an elevated and thus cardio-protective HDL is only relevant in the context of the typically high TC and LDL levels found in western society [14]. In regions where TC and LDL levels are quite low, HDL levels are usually also quite low and the TC/HDL ratios lose their predictive value for CAD. For example, Tarahumara Indians of Mexico, in whom CAD was virtually nonexistent, were found to have a mean TC value of 135 mg% and an HDL value of 26 mg% [42]. This gives a TC/HDL ratio of 5.2, which, according to norms used in this country, would put the Tarahumaras at the same risk for CAD as the average adult in the United States.

Responding to the AHA concerns, our data suggest that a diet quite low in fat (20%) and simple CHO, yet high in *unrefined* complex CHO and thus rich in fiber, combined with a daily 30-min walk—interventions that also contribute to proper weight adjustment—can effectively lower serum cholesterol values (>160 mg%) as well as triglycerides >200 mg%, which are relevant to coronary risk reduction [43].

Residential treatment-centered programs provide an almost metabolic ward-like environment, where healthier lifestyle patterns can be learned and where clinical results can be optimized in a medically protective and luxurious atmosphere. These centers, however, are costly ranging from US$12,000 to 20,000 per couple for a 4-week stay. In addition, many participants have to take time off from their jobs. And after the intense program is over, they still have to face the same private and public health-erosive infrastructures they left behind. Without adequate reinforcement and psychosocial support for the newly acquired lifestyle on the local level, adherence and relapse issues loom large.

Carefully planned community-based programs, however, may represent an important effort to help reduce these concerns. Their clinical outcomes appear not very dissimilar to those reported from residential programs. Their potential success and their emphasis on lifestyle changes through education, understanding, skill acquisition and mutual support, and through infra-structural changes consistent with a healthier lifestyle effecting local restaurants, bakeries, hospitals, and health care professionals, may foreshadow the feasibility of cultural transformation as the basis for effecting health in the community.

Maintaining and extending the clinical improvements of this pilot phase, and integrating the social–ecological model [31] with social learning theories [32] coupled with a strengthened "healthy lifestyle" orientation by health care providers plus the emergence of a well-functioning hospital supported Center for Complementary Medicine—all of these are helpful prerequisites that may contribute to the anticipated success of the cultural transformation of Rockford.

Conclusion

These short-term results of the CHIP pilot phase conducted in Rockford are very encouraging. They warrant the efforts of moving forward with the goal of enrolling a critical mass of 7,000 people over the next 7 years and to foster a health-supportive "subculture" as a nidus for influencing the community-at-large over time and to facilitate cultural transformation.

The true test, however, will be to what extent infrastructural changes can be made that will facilitate the adoption of healthier lifestyles and to what extent will people actually adhere to their new lifestyle and sustain and enlarge their short-term health benefits. And if they do, at what level can atherosclerotic arrest and regression

and improved myocardial perfusion be anticipated and documented?

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