

Nutritional Counseling For Dietary Cholesterol Reduction: The Effect Of Training A Second Member Of The Household

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A. Introduction

a. NCEP 1 (1988)

establishment of national guidelines for the management of hypercholesterolemia

b. Dietary Interventions

i. Step I Diet

<30% calories as fat, <10% SFAs, <300 mg/d cholesterol

ii. Step II Diet:

<7% SFA and <200 mg/d cholesterol

c. Efficacy

i. Meta-analysis of 37 clinical trials (Yu-Peth et al, 1999)

1. Step I: 7-10% reduction

2. Step II: 10-20% reduction

ii. Compare 5% dietary reduction to 27% reduction with a statin

iii. Also consider reduction of HDL and increases in TG with same diet

iv. "... the growing number of publications on studies of the efficacy of nutrition counseling ... demonstrating unimpressive results in regard to the management of blood lipid levels and the prevention of CHD events" (Kannel, 1996)

d. Other directions

i. Initial efficacy good, attenuates over time ; concerns are those of compliance (Henkin, 1992)

ii. Modifications of office practices (Caggiula et al, 1996)

iii. Worksite education programs (Baer, 1993)

iv. Gender barriers (Auld et al, 1991)

v. Racial barriers (Howard et al, 1995)

B. New proposal

to strengthen the home support by co-education of a family member

a. A. Major dietary changes have natural barriers

b. B. Though initial education effective and even translates into lifestyle changes, the effect is short lived

c. C. Perhaps by strengthening home support through co-education of a family member, dietary compliance can be improved and the initial effect can be maintained

C. Methods

a. Primary outcome: change in plasma LDL

i. Initial LDL from physicians practice averaged with second LDL upon entry into study

ii. LDL calculated at end of six months and again upon return to clinic

iii. Change calculated

b. Secondary outcomes

i. Plasma HDL and TGs, change

ii. Weight and body mass index, change

iii. Compliance with indicated diet

- iv. Nutritional awareness, improvement**
- c. Design**
 - i. RCT, unblended
 - ii. Patients recruited from resident clinics, indicated for dietary intervention, interested in sustained nutritional training
 - iii. Initial visit
 - 1. Verification of appropriateness for intervention**
 - 2. Informed consent**
 - 3. Initial data**
 - iv. **Randomization**
 - 1. To attend alone or with partner
 - a. Stratified by gender, starting LDL, target LDL
 - b. Biweekly class
 - 2. Individual assessments three times
 - 3. Compliance with diet, with readjustment
 - 4. Weight
 - 5. Completion of trial at six months with assessment of primary endpoints
- d. Statistical Analysis and Sample size**
 - i. Student t-test, two-tailed, unpaired
 - ii. Sample size of 100 will find 10% difference with power of 80%
- e. Study population**
 - i. Population recruited from resident clinics
 - ii. **Inclusion criteria:**
 - 1. Twenty or more years of age, men or women, English or Spanish speaking
 - 2. Commuting distance to CPMC, interest in participation
 - 3. LDL obtained during routine testing by PMD, assessed in conjunction with other risk factors for CAD, indicated by NCEP, ATP III guidelines for TLC diet
 - 4. Member of household that includes at least one other adult
 - a. This adult plays role in food selection and/or preparation
 - b. Eats at least 7 meals/weeks with subject
 - c. Preference: spouse before 1st degree relative before more distant relative before roommates / neighbors close friends
 - iii. **Exclusion criteria**
 - 1. Not on or indicated to receive lipid lowering agent
 - 2. No previous formal nutrition training
 - 3. Exclusion criteria does not apply to partner
 - iv. **Potential biases**
 - 1. Population :
 - a. Community bias -- limits general applicability, potential offense in introduction of Western diet
 - b. Gender bias - Likely more women than men
 - c. Study bias: Highly motivated individuals, decreases power
 - d. Not seriously ill: Under NCEP III guidelines, not indicated for statin ; may decrease power
 - e. Lack of knowledge about partner: may have hidden bias
 - v. **Recruitment**
 - 1. From resident clinics, select private offices
 - 2. May offer alternative to more expensive dietary interventions ; measures to prevent targeting vulnerable populations

vi. Future applications

1. Larger study involving more diverse populations
2. Alteration of guidelines to include alteration of household lifestyle modification
3. Application to other types of diets indicated for medical conditions

A. Study Purpose and Rationale

Since 1988 and the establishment of national guidelines for the management of hypercholesterolemia and hyperlipidemia, clinical studies have explored the efficacy of dietary modification in the treatment of these conditions. Two such programs of dietary management advocated by the National Cholesterol Education Program (NCEP) are the Step I diet (<30% energy as fat, <10% energy as saturated fatty acids (SFA), and <300 mg of dietary cholesterol/d) and the Step II diet (<7% SFA and <200 mg cholesterol/d). In 37 intervention studies performed prior to 1999 using one of these two interventions, results varied somewhat, with a meta-analysis of these studies showing mean reductions in LDL of 7-9% and 10-20%, respectively¹. Though effective, a randomly controlled trial in which patients were randomized to drug therapy vs. dietary intervention showed a reduction of 27% in patients receiving a statin vs. only an additional 5% reduction through a low-fat diet.² The efficacy of dietary fat reduction is also offset by decreases in HDL cholesterol and increases in triglycerides.^{1,2} There exists a dissatisfaction with dietary modification, with William B. Kannel of the Framingham Heart Study writing of "the growing number of publications on studies of the efficacy of nutrition counseling ... demonstrating unimpressive results in regard to the management of blood lipid levels and the prevention of CHD events"³

While the initial reduction of cholesterol levels with the institution of a diet low in SFA and cholesterol may be more dramatic, the effects decrease over time, with issues of compliance implicated in this attenuation.⁴ Programs which facilitate compliance with dietary changes have been explored, and have involved modifications of community office practices,⁵ and worksite nutrition education programs.⁶ Other efforts have explored the barriers presented by gender,⁷ and race.⁸ Though conflicting, these studies appear to show that there exists a group of people who - provided the necessary support - could significantly lower their plasma cholesterol levels through dietary modification alone. The continued inclusion of recommended dietary modifications in the third report of the Adult Treatment Panel (ATP III) of the NCEP⁹ encourages further attempts to clarify the efficacy of dietary interventions.

One aspect of the social support system, for the most part unexplored clinically, is the role of family members in helping a person adhere to a diet. Recommendations of dietary modifications usually focus on the person with disease, and either completely ignore -- or casually assume the complete support of -- other members of the household. With food selection and preparation a natural and even ritualistic aspect of family life, there is room to explore household dietary modification as an important part of the treatment of hypercholesterolemia. The study will attempt to explore the additional effect of nutritional counseling when expanded to include a second member of the household.

B. Study Design and Statistical Analysis

The study design is a randomized, controlled trial. Subjects will be adults who have had a routine, fasting lipid profile performed as part of their care at a Columbia affiliated clinic, and for whom dietary modification is indicated in their treatment. Upon agreeing to participate in the study, the subjects will participate in an intensive nutritional education program, and randomized to complete the training either alone or with concomitantly with another adult member of their household. The randomization will be stratified by gender, starting LDL, and target LDL.

Prior to involvement in the program, patients will supply demographic information including age and the presence of known risk factors for CAD, have a repeat fasting lipid profile, have assessments of weight and body mass index, and complete a dietary analysis (the Eating Pattern Assessment Tool, or EPAT) which quantifies the number of calories in their diet and provides an assessment of what percentage of those calories

come from SFAs, UFAs, and total cholesterol intake/d. In addition, and pencil and paper test will be administered to assess basic food knowledge.

Nutritional training will follow models used in previous studies.^{5,6,8} The objective will be compliance with the Therapeutic Lifestyle Changes (TLC) diet recommended by the NCEP in their ATP III guidelines.⁹ Over six months, patients will attend nutritional education training classes at the Institute of Nutrition in Presbyterian Hospital on the CPMC campus. Classes will be in a kitchen model, focusing on food preparation of foods low in cholesterol and SFAs. Classes will be biweekly, in groups of 10- 12, in both English and Spanish. Attendance at classes will be assessed, with any subject who misses two consecutive classes receiving a phone call.

In addition, there will be 3 additional individual sessions set up with the subject, with or without his or her partner, as indicated. At these times, weight/BMI will be assessed, and the EPAT administered to assess compliance with the recommended diet. Readjustments to the subjects' diets will be made at this time.

At the completion of six months, subjects will return for a final session. Fasting lipid profiles will be obtained, as well as weight, BMI, EPAT administration, and a repeat administration of the nutritional awareness survey. Subjects will be set-up with a followup appointment with their PMD, and a repeat fasting lipid profile within two weeks of the completion of their study.

Data will be assessed by unpaired, two-tailed, t-testing, under the intention-totreat analysis. The primary end-point will be change in LDL values, comparing the mean of the physician and study-obtained LDL values before and after completion of nutritional training. Assuming changes in LDL consistent with prior tests, 100 patients will need to be recruited to assess a 10% difference, given a power of 80% and alpha <.05. Secondary end-points will include: changes in serum triglycerides and serum HDL values, changes in weight and body mass index, compliance with the TLC diet as assessed by EPAT, changes in cholesterol/d and changes in SFA as a percent of total calories per day. Differences in frequency of attendance of group sessions will also be noted.

C. Study Procedure

This study will require the collection of two samples of blood from the subjects, in order to assess serum lipid profiles. This is in addition to the serum lipid profiles collected by the subject's primary medical provider prior to the study, and one scheduled at the conclusion of study as part of that patient's indicated medical follow-up.

This study also makes use of the Eating Pattern Assessment Tool (EPAT) as described above. This is a five-page test administered by a registered dietician that assesses a person's diet in terms of calories, total cholesterol/d, and percent of total cholesterol coming from SFAs. The administration of this test requires a patient to recall his or her diet for the last week, and takes between 15-20 minutes to complete. This test will be administered at the beginning and end of the study, and during three scheduled individual sessions during the study.

The nutritional training administered to each patient would be consistent with the idealized treatment indicated for these individuals, and exceeds what this patient population can typically expect from their primary medical providers.

The study will be conducted for six months, and require the subject to attend 4560 minute sessions at the beginning and end of the trial, as well as biweekly classes of 60-90 minutes, and three individual sessions with a nutritionist of 60-90 minutes. At the completion of the study, the patient will follow-up with their primary physician.

D. Study drugs

No drugs will be used in this study.

E. Medical Devices

No medical devices will be used in this study.

F. Study Questionnaires

The EPAT and copy of the nutritional knowledge assessment tests are included in the appendix.

G. Study Subjects

Entry criteria will be the following:

- Subjects will be twenty or more years of age, men or women, English or Spanish speaking. They will be members of a Columbia-affiliated clinic (AIM, ACNQ or private physician. They will live within easy commuting distance of CPMC, and have the freedom in their schedule to attend biweekly sessions.
- Subjects will have an LDL obtained during routine testing by their PMD which, when assessed in conjunction with their other risk factors for CAD, will indicate a dietary intervention under the guidelines laid out in the NCEP, ATP III protocol.
- Subjects will live in a household that includes at least one other adult. This adult must play at least some role in food selection and/or preparation, and eat at least 7 meals/weeks with the patient. Preference will be first to spouse or domestic partner, then to first-degree relatives including sibling, parent, or adult son or daughter, and then to more distant relatives, roommates, and lastly close friends or neighbors.

Exclusion criteria:

- No one on a lipid-lowering agent will participate, No one for whom a lipid lowering agent would be recommended by current NCEP, ATP III guidelines is eligible.
- No one who has previously undergone formal nutritional training will be included.
- None of the above listed exclusion criteria apply to the partner.

H. Recruitment of Subjects

Subjects will be recruited from primary physicians at the AIM and ACNC clinics, and from private physicians' offices.

I. Confidentiality of Study Data

Recruited patients will have an assigned study code, under which demographic, personal, and medical data will be recorded. This information will be shared with only the primary care physician, upon request.

J. Potential Conflict of Interest

None of the involved investigators or primary physicians has any potential conflict of interest.

K. Location of the Study

Subjects will be recruited from on-site (AM or off-site (ACNQ clinics, or from on-site private physicians. Nutritional training will be on the tenth floor of Presbyterian Hospital.

L. Potential Risks

Standard phlebotomy will occur on two occasions. No drug is being used.

M. Potential Benefits

Subjects will receive comprehensive nutritional training, the most ideal conceivable under standard medical guidelines for the treatment of their condition. This will be at no cost.

N. Alternative Therapies

None are involved.

O. Compensation to Subjects

There will be no compensation. The costs of nutritional training (insurance copay), are avoided.

P. Costs to Subjects

Transportation to the medical center is the only cost. The costs of nutritional training (insurance co-pay), are avoided.

Q. Minors as Research Subjects

None are involved

R. Radiation or Radioactive Substances

None are involved.

S. References

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