


A Randomized Controlled Trial of a Motivational Interviewing Intervention to Improve Whole-Person Lifestyle

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Abstract

The purpose of this randomized controlled trial was to examine the effects of a motivational interviewing intervention to improve whole-person lifestyle and reduce cardiovascular disease risk profile. A sample of 111 adults with type 2 diabetes and/or hypertension was recruited from a primary care physician practice. The intervention was facilitated by a program specialist trained in motivational interviewing. Outcomes included body mass index, cholesterol, hemoglobin A1c, blood pressure, waist circumference, wellness scores, and substance use. Differences in the changes in body mass index and waist circumference existed between the intervention and control groups after 6 months. In the intervention group, the proportion of high wellness scores increased after the program. A whole-person lifestyle intervention with motivational interviewing for patients with metabolic syndrome can improve one's health in terms of components in the cardiovascular disease risk profile, as well as overall wellness. Efforts to improve the health of these patients may incorporate motivational interviewing to guide goal setting and address mental and spiritual health in addition to physical health.

Keywords

diabetes, hypertension, motivational interviewing

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Introduction

Cardiovascular disease (CVD) is the leading cause of death in the United States and is responsible for 17% of national health expenditures. By 2030, 40.5% of the US population is projected to have some form of CVD.¹ Between 2010 and 2030, total direct medical costs of CVD are projected to triple, from \$273 billion to \$818 billion. Therefore, effective prevention strategies are still needed to reduce the growing burden of CVD.

Due to the strong links between individual health behaviors and cardiovascular health, the primary goal of the American Heart Association (AHA) is to preserve positive cardiovascular health by promoting healthy lifestyle behaviors. There are 7 metrics that define cardiovascular health: smoking, diet quality, physical activity level, body mass index (BMI), blood pressure, blood cholesterol, and fasting blood glucose.² There is much evidence that specific health behavior changes are linked with improved cholesterol, blood pressure, blood glucose, and medical outcomes.^{3,4} This suggests that an intervention focusing on health behaviors could improve patient outcomes and reduce costs to the healthcare system.

The “Five As” is a comprehensive treatment plan for health behavior change counseling conducted during a medical visit. The framework includes 5 counseling steps that a provider can complete in several minutes: (1) assess the risk behavior, (2) advise change, (3) agree on goals and an action plan via shared decision making, (4) assist with treatment, and (5) arrange follow-up.⁵ Motivational interviewing is a specific type of patient-centered counseling that leverages the “Five As” and has been used to foster health behavior changes. Although healthcare interactions commonly involve commanding or directive language, it is avoided in motivational interviewing. Instead, the provider asks open-ended questions and uses reflection to express empathy and to elicit patient-identified motivations for change. Motivational interviewing is

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intended to encourage self-reflection and to engage in the vocabulary of change.⁶

The AHA recognizes an individual-focused approach as a strategy that can lead to improvements in cardiovascular health and health behaviors. Evidence-based approaches include strategies such as setting specific, immediate goals, self-monitoring, scheduling regular follow-up, assessing progress, and engaging the patient's support network.³ In addition, AHA guidelines recommend the use of motivational interviewing to address health behaviors that increase risk for CVD. These behaviors include lack of physical activity, poor nutrition, tobacco use, and drinking too much alcohol.¹ In addition, the US Preventive Services Task Force (USPSTF) has recommended offering or referring adults who are overweight or obese and have additional CVD risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention.⁴

Clinicians have an opportunity to play an essential role in fostering healthier behaviors in their patients. More than 80% of adults have a usual source of health-care services, which gives healthcare providers a wide scope of influence. However, barriers such as limited patient-provider visit time, competing medical priorities, and insufficient financial incentives to the provider impede behavioral counseling from being consistently delivered to patients.²

As a result of these barriers and the projected increase in cost of care for people with CVD, there is a growing need for interventions that will provide patients with the time and attention needed to encourage healthy behavior change. CREATION is an acronym that stands for the whole-person health elements of choice, rest, environment, activity, trust, interpersonal relationships, outlook, and nutrition. This study involved a whole-person health intervention based on CREATION to address behavior change. The tailored intervention focused not only on physical wellness components, such as diet and exercise, but also on whole-person health components related to the mind and spirit. Using the techniques of motivational interviewing, the program specialist, who was a registered nurse, prompted participants to explore how to make lifestyle changes, such as healthier eating habits, increased physical activity, and more mindful decision-making. In this role, the program specialist served in an auxiliary capacity to the physician.

The objectives of this study were to determine the effect of the motivational interviewing intervention compared with a usual care control group on the whole-person lifestyle and CVD risk profile of participants with metabolic syndrome (ie, hypertension and/or type 2 diabetes). The variables of interest included systolic blood pressure (SBP), BMI, hemoglobin A1c (HbA1c), total cholesterol, waist circumference, self-reported wellness, and substance use.

Methods

Design

This study was a parallel randomized controlled trial (ClinicalTrials.gov identifier: NCT03412175) with an allocation ratio of 1:1. Participants randomized into the intervention group attended the program, while the participants randomized into the control group received usual care as provided by their primary care physician. Although usual care involved attending regular physician visits and taking any prescribed medications, it did not include motivational interviewing.

Participants

Inclusion criteria for participants were diagnosis of type 2 diabetes, fasting glucose >125 mg/dL, or HbA1c >6.5% and/or diagnosis of hypertension and age 18 years or over. Exclusion criteria were maintenance therapy or continued use of corticosteroids; current use of psychotropics for psychosis or bipolar disorder; use of weight loss medication in the past 3 months; psychiatric hospitalization in the past 3 years; cancer diagnosis or treatment in the past 3 years; history of myocardial infarction, coronary artery bypass graft, stroke, percutaneous transluminal coronary angioplasty, or balloon pump in the past 2 years; HbA1c \geq 12% on 2 occasions in the past 6 months; pregnancy; severe debilitating medical condition that would interfere with completion of intervention; and inability to speak, read, and understand English. Participants were recruited from a primary care physician practice during an 18-month period between July 2016 to February 2018.

Intervention

This intervention was based on CREATION whole-person health elements. The definitions of these elements (Table 1) were established through a literature search and focus groups of administrators, clinicians, patients, and families. These standardized definitions were used as the foundation of this intervention, which was intended to provide support for lifestyle modification. The intervention was facilitated by the program specialist, who was a registered nurse, trained in motivational interviewing.

Intervention group participants attended 6 assessment and coaching sessions with the program specialist over a 6-month period, including 1 initial assessment at baseline, four 60-minute motivational interviewing sessions, and 2 reassessments at 3 months and 6 months after baseline assessment. Control group participants only attended the assessment sessions at baseline, 3-month follow-up, and 6-month follow-up.

The one-on-one motivational interviewing sessions involved a collaborative process whereby participants

Table 1. Definitions of CREATION Elements.

Choice	Choice is a complex element that is affected by emotional, spiritual, physical, and environmental factors. The other elements influence choices; in turn, those choices play a part in our habits and behaviors.
Rest	Rest includes physical rest, cognitive breaks, and emotional and spiritual restoration.
Environment	Environment includes all components of our physical surroundings and resources, which includes living space, safety, workplace, food, healthcare, transportation, and recreational space.
Activity	Activity integrates physical, mental, and spiritual activities into our daily lives.
Trust	Trust encompasses connections with God, faith, loved ones, colleagues, and those who have been entrusted to lead.
Interpersonal relationships	Interpersonal relationships involve the support, connection, and belonging shared with family, friends, colleagues, and faith communities.
Outlook	Outlook involves the sum of attitudes, perceptions, and psychological health and influences daily life and relationships.
Nutrition	Nutrition is nourishment for the body and the source of energy for the mind. Healthy food is essential to wellness and disease prevention.

worked with the program specialist to identify successful strategies for progress toward and attainment of personal health goals. Each participant tailored an individual care plan, set health and personal goals, developed an action plan, learned techniques for self-monitoring and self-regulation, and identified barriers to change.

Intervention fidelity was ensured by tracking the content of each participant visit on encounter forms. Quality assurance assessments were completed by reviewing audiotapes of selected participant visits to confirm adherence to the protocol.

Data Collection

The following sociodemographic variables were assessed through a questionnaire at baseline: age, gender, race/ethnicity, education, marital status, employment status, annual household income, health insurance status, and comorbidities. Alcohol use and tobacco use was also measured through the questionnaire.

Wellness was measured by the Wellness Evaluation of Lifestyle (WEL).⁷ The WEL includes 20 scales: (1) spirituality; (2) self-regulation (composite score of scales 3 to 14); (3) sense of worth; (4) sense of control; (5) realistic beliefs; (6) emotional awareness and coping; (7) intellectual stimulation, problem solving, and creativity; (8) sense of humor; (9) nutrition; (10) exercise; (11) self-care; (12) stress management; (13) gender identity; (14) culture identity; (15) work; (16) leisure; (17) friendship; (18) love; (19) total wellness (composite score of all discrete scales); and (20) perceived wellness. Each item is answered on a 5-point Likert-type scale. Scores equal to or greater than 80 are interpreted as being moderately well with some room for improvement. Scores less than 80 reflect areas of importance for improving one's wellness.⁷

The following biological and physical variables were assessed through in-person measurements at the primary care physician practice or at a laboratory: height, weight, waist circumference, BMI, blood pressure, HbA1c, total

cholesterol, triglycerides, high-density lipoprotein cholesterol (HDL cholesterol), and low-density lipoprotein cholesterol (LDL cholesterol).

Sample

Sample Size. A statistical power analysis was done to determine an appropriate sample size of 138. Calculation of sample size was done using alpha set at .05 and power set at 80%. Clinical difference for SBP was set at 6 mm Hg with a standard deviation of 12.5 mm Hg.

Randomization. Randomization into the intervention group or control group was conducted by computerized protocol using SAS software, facilitated by a trained team member as the participants were enrolled into the study. A statistician generated the random allocation sequence. The program specialist enrolled participants and assigned them to a group. The random allocation sequence was concealed from the program specialist using slips of paper sealed in envelopes until it was time to assign a participant to a group. Blinding did not occur.

Data Analysis

The changes in the physical health indicators of waist circumference, BMI, SBP, total cholesterol, LDL cholesterol, triglycerides, and HbA1c were calculated into new variables by subtracting each participant's baseline measures from their 6-month measures. A favorable change would be reflected in a negative value. Independent-samples *t* test and Mann-Whitney *U* test were used as the parametric test and nonparametric test, respectively, to compare the changes in the intervention group and control group at the 6-month visit. McNemar's test was used to compare the proportions of total wellness scores (ie, <80 and ≥80) and the health risk behaviors of alcohol and tobacco use in the intervention group before and after the program. A *P* value <.05 was considered statistically significant.

Results

A total of 111 participants completed this study. This included 53 participants in the intervention group and 58 participants in the control group. The overall attrition rate was 26%. Table 2 shows the characteristics of the participants in the intervention group and control group. There were only significant differences between the groups in the baseline biometric measures of BMI and waist circumference.

Physical Health

There was no significant mean difference in the change in systolic blood pressure ($P = .19$) between the intervention group and control group at the 6-month visit based on the independent-samples t test (Table 3). There were statistically significant mean differences in the changes in BMI ($P = .01$) and waist circumference ($P < .001$) between the intervention group and control group at the 6-month visit based on the Mann-Whitney U test (Table 4). The negative changes in BMI and waist circumference were greater in the intervention group. As the intervention group had higher BMI and waist circumference compared with the control group at baseline, this greater change was expected. There were no statistically significant mean differences in the changes in total cholesterol ($P = .88$), LDL cholesterol ($P = .98$), triglycerides ($P = .52$), or HbA1c ($P = .57$) between the intervention group and control group at the 6-month visit. Table 4 also shows the medians of the changes in these variables for the intervention and control groups.

Wellness Scores

There was a statistically significant difference in the proportion of total wellness scores greater than or equal to 80 pre- and posttest ($P < .001$) among intervention group participants who completed the program (Table 5). The total wellness score for 16 intervention group participants increased from less than 80 at baseline to equal to or greater than 80 at the 6-month visit. No total wellness scores decreased to less than 80 among the intervention group participants.

Health Risk Behaviors

No statistically significant differences existed in the proportions of alcohol use between baseline and the 6-month visit ($P = 1.00$) or tobacco use between baseline and the 6-month visit ($P = 1.00$).

Discussion

This lifestyle intervention was designed to provide support for health behavior modification through motivational interviewing. The program curriculum included the 8 whole-person health elements of choice, rest, environment, activity, trust, interpersonal relationships, outlook, and

nutrition. Based on this CREATION acronym and the integration of recommendations by the AHA, these study results show improvement in self-reported total wellness scores for many intervention group participants. The scales of the WEL, which assessed wellness, align with these 8 elements.

The changes in 2 CVD risk profile components—BMI and waist circumference—at the 6-month visit were greater in the intervention group than the control group. However, there were no statistically significant differences between the 2 groups in the changes in systolic blood pressure, total cholesterol, LDL cholesterol, triglycerides, and HbA1c. This may be attributed to current pharmacological treatment of the conditions or to the limited duration of the study. Since motivational interviewing and resulting behavior change occurred throughout the 6-month period, there may not have been adequate time for changed health behaviors to manifest in statistically significant changes in these outcomes. Additionally, during the motivational interviewing sessions, participants set personal goals related to one or more of the whole-person health elements. Goal setting depends on an individual's element-specific level of activation. There are 4 levels of activation: (1) beliefs about the importance of a patient role, (2) confidence and knowledge necessary to take action, (3) taking action, and (4) maintaining action even when under stress.⁸ Individuals can be ready to take action to improve one aspect of whole-person health, while still feeling disengaged and overwhelmed about another element. Some goals focused on the mind and spirit rather than physical wellness. This may explain why the intervention group did not produce greater changes in all CVD risk profile components compared with the control group.

Each participant, regardless of group assignment, attended regularly scheduled physician visits throughout the intervention period, as well as the data collection time points with the program specialist at the 3- and 6-month visits. These visits may have increased accountability in all participants, which could have influenced the lack of differences in the changes of several physical health indicators between the intervention group and control group.

Overall, there was a strong improvement in self-reported total wellness scores and an improvement in CVD risk profile in terms of BMI and waist circumference. This may be attributed to the counseling component of motivational interviewing, which influenced the feelings of mental and emotional well-being in the participants.

No changes were observed in substance use. Although tobacco use was self-reported by the participants, no tobacco cessation assistance was offered unless a related goal was set. Future interventions will incorporate tobacco cessation to align with recommendations.⁴

Limitations

Randomized controlled trials evaluating lifestyle interventions generally have a more complex design than those

Table 2. Sociodemographic and Biometric Variables.

	Intervention (n = 53)	Control (n = 58)	P
Age, mean (SD)	58.6 (11.7)	60.2 (10.7)	.46
Female, n (%)	30 (56.6%)	37 (63.8%)	.44
Marital status, n (%)			.53
Divorced	8 (15.1)	8 (13.8)	
Married	31 (58.5)	38 (65.5)	
Separated	1 (1.9)	0 (0.0)	
Single	5 (9.4)	8 (13.8)	
Single living with partner	4 (7.5)	1 (1.7)	
Widowed	4 (7.5)	3 (5.2)	
Race/ethnicity, n (%)			.64
White, non-Hispanic	37 (69.8)	35 (60.3)	
Black, non-Hispanic	10 (18.9)	13 (22.4)	
Hispanic	4 (7.5)	7 (12.1)	
Other, non-Hispanic	1 (1.9)	3 (5.2)	
Black, unknown	1 (1.9)	0 (0.0)	
Highest education, n (%)			.27
Less than high school	1 (1.9)	0 (0.0)	
High school or GED	10 (18.9)	8 (13.8)	
Some college	18 (34.0)	14 (24.1)	
Associate's degree	7 (13.2)	6 (10.3)	
Bachelor's degree or higher	17 (32.1)	30 (51.7)	
Annual household income, \$, n (%)			.19
Up to 29 999	9 (17.0)	7 (12.3)	
30 000-59 999	15 (28.3)	21 (36.8)	
60 000-99 999	22 (41.5)	15 (26.3)	
100 000 or more	7 (13.2)	14 (24.6)	
Health insurance, n (%)			.39
None	0 (0.0)	2 (3.4)	
Private	34 (64.2)	31 (53.4)	
Medicaid	1 (1.9)	1 (1.7)	
Medicare	17 (32.1)	24 (41.4)	
Private + Medicare	1 (1.9)	0 (0.0)	
Employment status, n (%)			.32
Not working	0 (0.0)	2 (3.4)	
Working	30 (56.6)	35 (60.3)	
Retired	23 (43.4)	21 (36.2)	
Comorbidity score, n (%)			.54
0	22 (41.5)	26 (44.8)	
1	23 (43.4)	19 (32.8)	
2	5 (9.4)	10 (17.2)	
3	3 (5.7)	3 (5.2)	
Baseline biometrics, mean (SD)			
BMI, kg/m ²	36.0 (7.4)	33.0 (6.9)	.03
Waist circumference, cm	104.7 (16.3)	97.6 (15.1)	.02
Systolic blood pressure, mm Hg	134.7 (14.1)	132.6 (12.6)	.41
Total cholesterol, mg/dL	172.2 (36.0)	173.9 (37.7)	.82
LDL cholesterol, mg/dL	94.6 (29.0)	92.5 (32.0)	.73
Triglycerides, mg/dL	136.5 (68.1)	116.8 (62.1)	.12
HbA1c, %	6.2 (1.4)	6.1 (1.2)	.62
6-Month biometrics, mean (SD)			
BMI, kg/m ²	35.4 (7.4)	33.2 (7.1)	.10
Waist circumference, cm	101.0 (16.5)	98.7 (16.4)	.48
Systolic blood pressure, mm Hg	125.4 (12.5)	126.7 (9.3)	.53
Total cholesterol, mg/dL	172.8 (39.9)	176.2 (36.9)	.64
LDL cholesterol, mg/dL	94.4 (29.2)	95.6 (28.9)	.83
Triglycerides, mg/dL	139.6 (94.8)	115.4 (57.9)	.11
HbA1c, %	6.1 (1.2)	6.0 (0.9)	.40

Abbreviations: BMI, body mass index; LDL, low-density lipoprotein.

Table 3. Independent-Samples *t* Test for Changes in Systolic Blood Pressure.

	Paired differences				<i>t</i>	<i>df</i>	<i>P</i>
	Mean	SD	SE	95% CI			
Changes in systolic blood pressure	3.43	2.58	-1.68	8.55	3.43	109	.19

Table 4. Mann-Whitney *U* Test for Changes in Biometric Measures.

	Waist Circumference	BMI	Total Cholesterol	LDL Cholesterol	Triglycerides	HbA1c
Mann-Whitney <i>U</i>	686.50	1070.50	1354.00	1322.00	1277.50	1289.00
Wilcoxon <i>W</i>	2117.50	2501.50	2732.00	2597.00	2655.50	2720.00
<i>Z</i>	-4.935	-2.757	-0.154	-0.020	0.644	-0.574
<i>P</i>	<.001	.01	.88	.98	.52	.57
Median changes						
Control	0.50	0	-1.00	0	2.00	-0.10
Intervention	-4.00	-0.40	-4.50	1.00	-2.50	-0.10

Abbreviations: BMI, body mass index; LDL, low-density lipoprotein.

Table 5. Total Wellness Scores Before and After the Intervention.

Group	6-Month follow-up score <80	6-Month follow-up score ≥80	<i>P</i>
Control			
Baseline score <80	32	3	
Baseline score ≥80	2	13	1.00
Intervention			
Baseline score <80	20	16	
Baseline score ≥80	0	17	<.001

evaluating medical therapy, which could lead to unique challenges in evaluation.⁹ Due to the use of the WEL, there is the possibility of social desirability bias, which involves the tendency of respondents to answer survey questions in a favorable way. For example, respondents may overreport good behavior, such as fruit and vegetable consumption, and underreport bad behavior, such as tobacco use. Also, the ability of eligible patients in the primary care physician practice to choose whether they wanted to participate introduced self-selection bias into the study. Due to the attrition rate of 26%, there is the possibility of participation bias, which means that the individuals who completed the program were also those who were most motivated to improve their lifestyles and CVD risk profiles.

Conclusion

A whole-person lifestyle intervention with motivational interviewing for patients with hypertension and/or type 2 diabetes can improve one's health in terms of components in the CVD risk profile, as well as overall wellness. Future studies may include exploration of the effects of a similar intervention on medication dosage reduction, as well as the

effects of a similar program with a nonclinical interventionist. Efforts to improve the health of these patients may incorporate motivational interviewing to guide goal setting and to address mental and spiritual health in addition to physical health.



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