A randomized controlled trial of a public health nurse directed treatment program for rural patients with high blood cholesterol☆

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Abstract

Background. Many rural residents do not have access to high-quality nutrition counseling for high blood cholesterol. The objective of this study was to assess the effectiveness of an intervention program designed to facilitate dietary counseling for hypercholesterolemia by rural public health nurses.

Methods. Eight health departments (216 participants) were randomized to give the special intervention (SI) and nine (252 participants) to give the minimal intervention (MI). The SI consisted of three individual diet counseling sessions given by a public health nurse, using a structured dietary intervention (Food for Heart Program), referral to a nutritionist if lipid goals were not achieved at 3-month follow-up, and a reinforcement phone call and newsletters. Diet was assessed by the Dietary Risk Assessment (DRA), a validated food frequency questionnaire, at baseline, 3-, and 12-month follow-up; blood lipids and weight were assessed at baseline, 3-, 6-, and 12-month follow-up.

Results. Participants were largely female (71%), older (mean age 55), and white (80%). At 3-month follow-up, the average reduction (indicating dietary improvement) in total Dietary Risk Assessment score was 3.7 units greater in the SI group (95% confidence interval [CI] 1.9 to 5.5, $P = 0.0006$), while both groups experienced a similar reduction in blood cholesterol, 14.1 mg/dL (0.37 mmol/L) for SI and 14.5 mg/dL (0.38 mmol/L) for minimal intervention group (difference −0.4 mg/dL [−0.010 mmol/L], 95% CI −12.5 to 11.7 [−0.32 to 0.30], $P = 0.9$). At 12-month follow-up, the reduction in total Dietary Risk Assessment score was 2.1 units greater in the SI group (95% CI 0.8 to 3.5, $P = 0.005$), while the reduction in blood cholesterol was similar in both groups, 18.4 mg/dL (0.48 mmol/L) for SI and 15.6 mg/dL (0.40 mmol/L) for minimal intervention group (difference 2.8 mg/dL [0.07 mmol/L], 95% CI −7.5 to 13.1 [−0.19 to 0.34], $P = 0.6$). During follow-up, weight loss was greater in the SI group; the difference between groups was statistically significant at 3 (1.9 lb [0.86 kg], 95% CI 0.3 to 3.4 [0.14 to 1.55], $P = 0.022$) and 6 months (2.1 lb [0.95 kg], 95% CI 0.1 to 4.1 [0.04 to 1.86], $P = 0.04$). At 12 months, the difference was not significant (1.6 lb [0.73 kg], 95% CI −0.05 to 3.7 [−0.02 to 1.68], $P = 0.13$).

Conclusions. Improvement in self-reported dietary intake was significantly greater in the SI group, while reduction in blood cholesterol was similar in both groups.

Keywords: Diet therapy; Hypercholesterolemia; Public health nursing; Randomized controlled trial; Rural health

Introduction

Coronary heart disease (CHD) is a significant public health problem in the rural south [1]. Dietary behavior is a significant contributor to this increased risk [2], yet many rural residents do not have access to high-quality nutritional counseling services because public health nutritionists are in short supply (most funded through county health departments are committed to maternal and child health services) [3]. Programs are needed that can make use of other health

care providers to extend the services of nutritionists. Public health nurses are in a unique position to substantially extend nutrition services for CHD risk reduction [4] as they exist in greater numbers than most other health professionals serving rural areas [5]. However, there are many barriers to the delivery of nutrition services by public health nurses, such as lack of time, limited training in nutrition, low self-efficacy regarding lifestyle change counseling, and inadequate assessment and intervention materials [6].

While some intervention strategies have been developed and tested for nurses serving as adjuncts to physicians in suburban primary care practice settings [7], few if any have targeted public health nurses serving low-income patients in rural county health departments. Dietary intervention programs are needed that will (1) help public health nurses be more prepared to offer diet counseling for CHD risk reduction, (2) provide techniques and strategies to counsel patients about diet and heart disease, (3) increase counselor self-efficacy, and (4) overcome some of the organizational barriers faced by nurses in the health department setting. We developed a dietary treatment program for implementation by public health nurses that addresses these concerns. In this study, we report on the effectiveness of this nurse-directed intervention to modify patients' self-reported dietary intake and reduce their blood cholesterol during a 1-year follow-up period.

Methods

Study design

The design of this study, screening protocol, baseline characteristics of participants, and a detailed description of the intervention have been published elsewhere [8]. Briefly, as outlined in Fig. 1, participants were screened by their local health department for high blood cholesterol and baseline data were collected from those meeting eligibility criteria. Then, health departments were randomized to give the special intervention (SI) or the minimal intervention (MI) and participants returned for follow-up measures at 3, 6 and 12 months. The study protocol was approved by the Institutional Review Board on Research Involving Human Subjects at the University of North Carolina at Chapel Hill. Before enrolling participants, each health department signed a single project assurance agreement regarding the protection of human subjects and, prior to screening, informed consent was obtained from each participant.

Participants

County health departments in North Carolina provide a variety of clinical services to residents of their county, including preventive health services, and were eligible to participate if their county was considered rural, as defined by population density and proximity to a major metropolitan

area [9]. A convenience sample of these health departments was invited to participate. Each health department was responsible for recruiting nurses to participate in this study and for selecting one nurse to be the study's on-site coordinator to serve as a liaison with the research staff. All participating nurses attended a 2-hour session on screening for high blood cholesterol. Health departments were instructed to identify 30 participants with high cholesterol during a 3-month enrollment period. Participants were screened from a variety of settings, including primary care clinics, health screening clinics, and occupational settings. Participants were enrolled from August 1994 through June 1995, with final follow-up data collected in November 1996.

Randomization and sample size

To avoid contamination between SI and MI interventions, randomization was by county (health department) rather than by participant. Because of known differences in the demographic characteristics of counties in the eastern (primarily coastal plain with large percentage of African-American participants) compared to the western part of the state (primarily Appalachian mountains with a low percentage of African-American participants), randomization was stratified by region (east/west). Sample size calculations were based on the following assumptions: a one-sided test, with alpha = 0.05; power of 80% to detect a mean difference in total cholesterol of 12 mg/dL (0.31 mmol/L) between groups at 3-month follow-up; a cluster (county) randomized design with an intraclass correlation of 0.075; and 30 participants per county. Six health departments (180 participants) per group were required [10,11].

Screening protocol and referral to physicians

Patients were invited to be screened for this study if they were not receiving treatment for hyperecholesterolemia (defined as taking lipid-lowering medication or more than two diet counseling sessions by a health professional within the past 6 months), did not have severe chronic or acute medical conditions, were between the ages of 20 and 70 (inclusive), and if their total cholesterol level was 4.7 mmol/L or greater if checked within the past year. Those meeting these entry criteria were screened for high blood cholesterol according to guidelines of the Adult Treatment Panel II [12] of the National Cholesterol Education Program (NCEP). Screening blood work included a fasting lipid panel and thyrotropin level. Screenees were not enrolled if their low-density lipoprotein-cholesterol (LDL-C) could not be reliably calculated (triglycerides > 500 mg/dL [5.65 mmol/L] [13]), if they had hypothyroidism (thyrotropin > 2 times the upper limit of normal), or if they had an extreme elevation of cholesterol (LDL-C > 300 mg/dL [7.77 mmol/L]). Screenees were enrolled if their LDL-C was > 100 mg/dL
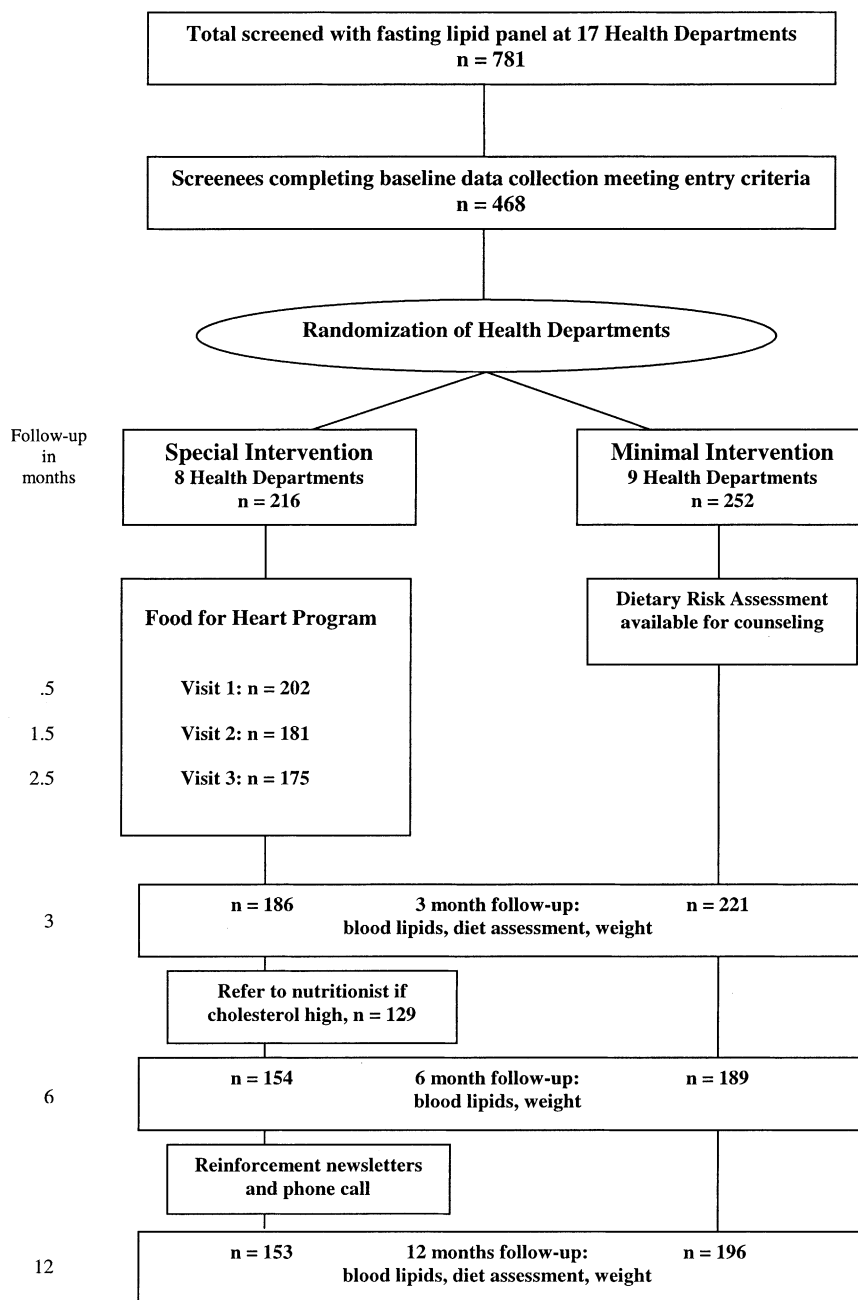
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┌─────────────────────────────────────────────────────────────┐
│      Total screened with fasting lipid panel at 17 Health     │
│                         Departments                           │
│                          n = 781                              │
└─────────────────────────────────────────────────────────────┘
                              │
┌─────────────────────────────────────────────────────────────┐
│  Screenees completing baseline data collection meeting entry  │
│                          criteria                             │
│                          n = 468                              │
└─────────────────────────────────────────────────────────────┘
                              │
                ╭──────────────────────────────╮
                │  Randomization of Health Departments  │
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Follow-up in months

	Special Intervention 8 Health Departments n = 216	Minimal Intervention 9 Health Departments n = 252
	Food for Heart Program	Dietary Risk Assessment available for counseling
.5	Visit 1: n = 202	
1.5	Visit 2: n = 181	
2.5	Visit 3: n = 175	
3	n = 186 3 month follow-up: blood lipids, diet assessment, weight n = 221	
	Refer to nutritionist if cholesterol high, n = 129	
6	n = 154 6 month follow-up: blood lipids, weight n = 189	
	Reinforcement newsletters and phone call	
12	n = 153 12 months follow-up: blood lipids, diet assessment, weight n = 196	

Fig. 1. Study flow diagram.

(2.59 mmol/L) with known CHD, 130–159 mg/dL (3.37–4.12 mmol/L) with two or more CHD risk factors (male ≥ age 45, female ≥ age 55, family history of premature CHD, current cigarette smoking, hypertension, low high-density lipoprotein-cholesterol [HDL-C] [<35 mg/dL (0.91 mmol/L)] or diabetes mellitus), or >160 mg/dL (4.14 mmol/L).

Participants were informed of their total cholesterol result by letter and all laboratory results were sent to their nurses. If blood lipids were very high at baseline and/or 3-month follow-up or high at 6- and/or 12-month follow-up (see Table 1), participants in both treatment groups were informed by letter that they should be under the care of a physician for their high cholesterol and were instructed to see their physician (in some instance, referral may have been to a nurse practitioner or physician assistant). Those who did not have a physician were asked to see a local physician willing to take referrals from the health department. A letter was mailed to physicians receiving referrals indicating the reason for referral and that use of lipid-lowering medication should be considered. Health departments nurses facilitated referrals, but participants were responsible for costs incurred.

Table 1
Risk factor and lipid criteria for referral to a physician for consideration of lipid-lowering medication and referral to a nutritionist for additional dietary counseling*

Physician

Lipid assessment	CHD[†] status	CHD risk factors	LDL-C[‡]	Total cholesterol
Screening and 3 months	No	NA**	≥220 mg/dL (5.70 mmol/L)	≥320 mg/dL (8.29 mmol/L)
	Yes	NA	≥190 mg/dL (4.92 mmol/L)	≥280 mg/dL (7.25 mmol/L)
6 and 12 months	No	NA	≥190 mg/dL (4.92 mmol/L)	≥280 mg/dL (7.25 mmol/L)
	No	≥2	≥160 mg/dL (4.14 mmol/L)	≥240 mg/dL (6.22 mmol/L)
	Yes	NA	≥130 mg/dL (3.37 mmol/L)	≥200 mg/dL (5.18 mmol/L)

Nutritionist

3 months	No	NA	≥160 mg/dL (4.14 mmol/L)	≥240 mg/dL (6.22 mmol/L)
	No	≥2	≥130 mg/dL (3.37 mmol/L)	≥200 mg/dL (5.18 mmol/L)
	Yes	NA	>100 mg/dL (2.59 mmol/L)	>160 mg/dL (4.14 mmol/L)

* Physician referrals were made for participants in both special and minimal intervention groups; nutritionist referrals were for special intervention group only. Referral was based on LDL-C unless it could not be reliably calculated (participant not fasting or triglycerides > 500 mg/dL 5.65 mmol/L), in which case, it was based on total cholesterol.

[†] CHD indicates coronary heart disease.

[‡] LDL-C indicates low-density lipoprotein-cholesterol.

** NA, not applicable, referral based on CHD status and blood lipids without regard to CHD risk factors.

Intervention

The SI (see Fig. 1) consisted of the following three components: (1) a public health nurse directed component using the Food for Heart Program (FFHP) during three counseling visits, (2) referral to a local nutritionist if lipids remained elevated at 3-month follow-up, and (3) a reinforcement program during the second half of the intervention, consisting of a phone call from the participant's nurse and two newsletters focusing on seasonal tips for food preparation and strategies to enhance dietary change. MI nurses were instructed to provide counseling for high cholesterol as they usually do. In addition, the Dietary Risk Assessment (DRA) instrument, without accompanying educational and counseling materials, was made available to MI nurses to use at their discretion.

For SI health departments, the on-site coordinator received a 4-hour tutorial and other participating nurses received a minimum of 2 hours of training on how to give the SI. When there was staff changeover at a particular site, the on-site coordinator was primarily responsible for teaching new nursing staff how to give the SI (research staff were available to assist the on-site coordinator on an as-needed basis). The on-site coordinator was also available to supervise SI nurses in all study-related activities.

Food for Heart Program

The FFHP is described in detail elsewhere [8]. It is a theory-based [14,15] dietary assessment and tailored counseling program for lower income patients with high blood cholesterol who reside in the southeastern United States. The FFHP intervention is initiated and guided by the DRA, a validated food frequency instrument designed for this

program [16] and also used in this study to assess baseline and follow-up dietary behaviors. The primary nutritional goals of the FFHP are to reduce consumption of foods high in saturated fat and increase consumption of fruits and vegetables and complex carbohydrates. Structured, individually tailored dietary counseling by public health nurses was facilitated by the DRA, illustrated goal sheets, educational pamphlets, and a "Southern style" cookbook. For example, if the frequency of hamburger consumption on the DRA falls into the problem category, the nurse uses a color-matched goal sheet that has specific suggestions regarding lean hamburger and other lower fat substitutions, which in turn is linked by number to appropriate recipes in the cookbook. Behavior change recommendations were broken into small, achievable steps, and specific strategies were recommended that addressed barriers to dietary change. The DRA was also used to monitor progress and facilitate reinforcement during a follow-up counseling session.

Nutritionist referral

SI participants were referred to a nutritionist for three counseling visits if their 3-month lipid levels remained above the NCEP cut-points for nutritional counseling (see Table 1). Referrals were to nutritionists at the participants' health department when available, or to nutritionists from local clinics, hospitals, or the cooperative extension service. Nutritionists were trained to use the FFHP materials and were provided with the 3-month DRA results along with documentation from the public health nurses concerning goal setting and progress to date. Nutritionists reviewed progress, helped address problems related to dietary change, and worked with participants to set new goals.

Data collection

Standardized protocols were used for collecting data and blood specimens on site at health departments. Participants were required to fast for the screening lipid panel. For follow-up testing, fasting was recommended, but not required. Weight and height (baseline only) were measured by health department personnel, using health department scales and stadiometers. The baseline demographic questionnaire was also administered by health department staff. Other baseline and follow-up questionnaires, including all three administrations of the DRA (baseline, 3-month, and 12-month follow-up) were conducted by trained telephone interviewers who were blinded to the participants' study group. Participating nurses completed self-administered questionnaires at baseline, 3-, and 12-month follow-up that addressed attitudes and practices concerning dietary counseling for high blood cholesterol.

The DRA is a 42-item food frequency questionnaire, which is divided into the following four categories: meats; side dishes, desserts, and snacks; diary and eggs; and spreads, salad dressing, and oil. Each item addresses a weekly or daily consumption frequency or preparation practice. Response options are categorized (scored) as "doing well" (0 points), "needs work" (1 point), or "problem" (2 points). The score for a food category is the sum of the points for items comprising the category and the total DRA score is obtained by summing food category scores. The baseline distribution of responses for each DRA item has been published [8].

Cholesterol and triglycerides were determined by automated enzymatic methods at the University of North Carolina Hospitals laboratory, a participant in the Centers for Disease Control and Prevention lipid standardization program. HDL-C was determined after precipitation with dextran sulfate-Mg2+ [17]. If triglycerides were ≤500 mg/dL (5.65 mmol/L) and the participant reported fasting status, LDL-C was calculated by using the Friedewald formula [18].

Statistical methods

Comparisons of baseline characteristics between study groups controlled for randomization by health department by using mixed-effects linear models [19]. This approach adjusts for any lack of independence among observations from the participants within each health department. In each model, the baseline characteristic being compared was the dependent variable; intervention group was treated as a fixed effect, and health department was treated as a random effect. All significance tests used the residual mean square error and degrees of freedom.

The primary hypothesis was that the SI would result in greater reduction of total cholesterol compared to the MI at 3-month follow-up. Secondary hypotheses were that the SI would result in greater reduction of LDL-C, body weight,

and DRA score compared to the MI at 3-month follow-up. In addition, an assessment was planned to determine if differences in outcomes between groups at 3 months were sustained, attenuated, or enhanced during a 1-year follow-up period. To conform with these hypothesis, one-sided tests were initially planned. However, because there was greater reduction in total cholesterol at 3-month follow-up (primary study outcome) for the MI group, two-sided P values and/or 95% confidence intervals (CIs) are reported. SAS software (SAS Institute, Cary, NC, USA) was used for all analyses.

Differences in study outcomes between groups from baseline to follow-up were assessed using mixed models [19]; separate models were used for each follow-up time point. As in the models for the baseline comparison, health department was treated as a random effect and intervention was treated as a fixed effect. To adjust the treatment comparison for baseline differences between groups, a set of variables was also included in the model as fixed effects. The set included baseline characteristics deemed relevant to lipid change a priori (age, gender, race, educational achievement, known CHD, number of CHD risk factors, and smoking) and one additional variable that was different between groups at baseline, percentage with high blood pressure. Statistical tests comparing changes in triglyceride levels were performed by using log-transformed data.

Our initial analysis of outcomes included all returnees with follow-up data. We also conducted an analysis setting change scores to 0 for participants who did not complete a follow-up dietary assessment or did not return for follow-up blood testing. Finally, to assess lipid change not associated with lipid-lowering medication, an analysis was done for participants who returned and were not taking such medication.

Results

Eight health departments (216 participants) were randomized to SI and nine (252 participants) to MI. Demographic data from the 1990 U.S. Census [20] were used to compare the counties represented by these health departments and there were no statistically significant differences between SI and MI counties [8]. The average population in these counties was 46,850, with 82% white, 16% African American, and 1% American Indian.

Ninety-five nurses, 44 at SI and 51 at MI health departments, completed a baseline questionnaire that was administered prior to their tutorial on screening for high blood cholesterol and enrolling subjects into this study. Comparing these SI to MI nurses, their means for age (45 for SI, 43 of UC, $P = 0.54$), number of years in community nursing (8.5 for SI, 9.2 for UC, $P = 0.66$), number of years in current setting (7.6 for SI, 8.9 for MI, $P = 0.45$), and their types of nursing degrees (associate, diploma, baccalaureate, $P = 0.44$) were similar. SI nurses, however, reported more

Table 2

Baseline lipids, weight, and Dietary Risk Assessment scores, adjusted for randomization by health department

Characteristic	Special intervention (N = 216)		Minimal intervention (N = 252)		P
	Mean	SE	Mean	SE	
Total cholesterol, mg/dL (mmol/L)	258 (6.68)	3.1 (0.08)	256 (6.63)	2.9 (0.08)	0.65
Triglycerides, mg/dL (mmol/L)	162 (1.83)	7.2 (0.08)	172 (1.94)	6.7 (0.08)	0.31
HDL-C,* mg/dL (mmol/L)	45 (1.17)	.88 (0.02)	43 (1.11)	.81 (0.02)	0.13
LDL-C,[†] mg/dL (mmol/L)	181 (4.69)	2.3 (0.06)	179 (4.64)	2.1 (0.05)	0.51
Weight, lb (kg)	175 (79.5)	4.5 (2.0)	176 (80.0)	4.2 (1.9)	0.89
Dietary Risk Assessment score					
Meats	10.1	.60	9.3	0.53	0.30
Side dishes, desserts, snacks	7.8	.36	7.8	0.34	0.90
Dairy, eggs	1.9	.14	1.9	0.13	0.73
Spreads, salad dressings, oils	3.3	.25	2.9	0.23	0.15
Total score	23.1	1.1	21.9	1.1	0.47

* HDL-C indicates high-density lipoprotein-cholesterol.

[†] LDL-C indicates low-density lipoprotein-cholesterol.

years of nursing experience (20.0 vs. 15.6 years), a difference that was statistically significant, $P = 0.049$. Nurses at participating health department screened 781 subjects. Of these, 468 met all eligibility criteria and participated in this study. During the 1-year follow-up period, there was one death and 24 withdrawals, 11 from SI and 13 from MI participants.

Baseline characteristics of participants

Baseline characteristics have been described in detail [8] and the study groups were similar. Overall, 6 of 91 comparisons of baseline variables reached a nominal 0.05 level of significance, about the number to be expected by chance alone. Participants were largely female (71%), older (mean age 55), and white (80%). Almost three-fourths were high school graduates, the majority had two or more CHD risk factors, and about 10% had known CHD at the time of screening. Though more than three-fourths reported a cholesterol check during the preceding year, only 11% reported counseling for high cholesterol from a doctor, nurse, or nutritionist during the preceding 6 months. Nonetheless, most reported modest intake of foods high in saturated fat and cholesterol [8]. Baseline lipid values, body weight, and DRA scores are shown in Table 2.

Dietary counseling

The first component of the SI consisted of three structured counseling visits given by health department nurses. Two hundred two (94%) SI participants returned for the first visit, 181 (84%) for the second, and 175 (81%) for the third. The second component of the SI consisted of referral to a nutritionist if the LDL-C goal was not achieved at 3-month follow-up. Of 186 SI participants who returned for the 3-month follow-up blood test, 146 (78%) met criteria for nutritionist referral. Of these, 17 also met criteria for phy-

sician referral for very high blood lipids and inadvertently were referred to physician only instead of physician and nutritionist. Of the 129 referred to a nutritionist, 82 (64%) attended the first session, 67 (52%) the second, and 45 (35%) the third.

During the 3-month follow-up interview, participants were asked if any health professional other than their health department nurse had given them dietary advice during the preceding 6 months. Nineteen percent of SI and 25% of MI participants reported receiving such advice. At 12-month follow-up, 51% of SI compared to 11% of MI participants reproted seeing a nutritionist during this study. At 3-month follow-up, MI nurses were asked to what extent they used the DRA to facilitate counseling with MI participants. Of 32 respondents, 17 (53%) did not use it at all and 10 (31%) used it with 3 or more participants.

Lipid lowering medication

The number of participants taking lipid-lowering medication during follow-up was small. At 3 months, 6 (3.2%) SI and 8 (3.6%) MI participants reported taking medication; at 6 months, 3 (1.9%) SI and 8 (4.2%) MI participants reporting taking medication; while at 12 months, there was an increase to 11 (7.2%) for SI and 15 (7.6%) for MI participants. The most frequently prescribed medications were statins. At 3-month follow-up, 25 (15 SI and 10 MI) participants had very high cholesterol and were referred to a physician who was instructed to consider initiating lipid-lowering medication. Of these, 21 (12 SI and 9 MI) returned for 6-month follow-up and 1 (0 SI and 1 MI) was taking lipid-lowering medication. At 6-month follow-up, 155 (70 SI and 85 MI) participants had high cholesterol and were referred for consideration of lipid-lowering medication. Of these, 129 (54 SI and 75 MI) returned for 12-month follow-up and 11 (5 SI and 6 MI) were taking such medication.

Table 3
Adjusted mean values for reduction in Dietary Risk Assessment food group and total scores from baseline and comparison of reduction between groups*

Component	Special Intervention					Minimal Intervention					Difference		
	N	Mean	(SE)	95% CI[†]		N	Mean	(SE)	95% CI		Mean	95% CI	
				Lower	Upper				Lower	Upper		Lower	Upper
Meat													
3 Month	199	2.8	(0.30)	2.2	3.5	225	1.1	(0.28)	0.5	1.7	1.7	0.8	2.5
12 Month	171	2.5	(0.26)	2.0	3.1	205	1.4	(0.23)	0.9	1.9	1.1	0.3	1.8
Side dishes													
3 Month	201	1.5	(0.26)	1.0	2.1	229	0.7	(0.24)	0.1	1.2	0.9	0.1	1.6
12 Month	172	1.0	(0.21)	0.5	1.4	210	0.8	(0.19)	0.4	1.2	0.2	−0.4	0.8
Dairy													
3 Month	201	0.7	(0.14)	0.4	1.0	229	0.4	(0.13)	0.2	0.7	0.3	−0.1	0.7
12 Month	172	0.6	(0.14)	0.3	0.9	210	0.5	(0.13)	0.2	0.8	0.1	−0.3	0.6
Oils													
3 Month	192	0.3	(0.13)	0.0	0.6	226	1.1	(0.14)	0.8	1.4	0.8	0.4	1.2
12 Month	167	1.2	(0.14)	0.9	1.5	207	0.6	(0.13)	0.3	0.9	0.6	0.2	1.0
Total score													
3 Month	191	6.2	(0.61)	4.9	7.6	222	2.6	(0.57)	1.4	3.8	3.7	1.9	5.5
12 Month	166	5.4	(0.48)	4.4	6.4	202	3.3	(0.43)	2.3	4.2	2.1	0.8	3.5

* A reduction in score indicates an improved diet. Adjusted for the following variables: age, gender, race, educational achievement, known coronary disease, number of coronary heart disease risk factors, smoking, and high blood pressure.

[†] CI indicates confidence interval.

Changes in dietary intake

At 3-month follow-up, 98% of SI and 96% of MI participants indicated they were currently "trying to eat a more heart healthy diet." At 12-month follow-up, these percentages were slightly lower, 93% and 95%, respectively. Table 3 shows change in self-reported dietary intake, by food category and total score, as assessed by the DRA at 3- and 12-month follow-up. For all participants, the reduction in DRA score from baseline was statistically significant at 3- and 12-month follow-up for each food category and total score. The reduction in score for each of the individual food categories was larger for SI compared to MI; for meats and oils the difference was statistically significant at both 3- and 12-month follow-up. At 3-month follow-up, the average reduction in total DRA score for the SI group was 3.7 units greater than for MI (95% CI, 1.9 to 5.5, $P = 0.0006$); at 12-month follow-up, it was 2.1 units greater (95% CI, 0.8 to 3.5, $P = 0.005$). The results were similar when analyzed with DRA change score set to 0 for participants who did not complete follow-up DRAs (data not shown).

Changes in blood lipids

The return rate for follow-up blood testing was 87% (86% SI and 88% MI) at 3 months, 73% (71% SI and 75% MI) at 6 months, and 75% (71% SI and 78% MI) at 12 months. During follow-up, the reduction in total and LDL-C from baseline was statistically significant in both treatment groups (Table 4). For total cholesterol, the reduction at 3-month follow-up was 5.6% for SI and 5.8% for MI; at 12 months, it was 7.1% and 6.3%, respectively. For LDL-C,

the reduction at 3 months was 7.2% for SI and 8.7% for MI; at 12 months, it was 11.0% and 9.6%, respectively.

For the primary outcome, the difference in total cholesterol between groups at 3-month follow-up (Table 4 and Fig. 2), there was a slightly greater reduction in the MI group (0.4 mg/dL [0.01 mmol/L]) that was not statistically significant ($P = 0.9$). At 6-month follow-up, there continued to be a slightly greater reduction in the MI group (0.9 mg/dL [0.02 mmol/L]), while at 12-month follow-up, there was a somewhat greater reduction in the SI group (2.8 mg/dL [0.07 mmol/L]) that was not statistically significant ($P = 0.6$). The reduction in LDL-C during follow-up was also similar between groups, i.e., at 3 months, there was a somewhat greater reduction in the MI group (3.2 mg/dL [0.08 mmol/L], $P = 0.5$); at 6 months, there was slightly greater reduction in the MI group (0.5 mg/dL [0.01 mmol/L]), while at 12 months, the reduction was somewhat greater in the SI group (2.8 mg/dL [0.07 mmol/L], $P = 0.5$). The results were similar when analyzed with lipid change set to 0 for participants who did not return for follow-up testing (data not shown).

Because use of lipid-lowering medication is a potent cointervention, an analysis was undertaken restricted to returnees who were not taking such medication (Table 4 and Fig. 2). The absolute reductions in total and LDL-C in both groups were slightly less than among all returnees (except for LDL-C reduction in SI group at 6 months) and there were small increases in the difference between treatment groups at 6- and 12-month follow-up, favoring the SI group. However, no differences between treatment groups approached statistical significance.

Changes in triglycerides and HDL-C are depicted in Fig.

Table 4
Adjusted mean values for reduction in total and low-density lipoprotein-cholesterol in mg/dL (mmol/L) from baseline and comparison of reduction between groups*

Component	Special intervention					Minimal intervention					Difference		
	N	Mean	(SE)	95% CI[†] Lower	Upper	N	Mean	(SE)	95% CI Lower	Upper	Mean	95% CI Lower	Upper
All returnees													
Total cholesterol													
3 month	186	14.1 (0.37)	(4.14) (0.11)	5.3 (0.14)	22.9 (0.59)	221	14.5 (0.38)	(3.85) (0.10)	6.3 (0.16)	22.7 (0.59)	−0.4 (−0.01)	−12.5 (−0.32)	11.7 (0.30)
6 month	154	15.4 (0.40)	(3.32) (0.09)	8.4 (0.22)	22.5 (0.58)	189	16.3 (0.42)	(3.08) (0.08)	9.7 (0.25)	22.9 (0.59)	−0.9 (−0.02)	−10.6 (−0.27)	8.9 (0.23)
12 month	153	18.4 (0.48)	(3.55) (0.09)	10.9 (0.28)	26.0 (0.67)	196	15.6 (0.40)	(3.23) (0.08)	8.7 (0.23)	22.5 (0.58)	2.8 (0.07)	−7.5 (−0.19)	13.1 (0.34)
LDL-C													
3 month	180	12.3 (0.32)	(3.36) (0.09)	5.1 (0.13)	19.4 (0.50)	211	15.5 (0.40)	(3.13) (0.08)	8.8 (0.23)	22.1 (0.57)	−3.2 (−0.08)	−13.0 (−0.34)	6.6 (0.17)
6 month	146	16.0 (0.41)	(2.76) (0.07)	10.1 (0.26)	21.9 (0.57)	173	16.6 (0.43)	(2.56) (0.07)	11.1 (0.29)	22.1 (0.57)	−0.5 (−0.01)	−8.7 (−0.23)	7.6 (0.20)
12 month	149	19.6 (0.51)	(3.15) (0.08)	12.9 (0.33)	26.3 (0.68)	179	16.7 (0.43)	(2.91) (0.08)	10.5 (0.27)	22.9 (0.59)	2.8 (0.07)	−6.4 (−0.17)	12.1 (0.31)
Returnees not taking lipid-lowering medication													
Total cholesterol													
3 month	180	13.2 (0.34)	(4.09) (0.11)	4.5 (0.12)	21.9 (0.57)	213	13.4 (0.35)	(3.82) (0.10)	5.3 (0.14)	21.6 (0.56)	−0.2 (−0.01)	−12.2 (−0.32)	11.7 (0.30)
6 month	151	14.8 (0.38)	(3.11) (0.08)	8.2 (0.21)	21.5 (0.56)	181	14.0 (0.36)	(2.89) (0.07)	7.9 (0.20)	20.2 (0.52)	0.8 (0.02)	−8.3 (−0.21)	9.9 (0.26)
12 month	142	16.1 (0.42)	(3.49) (0.09)	8.6 (0.22)	23.5 (0.61)	181	12.2 (0.32)	(3.20) (0.08)	5.4 (0.14)	19.1 (0.49)	3.8 (0.10)	−6.3 (−0.16)	14.0 (0.36)
LDL-C													
3 month	174	11.3 (0.29)	(3.34) (0.09)	4.1 (0.11)	18.4 (0.48)	204	14.8 (0.38)	(3.11) (0.08)	8.1 (0.21)	21.4 (0.55)	−3.5 (−0.09)	−13.3 (−0.34)	6.2 (0.16)
6 month	144	16.2 (0.42)	(2.58) (0.07)	10.6 (0.27)	21.7 (0.56)	165	14.2 (0.37)	(2.43) (0.06)	9.0 (0.23)	19.4 (0.50)	2.0 (0.05)	−5.7 (−0.15)	9.7 (0.25)
12 month	139	16.9 (0.44)	(3.17) (0.08)	10.2 (0.26)	23.6 (0.61)	165	13.6 (0.35)	(2.94) (0.08)	7.3 (0.19)	19.9 (0.52)	3.3 (0.09)	−6.0 (−0.16)	12.5 (0.32)

* LDL-C indicates low-density lipoprotein-cholesterol. Adjusted for the following variables: age, gender, race, educational achievement, known coronary disease, number of coronary heart disease risk factors, smoking, and high blood pressure.

[†] CI indicates confidence interval.

A

All Returnees

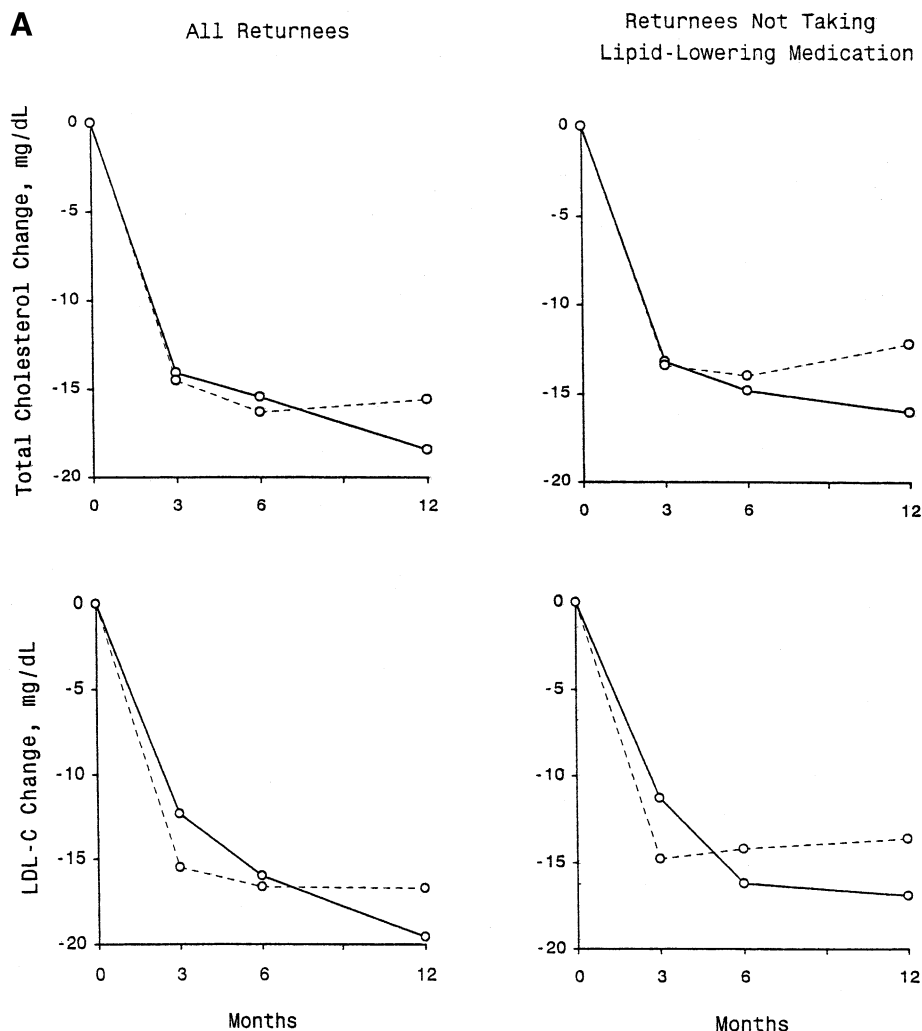Returnees Not Taking
Lipid-Lowering Medication

Fig. 2. Adjusted mean changes from baseline for total cholesterol, low-density lipoprotein cholesterol (LDL-C), triglycerides, and high-density lipoprotein cholesterol (HDL-C). Solid line indicates special intervention; broken line indicates minimal intervention. (To convert cholesterol in mg/dL to mmol/L, multiply by 0.0259; to convert triglycerides in mg/dL to mmol/L, multiply by 0.0113.)

2. For triglycerides, the differences within groups from baseline to follow-up and between groups during follow-up were small and not statistically significant (all P values for comparisons between groups > 0.4). For HDL-C, among all returnees there was a significant decrease of 1.0 mg/dL (0.03 mmol/L) (95% CI 0.0 to 2.0 [0.00 to 0.05]) from baseline to 3-month follow-up in the SI group and significant increases from baseline to 12-month follow-up in both groups, i.e., 1.8 mg/dL (0.05 mmol/L) for SI (95% CI 0.6 to 3.0 [0.02 to 0.08]) and 1.6 mg/dL (0.04 mmol/L) for MI (95% CI 0.6 to 2.6 [0.02 to 0.07]). However, there were no significant differences between treatment groups during follow-up (all P values for comparisons between groups > 0.2).

Weight change was modest in amount during follow-up. The reduction was statistically significant for the SI group at 3-month (2.8 lb [1.27 kg], 95% CI 1.7 to 4.0 [0.77 to 1.81]), 6-month (3.1 lb [1.41 kg], 95% CI 1.7 to 4.6 [0.077 to 2.09]), and 12-month follow-up (1.6 lb [0.73 kg], 95% CI

0.1 to 3.2 [0.05 to 1.45]). For the MI, weight loss was not statistically significant at 3 months (1.0 lb [0.45 kg], 95% CI -0.1 to 2.0 [-0.05 to 0.91]), 6 months (1.0 lb [0.45 kg], 95% CI -0.3 to 2.3 [-0.14 to 1.05]), or 12 months (no change from baseline). Comparing SI to MI, the greater reductions of 1.9 lb (0.86 kg) (95% CI 0.3 to 3.4 [0.14 to 1.55], $P = 0.022$) at 3-month follow-up and 2.1 lb (0.95 kg) (95% CI 0.1 to 4.1 [0.05 to 1.86], $P = 0.04$) at 6-month follow-up were statistically significant, while the greater reduction of 1.6 lb (0.73 kg) (95% CI -0.5 to 3.7 [-0.23 to 1.68], $P = 0.13$) at 12-month follow-up was not significant.

Discussion

Public health nurses are in a unique position to substantially extend nutrition services for CHD risk reduction in rural areas. In this study, we evaluated the effectiveness of a dietary intervention program designed to facilitate coun-
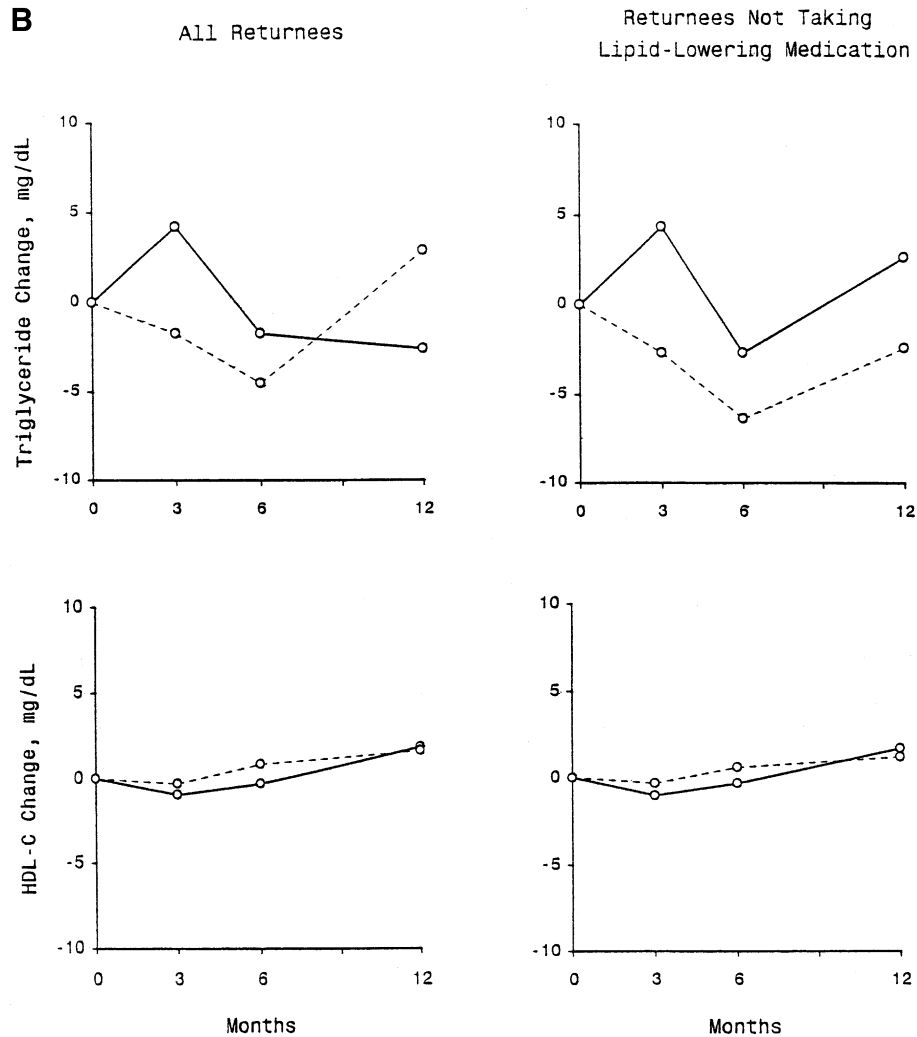
B

All Returnees

Returnees Not Taking
Lipid-Lowering Medication

Fig. 2 *(continued)*

seling for high cholesterol by rural public health nurses. Participants in both treatment groups reported statistically significant improvement in dietary intake during follow-up with changes in the SI significantly greater than those in the MI. Blood lipids also decreased significantly in both groups, but there was no statistically significant difference in lipid reduction between groups.

The absence of an intervention effect for the primary outcome of lipid change was due in part to the greater than expected total and LDL-C reductions in the MI group. It is possible that our MI was substantially more effective at lipid reduction than usual care. We are aware (based on observations of our field research staff) that some MI health departments undertook substantial educational efforts for their participants enrolled in this study and many MI nurses may have been motivated to give optimal care because they knew their patients' lipid changes were going to be carefully monitored. In addition, all participants knew they were in a cholesterol-lowering study and received the results of their lipid blood work, both of which may have served as a

motivator for behavior change. It is also worth noting that greater than 90% of participants in both treatment groups reported they were "trying to eat a more heart healthy diet" at both 3- and 12-month follow-up. Other factors that may have contributed to the lack of intervention effect include a relatively fat-restricted diet at baseline, an SI with insufficient effectiveness to lower lipids more than the MI, and/or inadequate implementation of the SI including inadequate training for nurses both at the outset and for newly hired nurses at SI health departments. These limitations have also been identified as possible explanations for nonsignificant intervention effects in other cholesterol-lowering trials [7,21–23].

Positive findings with respect to self-reported dietary change scores accompanied by small or no difference with respect to measured changes in blood lipids have been observed in clinical trials of dietary interventions to lower cholesterol [7,21]. This may be due in part to social desirability bias—that is, respondents know how they should be eating and are inclined to answer dietary assessment ques-

tions in such a way that reflects this knowledge [22,24,25]. Because the DRA was used to both guide the intervention and assess dietary intake during follow-up, we believe SI participants were more likely to know the correct answers to dietary assessment questions, and thus more likely to report desirable dietary behavior than MI participants. It is this reporting bias that is the most likely explanation for the observed difference between groups with regard to DRA score, but no difference between groups in lipid outcomes. It is also possible that participants in the SI group made more appropriate dietary changes than MI participants (as evidenced by greater weight reduction), but that these changes were not fully reflected by the observed reductions in total and LDL-C. More sensitive biomarkers of dietary intake, such as direct measurement of fatty acids levels [26], may be required to detect such changes.

Increasing appropriate use of lipid-lowering medication was not an objective of this study, but participants were referred to physicians for consideration of lipid-lowering medication if they had very high cholesterol at baseline or 3-month follow-up and if they met NCEP [12] cut-points for medication use at 6-month follow-up. It is noteworthy that only 1 of 21 participants with very high cholesterol at 3-month follow-up and only 11 of 129 who met NCEP criteria for medication at 6-month follow-up were taking lipid-lowering medication at their subsequent follow-up visit. We are unable to determine why participants were not taking lipid-lowering medication, but speculate many did not follow through with their referral visits, physicians may not have prescribed medications, or if prescribed, participants did not use or did not maintain their use of these medications, possibly due to high medication costs. Underuse of lipid-lowering medications has been reported in routine practice settings [27–30].

Conclusions

In conclusion, participants in both treatment groups reported a statistically significant improvement in dietary intake and experienced a statistically significant reduction in total and LDL-C that was similar to somewhat greater in amount than commonly observed in community- and clinic-based trials and was sustained during a 1-year follow-up period (Tang and colleagues [31] reported an average reduction of 5.3% in dietary trials of at least 6 months in duration). While there was no difference between groups for the primary endpoint of total cholesterol reduction at 3-month follow-up, SI participants reported greater improvement in dietary intake and experienced modest, but statistically significant greater weight loss. These findings suggest public health nurses in rural areas should offer dietary counseling to those identified with high blood cholesterol. More research is needed to determine the most efficient and effective counseling strategies to use in this setting.

Acknowledgments

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