

## Heart Disease Prevention for Alaska Native Women: A Review of Pilot Study Findings

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### ABSTRACT

**Background:** Although historically Alaska Native women have had a relatively low incidence of cardiovascular disease (CVD), this pattern has changed dramatically in recent years. Alaska Native leaders have identified decreasing cardiovascular risk as an intervention priority.

**Methods:** From October 2000 to April 2001, Southcentral Foundation, an Alaska Native-owned and managed health corporation in Anchorage, conducted a pilot randomized controlled trial of a heart disease prevention program tailored for Alaska Native women. The aim was to assess feasibility and cultural acceptability and to develop enrollment procedures. Of 76 women who enrolled, 44 were randomized to the intervention group. Thirty-seven of 44 attended at least two intervention sessions, 23 completed prequestionnaires and postquestionnaires, and 27 returned for 12-month follow-up screening. Thirty of 32 control group participants returned for 12-month follow-up screening. The intervention included 12 weekly sessions on lifestyle change and goal setting. At baseline and 12 months, participants' height, weight, resting blood pressure, fasting lipid levels, and blood glucose were measured. At sessions 1 and 12, participants completed assessments regarding diet, physical activity, tobacco use, and psychosocial status.

**Results:** At 12 weeks, significant improvements were noted in moderate walking and physical activity self-efficacy. Also observed was substantial movement from the contemplation and preparation stages to the action stage regarding physical activity and heart-healthy eating.

**Conclusions:** Although the small sample size precludes drawing conclusions about the intervention's effect, participants reported lifestyle and psychosocial changes. The pilot study resulted in protocol changes that improved the design and implementation of a subsequent large-scale study.

### INTRODUCTION

**T**HE INCIDENCE OF cardiovascular disease (CVD) and prevalence of CVD risk factors in

Alaska Native women surpass those in Alaskan non-Native women.<sup>1</sup> Whereas nationally the highest CVD death rate is found among African Americans, the highest rate among Alaskans is in

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Alaska Natives (137.4 deaths per 100,000 Native persons vs. 108.8 per 100,000 for non-Natives from 1994 to 1996).<sup>2</sup> Few CVD intervention programs have been developed that address this burgeoning problem or that are designed by and for Alaska Native women.

Alaskan women with diabetes, those with hypertension or elevated cholesterol or both, and smokers are at highest risk of heart disease and stroke.<sup>2</sup> Although smoking rates in Alaska have remained relatively constant since 1991, the year that reliable data from the Behavioral Risk Factor Surveillance Survey (BRFSS) first became available,<sup>3</sup> analyses of 1998–2000 BRFSS data found that 40% of Alaska Native women surveyed were currently cigarette smokers compared with 23% of non-Native women.<sup>1</sup> Smokeless tobacco use is also significantly higher among Alaska Native women than among non-Native women (11% vs. <1%).<sup>1</sup>

Obesity is more prevalent among Alaska Native women than among women from a broad range of racial and ethnic backgrounds screened in the second National Health and Nutrition Examination Survey (NHANES II).<sup>4</sup> Dietary analyses of Alaska Native adults indicate that Alaska Native women consume more energy, fat, carbohydrates, and protein and fewer fruits and vegetables than does the combined population of women in the United States, as determined by NHANES II.<sup>5</sup> Within Alaska, 30% of Native women of all ages are obese compared with 18% of non-Native women.<sup>1</sup> Fewer Alaska Native women participate in regular physical activity (active for at least 20 minutes at least three times per week) than non-Native Alaskan women (38% vs. 50%).<sup>1</sup>

To address the increasing burden of heart disease, Southcentral Foundation developed a pilot study within a primary care setting to test an innovative intervention approach specifically adapted for Alaska Native women. The study was conducted as part of the Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program, funded by the Centers for Disease Control and Prevention (CDC). The pilot study's primary aims were to determine the feasibility of implementing the intervention on a larger scale (in a randomized controlled trial), to identify intervention components acceptable to Alaska Native women that minimized the time required of participants and staff, and to develop enrollment procedures. This paper describes the design and implementation of the pilot intervention, pilot study outcomes, and modifications

made to the study protocol to increase the feasibility of large-scale implementation.

## MATERIALS AND METHODS

### *Setting*

Southcentral Foundation is a tax-exempt regional health corporation operating under the tribal authority of Cook Inlet Region, Inc. The foundation's mandate is to improve the health and well-being of Alaska Natives and American Indians by developing and implementing comprehensive health-related services that meet changing needs, enhance culture, and empower individuals and families to take charge of their lives.

The WISEWOMAN pilot study was conducted at the Anchorage Native Primary Care Center, which is part of the Alaska Native Medical Center and serves Alaska's southcentral region. All Alaska Native and American Indian women in the Anchorage area are eligible for its services.

### *Design*

Four family practice physicians participated in the pilot study, conducted between October 2000 and April 2001. Although the intervention was tailored primarily for Alaska Native women, American Indian women living in the study area were also eligible to participate. The study population was defined as Alaska Native and American Indian women aged 40–64 who lived on the road system within a 50-mile radius of Anchorage, were due for an annual Pap smear test, and had previously selected one of the four participating physicians as their primary care practitioner. An introductory letter and a brochure that described the project were mailed to 321 women who met these criteria, followed by phone contact 1 week later. The outreach representative attempted to contact each woman until she was reached and either scheduled an appointment or declined participation, placing up to four calls to each woman over a 3-month period.

Interested eligible women were scheduled for one or two clinic visits (depending on their preferences) to provide baseline clinical measures. Three sets of measures were obtained. First, a certified medical assistant (CMA) or licensed practical nurse (LPN) obtained fasting serum blood measurements, a urinalysis, and an electrocardiogram (ECG). Second, a registered nurse (RN)/case manager obtained anthropometric and phys-

iological measures. Third, the participant's primary care physician determined the participant's overall health and medical fitness to participate in the intervention. Four RN/case managers were trained to collect screening measures using standardized methods. Each participant completed a brief medical history questionnaire.

After giving informed consent, undergoing clinical tests, and receiving physician approval, women were enrolled in the study and were informed that they would be asked to return for annual screenings until the study's completion in October 2004. After enrollment, participants were randomized to intervention or control (delayed intervention) groups using a database random number generation function (Rnd). They were notified of their status by mail.

### Measurements

We referred to two intervention studies that involved similar populations to guide our selection of measures and to allow future comparisons among study populations: the Strong Heart Study,<sup>6</sup> conducted in 13 American Indian tribes across three geographic areas, addressing regional differences in CVD and CVD risk factors in American Indian men and women aged 45–74 years, and the Alaska Siberia project,<sup>4,7,8</sup> which is studying risk factors in three populations of Eskimos in Alaska's Bering Straits Region. Our screening examination incorporated several measures used in both studies, including height and weight (using a calibrated Stadiometer (Perspective Enterprises, Portage, MI) and Scale-tronix (Scale-tronix, Carol Stream, IL) scale, respectively), waist circumference and hip circumference (using a Novel Products Figure-Finder<sup>®</sup> nonstretchable tape measure; Novel Products Inc., Rockton, IL), resting blood pressures, triglycerides, total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, creatinine and albumin, resting 12-lead ECG, and bioelectrical impedance analysis for body composition (using an RJL Systems BIA-101A analyzer; Clinton Twp., MI). We also analyzed blood samples for glucose, high-sensitivity C-reactive protein (hs-CRP), homocysteine, lipoprotein(a), serum urea nitrogen, and complete blood cell (CBC) count. Several of our quality assurance measures were adapted from the Strong Heart Study.<sup>6</sup>

### Intervention

We worked closely with Alaska Native staff and community members to design an interven-

tion program that would build on the strengths of Alaska Native traditions. After reviewing a variety of CVD intervention programs, we identified two interventions for women that could be adapted to reflect Alaska Native cultures. *A New Leaf . . . Choices for Healthy Living*, a program developed for the North Carolina WISEWOMAN project and primarily tailored to African American women, offered many positive elements in terms of assessing and promoting behavior change in women.<sup>9</sup> The *New Leaf* program includes a structured assessment of nutrition, physical activity and tobacco use; goal-setting activities; and a manual and cookbook. The *Native Nutrition Circles* program developed by the Center for American Indian Research and Education (CAIRE) consists of a 12-week series of small group gatherings for women that focus on nutrition.<sup>10</sup> Each gathering begins with a traditional story tied to the weekly topic and follows a talking circle format.

Using the *New Leaf* and *Native Nutrition Circles* programs as guides, we designed an intervention called *Traditions of the Heart*, which retained the manual and cookbook components of *A New Leaf* and used the more culturally appropriate format of the *Native Nutrition Circles* program. To refine our intervention, we conducted formative research to determine if the selected elements were acceptable to Alaska Native women, to identify the topics of greatest interest to eligible women, to ascertain convenient times and locations for group meetings, and to modify the *New Leaf* manual. The *Traditions of the Heart* manual emphasizes the healthfulness of subsistence foods (e.g., berries, fish, game meat), includes common Alaska Native activities (e.g., berry picking, hiking), and replaces the *New Leaf* manual's clip art with photos of Alaska Native women and families. While retaining the 12-session small group format of the *Native Nutrition Circles* program, we expanded its nutrition focus and adopted a more holistic wellness approach that also includes modules on physical activity, tobacco use, and stress management (Table 1).<sup>11,12</sup>

The intervention consisted of 12 weekly 2-hour educational sessions taught by a multidisciplinary team (nutritionist, exercise specialist, health educator, and traditional wellness coordinator). Participants assigned to the intervention group were contacted 2 weeks before the sessions began and were offered a choice of four weekly meeting times—one morning, one afternoon, and two

TABLE 1. TOPICS COVERED DURING *TRADITIONS OF THE HEART* 12-WEEK INTERVENTION PROGRAM<sup>a</sup>

<i>Content area</i>	<i>Topics</i>
Physical activity	Becoming more active Checking your heart rate Safety tips for exercise Using your pedometer Strength exercises with Thera-bands® (The Hygenic Corporation, Akron, OH) Stretching tips Making a plan for physical activity The Activity Pyramid Chair exercises
Nutrition	Beginning a walking program Heart-healthy eating—you can do it! Your cholesterol number The Food Guide Pyramid Reading the food label Spice it up without salt! Good food choices Fast food facts Eating healthy on a budget Helping others make healthy food choices Cooking for one or on the run
Traditional wellness and stress management	What is stress? Good and bad stress Physical effects of stress Stress and illness Coping with stress What is relaxation? Stress management techniques (imagery, breathing, muscle relaxation) Wellness tips (time management, positive thinking) Effect of psychosocial issues on stress level Supportive relationships Using traditional activities to reduce stress (talking circles, steams, Native dance)
Tobacco use	The effects of smoking What happens when I quit? The potential risks of smoking with R-I-S-K-Y BINGO The benefits and rewards of quitting with I-Q-U-I-T BINGO A story of cessation What will work for me? "It's Your Life" video <sup>11</sup> Presentation of the "Trial Guide to Being Tobacco-Free" <sup>12</sup>

<sup>a</sup>Not all components were presented every week.

evening options. Participants were asked to attend the same session period throughout the intervention. We developed and mailed to each participant a calendar (with magnets for convenient posting) that highlighted all 12 class dates and gave instructions for the first session. During the second session, each participant received a *Traditions of the Heart* manual and cookbook that featured Alaska Native recipes with heart-healthy preparation methods. Each of the 12 sessions included taste testing of recipes from the cookbook.

Resting blood pressure and heart rate measurements were taken at sessions 1 and 12. At those two sessions, participants also completed

detailed questionnaires on physical activity, tobacco use habits, and nutrition and on psychosocial factors associated with modifying these behaviors. Participants reported their level of physical activity (moderate walking) as none, not much (less than 1/2 hour per week), some (1/2 to 1 hour per week), or a lot (more than 1 hour per week). Participants reported whether they were currently using or did not use tobacco products, reasons for their tobacco use, and their desire and attempts to quit.

The nutrition assessment was scored by assigning points to three categories of responses. The frequency response for each food or dietary

behavior was classified as “problematic” (0 points), “needs improvement” (1 point), or “doing well” (2 points) depending on the quality and amount of fat consumed. The assigned points were totaled for session 1 and for session 12.

Scores for responses to psychosocial questions were also totaled for sessions 1 and 12. These questions included items related to social support and isolation, stress, and positive or negative coping strategies (e.g., going for a walk, overeating when under stress). Responses indicating a more beneficial attitude or behavior in terms of CVD risk reduction were given higher scores. Participants reported their level of confidence in their ability to eat at least five servings of fruits and vegetables per day and to perform physical activity four or more times each week as “not at all sure,” “somewhat sure,” “sure,” and “very sure.”

To determine the number of participants at a specific stage of change regarding physical activity and heart-healthy eating (as proposed by the transtheoretical model), participants were asked about their behaviors over the past 6 months and their projected plans.<sup>13</sup> Responses were categorized into five stages: precontemplation, contemplation, preparation, action, and maintenance. Precontemplation was defined as not engaging in the behavior with no plans to change, and maintenance was defined as engaging in the behavior for 6 months or more.

The 12 sessions were conducted from January through early April. Because April in Alaska remains cold with snow-covered ground and no significant changes in the availability of fruits and vegetables or accessibility to outdoor activities, we did not evaluate seasonal changes in physical activity and diet. In three goal-setting sessions (sessions 2, 5, and 11), participants set goals based on their initial assessments and personal expectations. Each participant set an achievable goal for nutrition and physical activity, and participants who used tobacco products were urged to set a goal to reduce tobacco use. Participants revisited the session 2 goals at session 5, either revising them or, if achieved, setting new goals. The goals were again reassessed at session 11, and long-term goals were set. Participants met with the same team member for each goal-setting session.

### *Evaluation*

Intervention participants were asked to complete an evaluation at the end of each weekly ses-

sion and suggest changes. During session 11, they completed an overall evaluation to comment on positive and negative aspects of the class setup, effectiveness of the session facilitators and goal-setting sessions, and most-enjoyed and least-enjoyed topics.

### *Analysis*

Responses of intervention group participants to questionnaires completed during sessions 1 and 12 were compared to identify change over the 12 weeks. Paired *t* tests of differences in means were used to compare baseline and 12-month follow-up measures for the intervention and control groups. Statistical significance was defined as  $\alpha = 0.05$ .

## RESULTS

Of 76 women enrolled in the pilot study, 44 were randomized to intervention and 32 to control (delayed intervention). Because recruitment was lower than expected, the percentage of women randomized to the intervention group was increased. The average age of intervention participants was 52.4 years vs. 52.9 years for women in the control group. Of the 44 randomized to the intervention, 37 attended at least two intervention sessions, 23 completed prequestionnaires and postquestionnaires at sessions 1 and 12, and 27 returned for 12-month follow-up. Seven intervention participants declined the intervention, had scheduling conflicts or could not be contacted, and were analyzed as part of the control group. Therefore, 39 were assessed as controls. Thirty of the 39 control group participants returned for the 12-month follow-up (Fig. 1). The average ages at the 12-month follow-up were 51.5 (intervention) and 53.6 (control).

Mean individual changes between initial and 12-month follow-up examinations were modest in both the intervention and control groups (Table 2). No statistically significant differences were found between changes in intervention and control group participants for cholesterol (total, HDL, and LDL cholesterol), blood pressure, or body mass index (BMI).

Responses to the tobacco use question by the 57 study participants who returned for 12-month follow-up revealed that 19 used tobacco at baseline vs. 17 at follow-up. Two participants (1 from

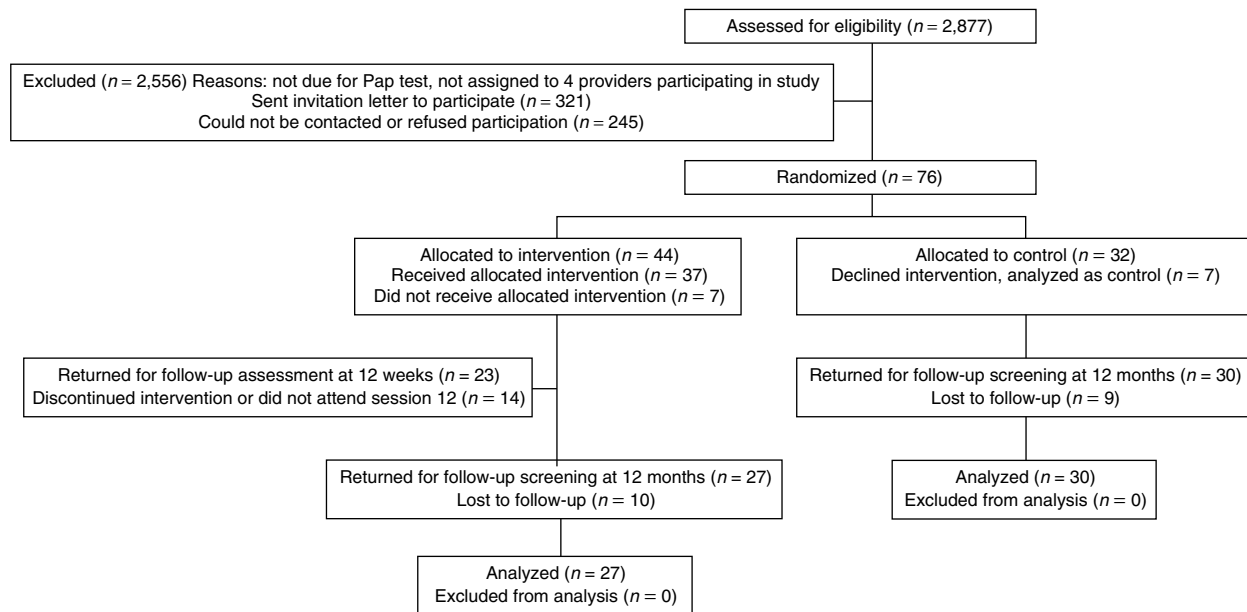


FIG. 1. Consort diagram describing participant progression throughout project.

each intervention group) quit using tobacco over the 12-month period.

No significant decrease was observed between heart rate or blood pressure measurements taken at sessions 1 and 12 of the intervention. Although 23 participants completed the intervention, less than 23 prerespouses and postrespouses were available for some assessments. Our analysis reflects the number of participants who answered the specific question at both the preassessment and postassessment.

We observed significant improvements in reported levels of physical activity (moderate walking frequency) among intervention participants from session 1 to session 12 ( $p < 0.04$ ) (Fig. 2). The number of participants who reported walking “a lot” rose from 2 of 18 at session 1 to 9 of 18 at session 12. Similarly, the number who reported not walking at all decreased from 4 of 18 to 1 of 18 over the 12 weeks.

Twenty-one of 23 participants improved their total nutrition score after the 12-week interven-

TABLE 2. MEAN VALUES FOR INTERVENTION AND CONTROL GROUPS AT BASELINE AND 12-MONTH FOLLOW-UP

	Total cholesterol (mg/dl)	LDL <sup>a</sup> (mg/dl)	HDL (mg/dl)	BMI (kg/m <sup>2</sup> )	Systolic (mm Hg)	Diastolic (mm Hg)
Intervention <sup>b</sup>						
Baseline (n = 37)	203.9	112.4	57.4	31.2	132.7	74.7
12 months (n = 27)	202.3 <sup>c</sup>	115.0 <sup>d</sup>	56.9 <sup>c</sup>	31.6	125.9 <sup>c</sup>	75.7 <sup>d</sup>
Control						
Baseline (n = 37)	208.0	116.2	64.1	31.3 <sup>e</sup>	128.0 <sup>e</sup>	75.8 <sup>e</sup>
12 months (n = 30)	208.9	120.5	61.3	31.7	122.2	74.4 <sup>f</sup>

<sup>a</sup>LDL, low-density lipoprotein cholesterol; HDL, high-density lipoprotein cholesterol; BMI, body mass index; Systolic, systolic blood pressure; Diastolic, diastolic blood pressure.

<sup>b</sup>Thirty-seven women attended at least two intervention sessions.

<sup>c</sup>n = 26.

<sup>d</sup>n = 25.

<sup>e</sup>n = 36.

<sup>f</sup>n = 29.

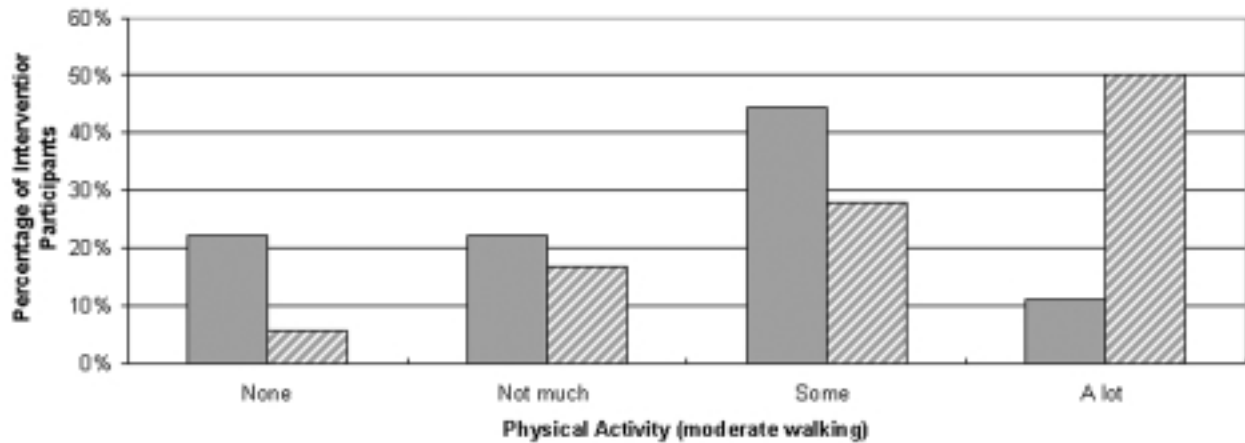


FIG. 2. Intervention participants' assessment of physical activity (moderate walking) at session 1 (gray bars) and session 12 (striped bars) ( $n = 18$ ).

tion. Twelve participants displayed up to 10 points of dietary improvement, and 9 participants improved by 11 points or more. All but 1 participant (22 of 23) had improved scores on the psychosocial questionnaire at session 12. Comparing individuals' total summed scores for self-reported nutrition and psychosocial status before and after the intervention showed a significant change in the average summed scores for the group ( $p < 0.01$ ). Women were less likely to report blaming themselves for being in a stressful situation and more likely to ask family and friends for help. They reported less frequent stress-induced eating ( $p = 0.03$ ) and a greater likelihood of working off stress with physical activity ( $p = 0.02$ ).

Although not statistically significant, women reported changes in confidence in their ability to

eat at least five servings of fruits and vegetables a day from session 1 to session 12 (Table 3). The number of women reporting that they were "not at all sure" that they could eat at least five servings of fruits and vegetables per day decreased, and the number of women who reported being "somewhat sure" rose. Fewer women, however, reported being "sure" or "very sure" at session 12. Women reported a statistically significant ( $p < 0.03$ ) rise in confidence level in doing at least 30 minutes of physical activity four or more times each week at the end of the 12-week intervention (Table 3).

The number of participants who reported being physically active for less than 6 months (action stage) rose from 2 of 22 at session 1 to 8 of 22 at session 12, representing a statistically significant ( $p < 0.001$ ) progression from the con-

TABLE 3. INTERVENTION PARTICIPANTS' CONFIDENCE IN ABILITY TO EAT HEART-HEALTHY FOODS AND PARTICIPATE IN PHYSICAL ACTIVITY

<i>How sure are you that you could</i>	<i>Week 1</i> %	<i>Week 12</i> %
<i>Eat 5 or more fruits or vegetables per day?<sup>a</sup></i>		
Not at all sure	14	0
Somewhat sure	36	59
Sure	32	18
Very sure	18	23
<i>Do at least 30 minutes of physical activity 4 or more times per week?<sup>b</sup></i>		
Not at all sure	13	9
Somewhat sure	17	9
Sure	48	39
Very sure	22	43

<sup>a</sup> $n = 22$ .

<sup>b</sup> $n = 23$ .

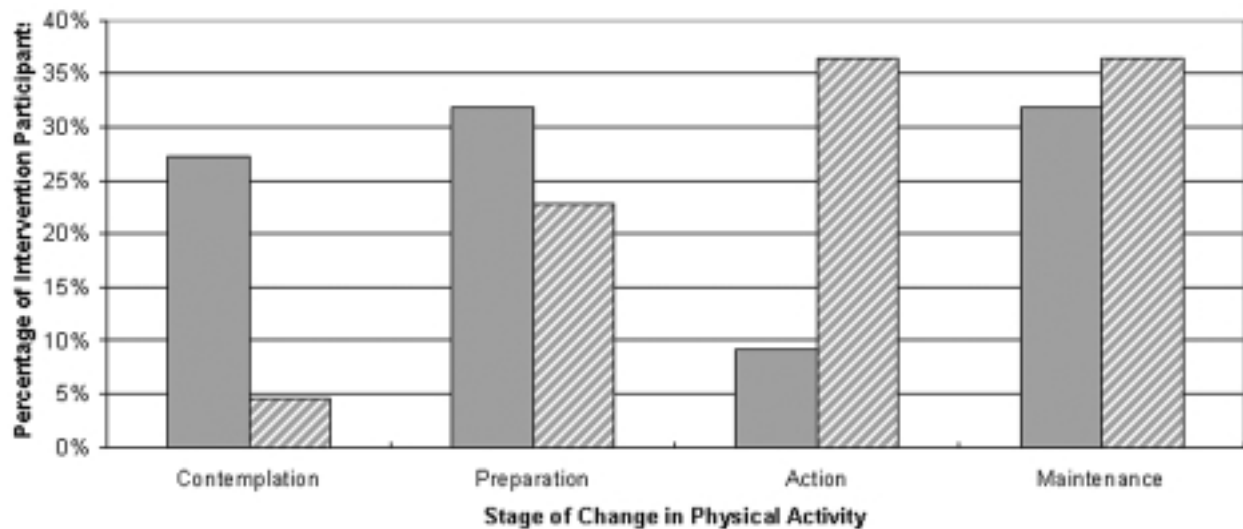


FIG. 3. Intervention participants' stages of change in physical activity at session 1 (gray bars) and session 12 (striped bars) ( $n = 22$ ).

templation and preparation stages to the action stage (Fig. 3). There was a corresponding decrease in the number of participants who reported being in the contemplation stage at session 12 (1 of 22 vs. 6 of 22 at session 1). Similarly, the number of participants who reported eating heart-healthy foods (action stage) increased from 2 of 23 at session 1 to 10 of 23 at session 12, whereas the number thinking about improving their diet within the next 30 days (preparation

stage) decreased from 18 of 23 to 9 of 23 ( $p < 0.002$ ) (Fig. 4).

At the end of the 12-week intervention, 14 participants completed assessments of the *Traditions of the Heart* materials and intervention components. Most participants (13 of 14) stated that they would recommend the intervention to others, and many (10 of 14) described the individual counseling and goal-setting as "very helpful." All 14 participants rated the heart-healthy recipes as

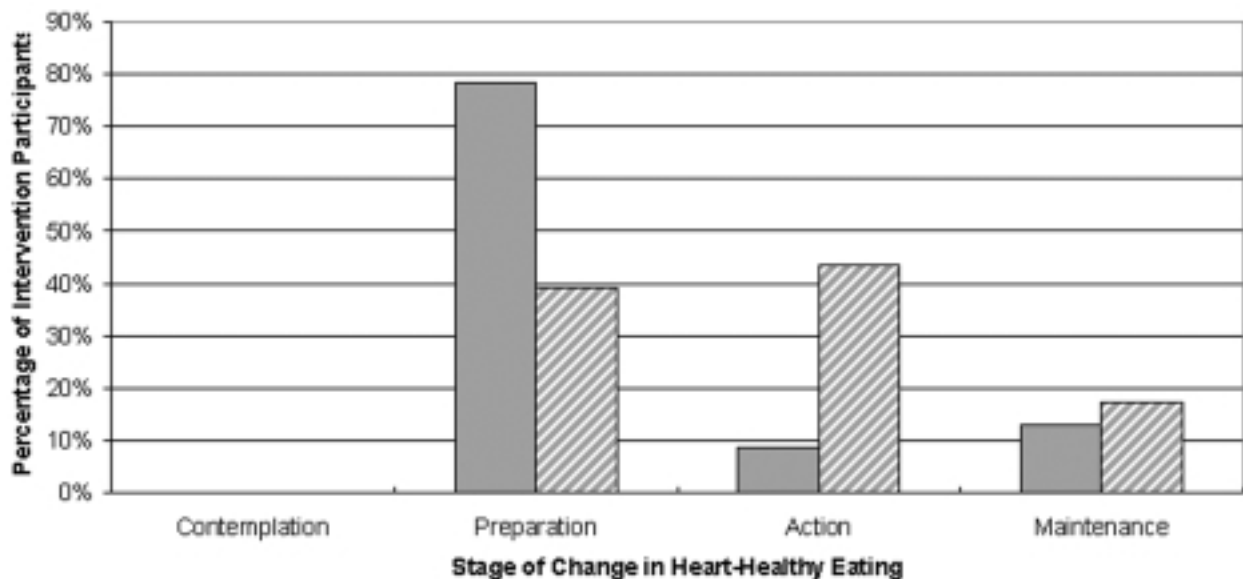


FIG. 4. Intervention participants' stages of change in heart-healthy eating at session 1 (gray bars) and session 12 (striped bars) ( $n = 23$ ).



“good” or “very good,” and most (12 of 14) reported that they would continue to use the manual and cookbook at home. Most participants thought that the duration of the intervention (12 weeks) and individual sessions (2 hours) was “just right” (12 of 14 and 11 of 14, respectively). The topics most enjoyed by participants were, in order of preference, exercise, nutrition, and stress management. The least-enjoyed topic was tobacco information.

## DISCUSSION

The high and increasing prevalence of CVD risk factors in the Alaska Native population highlights the need to implement effective interventions for CVD prevention and to further assess risk factors. Our study protocol, developed with and for Alaska Native women, represents a critical step in that direction. Although our small sample size precludes drawing any conclusions about the effectiveness of the 12-week *Traditions of the Heart* intervention, we are encouraged that participants perceived the intervention as valuable and that they exhibited significant improvements in certain areas of diet and physical activity. After the 12-week intervention, more participants reported more physical activity and higher confidence in their ability to achieve regular physical activity. Similarly, more participants reported improvements in their general nutrition and psychosocial status.

A central purpose of this pilot study was to develop, assess, and modify a study protocol to lay the foundation for a larger randomized controlled trial of the *Traditions of the Heart* intervention. Our pilot study allowed us to make several improvements. Our screening protocol was exceedingly time consuming for participants. We closely reviewed the screening measures and decided to exclude the bioelectrical impedance analysis measurement, particularly because asking participants to fast (>10 hours) for serum measurements and preventing normal hydration may have skewed our measure.<sup>14</sup> Moreover, the bioelectrical impedance measure narrowly focused participants' attention on weight loss goals rather than on the goals of healthy eating and physical activity. We also eliminated the hip circumference measure because studies show that heart disease risk can be evaluated adequately using waist measurements alone.<sup>15</sup>

Because we included measurements used in both the Strong Heart Study<sup>6</sup> and the Alaska Siberia project,<sup>4,7,8</sup> our *Traditions of the Heart* results can be compared with those of other studies. After the pilot study, we also modified the participant intake questionnaires to incorporate minimum data elements (MDEs) that allow comparison with other WISEWOMAN projects and BRFSS data. We intend to compare the risk factor prevalence in our study population with that in other WISEWOMAN populations and to compare the efficacy of our 12-week structured intervention with that of other intervention programs that incorporate similar approaches. Thus, we can begin to effectively address questions about CVD and risk factors in Alaska Native and American Indian women.

National initiatives, such as the WISEWOMAN program, that screen for cardiovascular risk factors and provide risk reduction interventions must be tailored to specific populations. By taking the time and effort to seek community support and input and build on the strengths of the Alaska Native culture, we gained greater community acceptance for our pilot study. Our results helped us to refine essential study procedures to increase their acceptability and suggested promising future directions for culturally relevant interventions for Alaska Native and American Indian women.

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