

Effectiveness of the Complete Health Improvement Program in Reducing Risk Factors for Cardiovascular Disease in an Appalachian Population

Christopher Leibold, OMS III; Jay H. Shubrook, DO; Masato Nakazawa, PhD; and David Drozek, DO

From the Ohio University Heritage College of Osteopathic Medicine in Athens (Student Doctor Leibold); the Department of Primary Care at Touro University California, College of Osteopathic Medicine in Vallejo (Dr Shubrook); and the Office of Research Grants (Dr Nakazawa) and the Department of Specialty Medicine (Dr Drozek) at the Ohio University Heritage College of Osteopathic Medicine in Athens.

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Address correspondence to Jay H. Shubrook, DO, Primary Care Department, Touro University California, College of Osteopathic Medicine, 1310 Club Dr, Vallejo, CA 94592-1187.

E-mail: jay.shubrook@tu.edu

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Context: In 11 counties in Appalachian Ohio, the self-reported prevalence of diabetes mellitus (11.3%) is higher than the state (7.8%) or national (7.2%) average. Direct medical costs for diabetes in the United States are estimated at \$176 billion annually. Indirect costs from disability, work loss, and premature death add up to another \$69 billion.

Objective: To determine the effectiveness of the Complete Health Improvement Program (CHIP) in reducing cardiovascular disease (CVD) risk factors in a sample of Appalachian participants with elevated fasting blood glucose (FBG) levels or a diagnosis of type 2 diabetes mellitus (T2DM).

Methods: In a retrospective study, data from 6 CHIP cohorts conducted in Appalachian Ohio from 2011 to 2012 were combined and analyzed for short-term changes in CVD risk factors from baseline. This study focused on a subsample of the overall CHIP, whose participants had elevated FBG levels or T2DM. Statistical analysis was completed by calculating means and SDs and using paired *t* tests to compare differences in variables.

Results: After the CHIP intervention, 110 participants with baseline elevated FBG levels showed notable reductions in FBG levels, total cholesterol, low-density lipoprotein cholesterol, body mass index, and systolic blood pressure (all *P* values <.001). Likewise, participants in the subsample with T2DM experienced reductions in all CVD risk factors (all *P* values <.05).

Conclusion: The CHIP lifestyle intervention was effective in reducing CVD risk factors in this Appalachian population with elevated FBG levels or with T2DM.

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Currently, 29.1 million people, or 9.3% of the US population, have diabetes mellitus.¹ Complications in patients with diabetes include cardiovascular disease (CVD), stroke, limb amputation, and microvascular complications such as nephropathy, neuropathy, and retinopathy. The Centers for Disease Control and Prevention has estimated that total direct medical costs for all types of diabetes in the United States are estimated at \$176 billion annually.¹ Indirect costs from disability, work loss, and premature death add up to another \$69 billion.¹

Although taking medications to control blood glucose, lipid levels, and blood pressure is important for people with type 2 diabetes mellitus (T2DM), developing a healthy lifestyle consisting of a well-balanced diet and physical activity is also essential for controlling CVD risk factors and preventing the multitude of difficult and costly complications that accompany this chronic disease.¹⁻³

Many diets and lifestyle intervention programs have proven beneficial for people at risk for or who already have a diagnosis of T2DM. One such program, the Complete Health Improvement Program (CHIP), a community-based lifestyle intervention focused on a plant-based, whole-food diet, has demonstrated improvements in various chronic diseases, including T2DM, across different settings in the United States and around the world.⁴ This program is facilitated by volunteers trained and approved by Lifestyle Medicine Institute LLC. In Athens, Ohio, CHIP is administered locally by Live Healthy Appalachia, a 5013C group.

Poorer Appalachian regions struggle with higher rates of disease, lack of health care providers, limited access to health care, and greater rates of uninsured people.⁵ In 11 counties in Appalachian Ohio, the self-reported prevalence of diabetes (11.3%) is higher than the state (7.8%) or national (7.2%) average.⁶ Athens County is a part of Appalachia, a stretch of land covering 420 counties and 13 states from Mississippi to New York.⁷ Athens is identified as a “distressed county” of Appalachia and is ranked in the lowest 10% of the nation’s counties in terms of economic status.⁸ The population has been found to be at high risk for T2DM.⁹ The objective of this study was to evaluate the effectiveness of CHIP in reducing CVD risk factors in people living in Appalachian Ohio with elevated fasting blood glucose (FBG) levels or diagnoses of T2DM. We hypothesized that participants with dysglycemia would also achieve substantial benefits in cardiovascular risk factors after completing CHIP.

Methods

Study Participants

This retrospective study reports on a subgroup of a previously published CHIP study⁹ and was approved by the Ohio University Institutional Review Board. The present study analyzes the results of the first 6 CHIP cohorts (overall CHIP) studied in Athens from 2011 to 2012.

For the larger study, participants were recruited through announcements in churches, the local media, or from local health care providers. They attended 1 of several informational sessions presented throughout the community where they attended a combination of video and live presentations, had their questions addressed, and were offered an opportunity to enroll in the study. Inclusion criteria for the present study were enrollment in the CHIP cohorts and either a self-reported history of T2DM or an abnormal glucose level (>100 mg/dL) on intake laboratory results. All participants were informed that the present study results would be aggregated and reported for research purposes. They were given the option of having their data excluded without affecting their eligibility to participate in CHIP. All study participants signed a consent form.

Description of CHIP

The primary focus of CHIP was the consumption of whole foods, such as fresh fruits, vegetables, whole grains, legumes, nuts, and 8 ten-oz glasses of water daily. More specific goals included overall dietary fat content below 20% of total calories, daily intake of added sugar less than 10 tsp, daily sodium less than 2000 mg, cholesterol below 50 mg, and high fiber intake (>35 g/d). Stress reduction techniques and flexibility exercises were taught and encouraged, along with at least 30 minutes (or 10,000 steps) of daily aerobic exercise. The intent of CHIP was to nurture intelligent self-care through enhanced understanding of the causes, effects, and risk factors associated with chronic Western diseases.⁴ The CHIP curriculum included instruction on Western medicine’s accomplishments and limitations, atherosclerosis, CVD risk factors, smoking, exercise, dietary fiber, cholesterol, plant-based nutrition, obesity, diabetes, hypertension, dyslipidemia, lifestyle and health, behavioral change, anger management, and self-worth. Participants were encouraged but were not required to consult their physicians throughout the program. Medications for hypertension and T2DM were often reduced during the course, owing to the rapidly achieved benefits of the intervention.¹⁰

Each of the 6 cohorts consisted of 16 two-hour group sessions over a 4- to 8-week period. Four sessions were conducted in 4 weeks and met 4 times per week, and 2 cohorts were 8 weeks long, with fewer meetings per week. Participants in this study were represented in both group sessions. Cohorts were usually managed by 2 trained facilitators with 1 or 2 additional non-trained helpers. The number of participants per cohort ranged from 13 to 50. A typical session included an instructional video, cooking demonstration, group discussion, and an exercise component. Participants paid the tuition out of pocket or received scholarship assistance from their employer or local community organization. The cost of the course included 2 biomedical assessments performed at baseline and near the end of the program, food samples, textbook, workbook, cookbook, water bottle, pedometer, and supplementary reading and reference materials. The course tuition increased incrementally over the time frame covered by the study from \$350 to \$450.

Data Collection and Reporting

Biomedical assessments were held at baseline and near the conclusion of the program. Preprogram and postprogram differences were measured at 4 or 8 weeks depending on the duration of that cohort. Participants completed a lifestyle questionnaire assessing their dietary and exercise practices, current illnesses, and medication use at baseline. A physical examination was performed at baseline to assess weight, height, pulse rate, and blood pressure. At baseline and at the conclusion of the sessions, blood was collected via venipuncture by trained phlebotomists to determine total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triglyceride (TG), and FBG levels.

Data for each participant were entered into a password-protected proprietary Microsoft Access-based database (Microsoft Corporation) maintained on the CHIP administration computer at the Live Healthy Appalachia

office, as part of the overall CHIP routine, and separate from the data collection for this study. For this study (CHIP diabetes), CHIP administration provided aggregated data, without personal identifiers, in a password-protected Excel (Microsoft Corporation) database file.

After the second biomedical assessment was completed (before the final class session), personal and deidentified aggregated session results were given to each participant so they could see their personal improvements and how they compared with the group as a whole. The distribution of results was accompanied by a video presentation on the interpretation of the results, and participants were urged to continue with the newly acquired lifestyle changes. Participants were encouraged to share additional copies of the results with their primary care physician. After the final class session, participants were invited to join the local CHIP alumni group for ongoing support of lifestyle changes initiated during the intervention.

Statistical Analysis

A previous study⁹ analyzed the data from 6 CHIP cohorts conducted in Athens, Ohio, from 2011 to 2012, with a total enrollment of 225 volunteer participants. Data for participants who either self-reported a diagnosis of T2DM, were receiving medication for T2DM, or had an elevated FBG level on 1 of the biomedical assessments were included in the present study for analysis.

Means and SDs were calculated for the change from baseline in all CVD risk factors. Mean change (baseline mean vs postintervention mean) was also calculated to demonstrate the extent of change. Paired samples *t* tests were applied to the mean changes to determine whether the changes were statistically significant across all participants or within subgroups (eg, men vs women). Mean percent change ($100 \times \text{mean change} / \text{baseline mean}$) was also computed. The Welch modified 2-sample *t* tests were computed to compare the size of changes between this study subset population and the overall CHIP.⁹

Results

Of 225 participants in the overall CHIP,⁹ 110 participants who had elevated FBG levels or T2DM met the current inclusion criteria (*Table 1*). Sixty-four participants had elevated FBG levels, and 46 had T2DM. Of 110 participants, 75 were women (68%). Ages of participants ranged from 25 to 80 years, with a mean age of 56.6 years. The demographics of the population with elevated FBG levels and T2DM were similar to the overall CHIP. Between the 2 subgroups of elevated FBG levels and T2DM, we found similarities in mean age, age range, and percentage of women and men.

Table 2 shows the percent mean difference between pre- and postprogram values for all the CVD risk factors. A statistically significant ($P < .05$) reduction in TC levels, HDL-C, LDL-C, FBG levels, body mass index, and systolic blood pressure was found after CHIP. Although triglyceride levels and diastolic blood pressure (DBP) were reduced, changes were not statistically significant ($P > .05$). *Table 2* also shows the mean percent changes of the 225 participants in the overall CHIP, which were similar to those in the current study.⁹

Participants with elevated FBG levels at baseline ($n=64$) had a statistically significant ($P < .05$) reduction in all measured CVD risk factors, with TC levels showing the greatest reduction after CHIP ($P < .001$). Participants with T2DM at baseline ($n=46$) also experienced a reduction in all risk factors. All CVD risk factor reductions in the T2DM subgroup were statistically significant ($P < .05$) except TC levels and DBP ($P > .05$).

Women in the study ($n=75$) had a statistically significant ($P < .05$) reduction in all CVD risk factors except DBP ($P > .05$). For the men ($n=35$), all measures demonstrated a statistically significant ($P < .05$) reduction.

Table 3 provides further detail, listing the pre- and postprogram values for the 2 subgroups: those with elevated FBG levels and those with T2DM.

Table 1.
Comparison of Mean Age and Sex Distribution of Patients in CHIP Diabetes vs Overall CHIP⁹ Groups

Characteristic	CHIP Diabetes (n=110)	Overall CHIP (N=225)
Age, mean (SD), y	56.6 (11.1) ^a	56.0 (12.2) ^b
Sex, No. (%)		
Men	35 (32)	63 (28)
Women	75 (68)	162 (72)

^a Age range, 25-80 y

^b Age range, 24-81 y

Abbreviation: CHIP, Complete Health Improvement Program.

Discussion

Our findings demonstrate the short-term effectiveness of the CHIP program in reducing CVD risk factors in an Appalachian population of 110 participants with elevated FBG levels or a diagnosis of T2DM. Almost all of the CVD risk factors were significantly improved by this program. The results in this study were consistent with the overall CHIP results previously published.⁹

The CHIP is a lifestyle intervention that is unique in several ways. It engages the community to strive for and reach better health. The program is short in duration but prepares participants with structure to continue a healthy lifestyle in the future. Participants are encouraged to maintain a low-fat, vegan diet with 20% of total calories coming from fat and an unlimited intake of complex carbohydrates and other plant-based, whole foods rather than animal products (eg, meat, dairy, and eggs) and fatty foods (eg, added oils, fried food). Barnard et al¹¹ reported the results of a similar low-fat, vegan diet demonstrating notable reductions in body weight, hemoglobin A_{1c}, FBG level, and plasma lipids over 74 weeks compared with an American Diabetes Association diet.

In the present study, the mean FBG level was significantly reduced by an absolute value of 11.1 mg/dL,

Table 2.
Changes in Cardiovascular Disease Risk Factors Among
Patients in CHIP Diabetes vs Overall CHIP Groups^a

Risk Factors	CHIP Diabetes Change,				Overall CHIP				P Value: CHIP Diabetes vs Overall CHIP
	n	Change, Mean (%)	SD	P Value	n	Change, Mean (%)	SD	P Value	
BMI, kg/m ²	109	-3.68 (-1.27)	0.898	<.001	208	-1.2 (-3.5)	4.0	<.001	>.2
SBP, mm Hg	106	-5.65 (-7.46)	14.5	<.001	203	-7.1 (-4.7)	11.5	<.001	>.2
DBP, mm Hg	106	-1.94 (-1.49)	10.0	.130	203	-2.0 (-1.7)	13.6	.085	>.2
TC, mg/dL	110	-9.64 (-17.7)	29.4	<.001	214	-20.4 (-10.4)	13.2	<.001	>.2
LDL-C, mg/dL	106	-11.4 (-12.4)	25.4	<.001	210	-14.0 (-10.3)	21.5	<.001	>.2
HDL-C, mg/dL	110	-11.9 (-5.48)	6.52	<.001	214	-5.5 (-10.2)	13.0	<.001	.120
TG, mg/dL	110	-6.48 (-10.1)	64.3	.103	214	0	38.0	>.2	>.2
FBG, mg/dL	110	-9.31 (-11.1)	28.9	<.001	213	-6.4 (-4.1)	11.0	<.001	.07

^a Values in parentheses indicate absolute mean changes from baseline. Data were not available for all participants.

Abbreviations: BMI, body mass index; CHIP, Complete Health Improvement Program; DBP, diastolic blood pressure; FBG, fasting blood glucose; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; SBP, systolic blood pressure; TC, total cholesterol; TG, triglycerides.

or 9.31%. Our findings are similar to those in the Diabetes Prevention Program study.¹² Another similarly structured study with the Dietary Approaches to Stop Hypertension diet¹³ showed comparable findings, adding further support for dietary intervention as a means to decrease the risk factor profile in T2DM. The participants in the Dietary Approaches to Stop Hypertension study¹⁴ had a greater reduction in FBG levels (29.4 mg/dL) but also had a greater baseline FBG level (160.9 mg/dL) compared with participants in the present study (137.5 mg/dL).

One factor contributing to the reduction of FBG levels could be increased fiber intake. A systematic review and meta-analysis of 11 studies on high-fiber diets showed a similar reduction in FBG levels of 9.97 mg/dL.¹⁴ Natural fiber from whole grains, nuts, fruits, and vegetables benefits those with T2DM and are encouraged as part of a dietary intervention for T2DM.¹⁵ Another systematic review of 10 large prospective studies on the prevention of T2DM by dietary patterns showed a relative risk reduction of T2DM diagnosis ranging from

15% to 83% with a diet high in fruits and vegetables, whole grains, fish, and poultry, along with decreased consumption of red meat, processed foods, and sugar-sweetened beverages.¹⁶

Participants in the present study, as well as those in the overall CHIP, had significant reductions in HDL-C. Another study of a low-fat, plant-based diet and its effects on blood lipid level showed similar reductions in HDL-C.¹⁷ Typically, an increase in HDL-C is desirable to provide a protective effect against CVD, especially for people with comorbidities who are at increased risk.¹⁸ A meta-analysis¹⁹ of 70 studies on weight reduction analyzed changes in blood lipids by diet type and found that participants who were actively losing weight had reductions in HDL-C. However, the analysis found that once the participants were at a stabilized, reduced weight, their HDL-C levels increased.¹⁹

In the current study, other than DBP and triglyceride levels, all other CVD risk factors lowered significantly. All CVD risk factors in the present study's population

Table 3.
Comparison of Elevated FBG Levels and T2DM Before and After CHIP Implementation

Risk Factors	n ^a	Mean			P Value
		Before CHIP	After CHIP	Absolute Change	
Elevated FBG Levels					
BMI, kg/m ²	63	32.99	31.62	-1.29	<.001
SBP, mm Hg	61	129.82	122.03	-7.80	<.001
DBP, mm Hg	61	77.75	75.33	-2.26	.101
TC, mg/dL	64	187.58	166.06	-21.5	<.001
LDL-C, mg/dL	64	116.0	99.95	-16.1	<.001
HDL-C, mg/dL	64	46.91	40.81	-6.09	<.001
TG, mg/dL	63	138.33	133.17	-5.46	.366
FBG, mg/dL	64	106.13	102.23	-3.91	<.001
T2DM					
BMI, kg/m ²	46	36.77	35.53	-1.24	<.001
SBP, mm Hg	45	135.31	128.20	-7.0	<.001
DBP, mm Hg	45	75.38	74.87	-0.44	.748
TC, mg/dL	46	177.15	164.85	-12.3	.0014
LDL-C, mg/dL	42	99.74	93.52	-6.92	.041
HDL-C, mg/dL	46	44.89	40.26	-4.63	<.001
TG, mg/dL	46	187.46	171.39	-19.0	.171
FBG, mg/dL	46	137.48	116.37	-21.1	.0014

^a Data were not available for all participants.

Abbreviations: BMI, body mass index; CHIP, Complete Health Improvement Program; CVD, cardiovascular disease; DBP, diastolic blood pressure; FBG, fasting blood glucose; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; SBP, systolic blood pressure; TC, total cholesterol; TG, triglycerides; T2DM, type 2 diabetes mellitus.

had a greater reduction compared with the overall CHIP study findings except for TC, which was -9.64% in the prediabetes group and -10.3% in the T2DM group. A previously published CHIP study suggested that those with a higher risk at baseline had greater reductions after conclusion of the CHIP course.²⁰ This finding is important for reducing the risk of macrovascular complications, such as myocardial infarction, coronary artery disease, and stroke.²¹ Cardiovascular disease is the leading cause of death among patients with T2DM.²²

To date, CHIP has been shown to be effective in maintaining reductions of CVD risk factors up to 3

years after completion of the program.²³ Future research could examine CHIP as the primary prevention for CVD, similar to a study conducted on the Mediterranean diet.²⁴ Long-term studies looking at major outcomes such as remission, CVD, stroke, and death of CHIP participants are needed. Continued studies focused on maintaining the positive effects and adherence to healthy lifestyle changes after completion of CHIP are important.²⁵ The current study found results consistent with previous studies that evaluated plant-based diets in patients with diabetes.^{26,27}

Limitations

Although the CHIP program demonstrated statistically significant results over a short period of time, the self-selected population in the present study was motivated to make changes in diet and exercise, which does not necessarily represent the general population. No control group was used.

The short period of intervention (4-8 weeks) with 2 data points and limited follow-up are additional limitations. New healthy behaviors are subject to decay when the intervention is complete.²⁵ Long-term reductions in CVD risk factors and decreased major events and outcomes such as myocardial infarction and stroke cannot be determined.

The variable length of the CHIP classes was a possible limitation. Four of the sessions were conducted over 4 weeks, and 2 of the sessions were 8 weeks in duration. The differences in session duration could have contributed to variability in the data and decreased the statistical significance. However, a previous study demonstrated similar outcomes despite the differences in session duration.²⁸

Of the 28 participants in the study who were taking diabetes medications, none reported an increase in medication dose during the course of the program, whereas 9 reported a decrease in medications either in dose or number of medications or doses. The participants did not report whether it was the physician who initiated the change. The decrease in medications could have attenuated the change in FBG levels, leading to an underrepresentation of the actual magnitude of influence of the intervention on FBG level.

Conclusion

The CHIP was effective in reducing CVD risk factors in an Appalachian population with elevated FBG levels and T2DM. Further studies are needed to examine long-term outcomes of CHIP and its effects on macrovascular complications and health outcomes. We will continue to follow up with the participants to determine whether

these changes can be sustained and whether they are predictors of success after CHIP.

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Author Contributions

Drs Shubrook, Nakazawa, and Drozek provided substantial contributions to conception and design, acquisition of data, and analysis and interpretation of data; all authors drafted the article or revised it critically for important intellectual content; all authors gave final approval of the version of the article to be published; and Drs Shubrook, Nakazawa, and Drozek agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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