

# VA Summer Epidemiology Session

## Developing Scientific Research Proposals (Grant Writing)

### Session 4 (Readings)

#### Experimental Design, Procedures and Methods

- A. Design and Procedures – Getting Started
- B. Design and Procedures – Overview
- C. Experimental Design and Methods

#### A. GETTING STARTED

The Methods section is the most important in your proposal. You have between 10 and 15 pages to describe your design, methods, procedures, analysis, power and timeline. The Methods section is where you show scientific wisdom, creativity, intelligence and judgment. And, even presuming you have all of these in spades, writing the Methods section is hard.

Before you even begin the Methods section, work through all of the details of your study. Decide on the design, participants, recruitment, independent and dependent variables, covariates or confounders, and analyses. Do a rough power analysis, using your best estimates of critical parameters to make sure the study is feasible. Contact collaborators, select questionnaires, develop a timeline. Then get to work!

Here are some important guidelines to keep in mind when writing your Methods section.

**Justify your decisions.** For almost all questions, starting with design (a case-control vs. a cohort study?) and ending with a statistical model for each specific aim (odds ratio from a logistic regression after dichotomizing the outcome vs. a regression coefficient from a linear model?), you had to make decisions. Make sure you justify your choices.

**Give enough detail.** Describe procedures in enough detail that reviewers know what you will do. Because you are limited in space, you can't give details on everything. Focus on what is new, unusual, unpublished, or controversial. And remember that most reviewers (but alas, not all) want to read about the science, not the procedural details. Try to separate science from procedures.

**Be organized.** Use headings, subheadings, and sub-subheadings. Use tables to give lists of variables or to otherwise give detailed information that can get lost in text. Use figures to show complex procedures, timelines, organizational structures, theoretical models, and the like. Remember that rules on type size are relaxed for tables and figures. Tables using ten point type with a variable width font (Times New Roman works very well), especially when imbedded in

text, are good ways to break up pages of densely packed text and increase the amount of information per page.

The organization of the Methods section will vary, depending upon the type of study you propose. Regardless, it is a good idea to start with an overview of the entire proposal, which gives the key points of design, participants, measures, outcomes, and analysis. This overview then provides the structure for the details that follow. See the three examples below.

For epidemiologic studies use the following sequence of topics for major headings.

- a) Participants, including recruitment and eligibility
- b) Treatment (if an intervention or treatment trial)
- c) Exposure assessment
- d) Endpoint assessment
- e) Quality control, data management, and any other procedural issues that are important to the science
- f) Analysis and power

The examples below illustrate the various approaches to organizing a methods section.

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## **B.1 OVERVIEW OF METHODS**

We propose a cohort study of the relation of dietary supplement use with total cancer incidence. Using names obtained from a commercial list, with enhancements to increase minority enrollment, a mailing will be sent to 225,000 men and women age 50-74 in the 13 counties of western Washington State. The mailing will include a recruitment letter targeting supplement users and a questionnaire. The recruitment procedures have been tested, and should yield 35,000 male respondents and 40,000 female respondents with 75% of respondents having used at least one nutritional supplement in the last 10 years. The questionnaire solicits detailed information on supplement use over the preceding 10 years, some information on lifetime use of supplements, and information on covariates that may be associated with supplement use and with future risk of cancer and death (e.g., medical history, cancer risk factors, cancer screening, reasons for supplement use). The questionnaire also incorporates a food frequency questionnaire, based on a well tested instrument, with additional items on supplemented foods, such as breakfast drinks. A second mailing to respondents 2-4 months later will supply a tape measure for anthropometric measures and brushes for buccal brushings for collection of DNA. Studies to quantify the relative validity of our primary exposure measures will be conducted.

Endpoint information will be ascertained by linkage to the western Washington SEER cancer registry and the Washington State death tapes. Out-migration from the catchment areas of these files will be monitored by linkage to the National Change of Address tape. The primary analysis will be an evaluation of the association of supplemental intakes of vitamin C, vitamin E, calcium,

and multivitamins over the 10 year period ending at baseline with the incidence of cancer (all sites combined), controlling for diet, medical history, and other factors.

## B.2 RECRUITMENT OF THE COHORT AND BASELINE MAILINGS

**Eligibility criteria.** The cohort eligibility criteria are: age 50-74, living in the 13 county..

**Participant identification.** We propose to identify potential participants using a list ..

**Recruitment mailings.** The target sample size is 75,000 participants, with 40,000..

**Gender and minority inclusion and targeted recruitment of hard-to-reach**

**populations.** Based on the age, sex and race distribution from the 1990 Census for the thirteen counties, we expect the following distribution of participants: ...

## B.3 BASELINE (B1) DATA COLLECTION QUESTIONNAIRES

**Supplement questionnaire.** Supplement use is the principal exposure variable in this study, and therefore our supplement questionnaire is considerably longer and more detailed than..

Table 6. Supplements Measured by Study Questionnaire

<u>Multivitamins</u>	<u>Individual Vitamins</u>	<u>Individual Minerals</u>	<u>Other Supplements</u>
Multivitamins <sup>b</sup>	Vitamin A	Calcium, including Tums <sup>b</sup>	Other mixtures
Multivitamins plus minerals <sup>b</sup>	β-carotene <sup>b</sup>	Iron <sup>a</sup>	Fiber supplements <sup>b</sup>
“Stress” mixtures <sup>a</sup>	Vitamin C <sup>b</sup>	Zinc <sup>a</sup>	EPA capsules
B-complex <sup>b</sup>	Vitamin E <sup>b</sup>	Selenium	Melatonin
Anti-oxidant mixtures <sup>b</sup>	Vitamins B1, B2, B6, B12	Magnesium <sup>a</sup>	Garlic pills <sup>a</sup>
	Niacin <sup>a</sup>		All others (open-ended)
	Folic acid		

<sup>a</sup>Used by >5% of Supplement Pilot Study sample in last 10 years.

<sup>b</sup>Used by >10% of Supplement Pilot Study sample in last 10 years.

**Multivitamin Database.** We plan to develop and maintain a computerized database that

**Food Frequency Questionnaire (FFQ).** For the large scale epidemiologic research...

Table 7. Variables of Interest from the Food Frequency Questionnaire

<u>Primary Aim</u>		<u>Covariates</u>
Vitamin C (mg)	Energy (kcal)	Vitamin A (mcg RE)
Vitamin E (mg α-tocopherol equivalents)	Fat (gm or % kcal)	β-Carotene (mg)
Calcium (mg)	Alcohol (gm or drinks per day)	Folic Acid (mcg)
	Fruit (servings per day)	Zinc (mg)
	Vegetables (servings per day)	Iron (mg)
	Fiber (gm)	Caffeine (mg)

**Other covariates.** Other variables to be collected at baseline are given in Table 8..

Table 8. Other Variables Collected at Baseline

**Identifiers and demographic factors-** name, address, phone number, birthdate, sex, race/ethnicity, marital status, educational attainment, social security number, place of birth, family doctor’s name

**Health history-** history of cancer by anatomic site, hysterectomy, ulcerative colitis, Crohn’s disease, polyposis, cholecystectomy, benign breast biopsies, myocardial infarction, coronary bypass surgery, angioplasty, hypercholesterolemia, hypertension, diabetes, osteoporosis, hip fractures, 1<sup>st</sup> degree family history of the cancers of interest, parents’ ages at death

**Drugs-** aspirin and other NSAIDs, Tums and other calcium containing antacids, OC use, HRT use in the last 10 years

**Reproductive history (women)**- age at menarche, age at menopause, hysterectomy and oophorectomy, parity, age at first birth

**Other risk factors for cancer or death** - number of days hospitalized in last year, number of prescription medications, self-rated health, smoking history, exercise, height, weight, maximum lifetime weight, asbestos exposure, sun sensitivity

**Cancer screening**- mammography, clinical breast exam, pelvic exam, Pap smear, sigmoidoscopy and colonoscopy, hemocult test, polypectomy, PSA, digital rectal exam, removal of nevi

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#### **B.4 SECOND BASELINE (B2) DATA COLLECTION FOR BODY MEASUREMENTS AND SPECIMEN COLLECTION**

**Anthropometric measurements.** Body measurements and their ratios (e.g., waist/hip..

**Buccal cell collection and processing.** There is increasing evidence that gene-nutrient..

#### **B.5 DATA HANDLING TECHNICAL METHODS AND QUALITY CONTROL**

Techniques will be used to reduce measurement errors at each phase of the study..

**Data collection.** Since the primary data source will be participant-completed..

**Data-capture.** Each questionnaire will be printed with a sequential bar code, which will.

**Verification/editing.** Bar codes (e.g., participant IDs) are read with 100% accuracy...

**The archival system for the buccal brushes.** The buccal brush manufacturer will bar..

**Endpoint ascertainment.** Accuracy in determining endpoints is enhanced by increasing.

**Structure of the database.** The primary data management and analysis tool will be..

#### **B.6 VALIDITY STUDY**

We propose to study the relative validity of the study instruments used to assess micronutrient intake from supplements and from food. The purpose of this substudy is to quantify the measurement properties of these instruments to provide important support for the interpretation of study results.

**Selection of validation instruments.** Figure 1 gives an overview of the validity study..

**Protocol for validity study.** We will randomly select 150 participants from the..

**Validity study: data analyses and power.** The analyses will be based on standard..

**Laboratory quality control.** The FHCRC core laboratory at which the clinical data for..

#### **B.7 FOLLOW-UP OF COHORT FOR CANCER AND MORTALITY**

**Length of follow-up.** The midpoint of recruitment is month 21 of the study and the..

**Cancer incidence.** Incident cancer cases will be ascertained by linking the study cohort..

**Table 9. SEER Data Items**

<b>Identifiers</b>	<b>Other Demographics</b>	<b>Tumor Characteristics and Treatment</b>
Name	Dx date	Dx confirmation
Address at dx	Age at dx	Anatomic site – ICD-O2 code
Place of birth	Vital status	Laterality
Birthdate	Follow-up date	Histology – ICD-O2 code
Sex		Summary stage—in situ, local, regional, distant
Race		Extent of disease—site-specific e.g., tumor size, extension, lymph node involvement
Marital Status at dx		First course of therapy—surgery, radiation, chemotherapy, hormonal therapy
Social Security number		

**Registry data quality control.** Considerable effort goes into the development and...

**Linkage to SEER.** Every 12 months we will link the cohort to a copy of the SEER file...

**Table 11. Death File Items**

<u>Identifiers</u>	<u>Other Demographics</u>	<u>Death Information</u>
Name	PIN (unique WA State identifier for all vital records)	Underlying cause of death(ICD-9)
Address at death		Contributing causes of death (ICD-9 codes)—multiple codes
Place of birth	Soundex code (phonetic code of last name)	Hospital death (yes/no)
Birthdate	Date of death	Facility code
Sex	Place of death	Injury (accident/suicide/homicide/other)
Race	Informant’s name and address	
Marital status at death		
Social Security number		

**B.8 TRACKING OF COHORT FOR CENSORED DATES**

**Approach and rationale.** Subjects will be censored (i.e., will no longer lead to...

**Linkage to NCOA/ACR.** The US Postal Service developed the National Change of ...

**Tracking substudies.** As noted above, the assumption for follow-up...

**C. EXPERIMENTAL DESIGN AND METHODS**

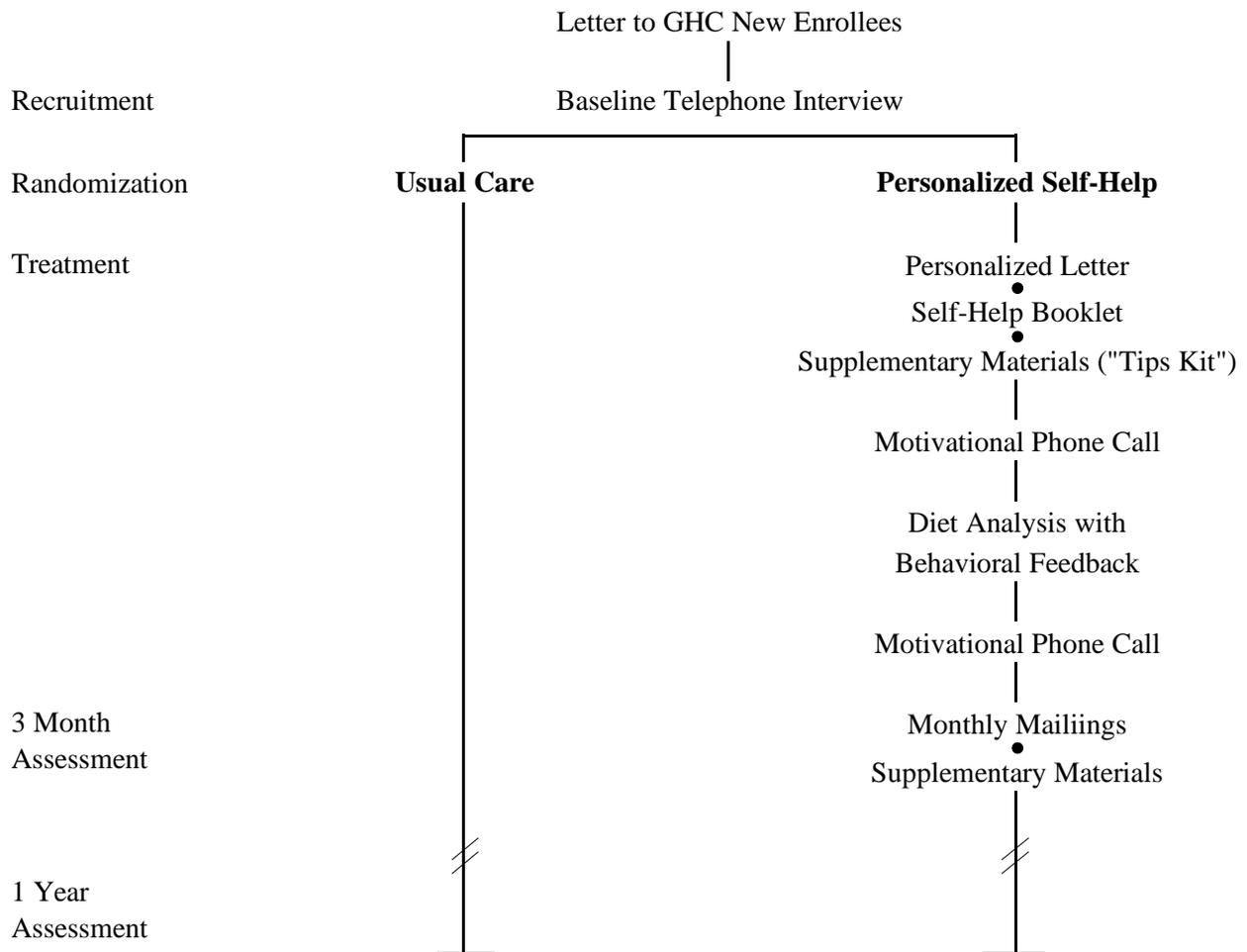
**C.1 OVERVIEW**

We propose a randomized trial to assess the effectiveness of a comprehensive, self-help dietary change intervention to promote lower-fat and higher-fiber dietary patterns. The study flow diagram is given in Figure 1. We will randomize persons newly enrolled in a large health maintenance organization into one of two groups: 1) Personalized Self-Help (PSH), a program based on a self-help booklet enhanced with personalized motivation components and dietary assessment with behavioral feedback; and 2) Usual Care (UC), no diet intervention. We will measure the impact of the intervention (at baseline, 3 and 12 months) using a set of well-validated telephone-administered instruments appropriate for evaluating public health nutrition programs: unannounced 24-hour dietary recalls, fat- and fiber-related dietary habits; and stage of dietary change. A subsample of participants will receive more intensive assessment, including repeated, telephone-administered 24-hour dietary recalls. This study is designed to: a) obtain maximum participation from a well-defined, generalizable population; b) study practical, self-help dietary change programs; and c) evaluate intervention effectiveness in the most rigorous manner possible.

**C.2 POPULATION**

Group Health Cooperative of Puget Sound (GHC) provides health care to over 350,000...

**FIGURE 1. FLOW DIAGRAM OF STUDY DESIGN**



**C.3 RECRUITMENT, BASELINE ASSESSMENT AND RANDOMIZATION**

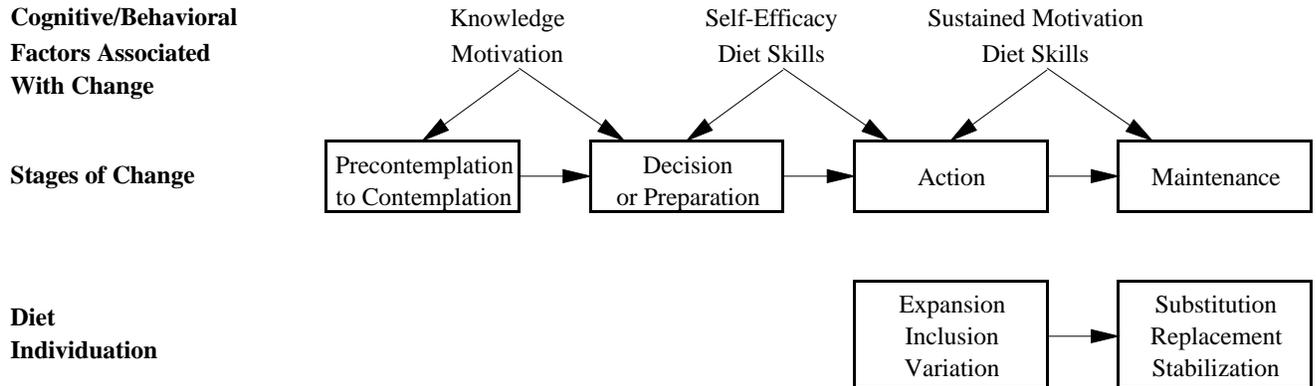
Each month we will mail an introductory letter to a random sample of new GHC enrollees, age...

**C.4 INTERVENTION**

**C.4a Conceptual Framework**

Our self-help interventions are based on three complementary models of behavior change:...

**FIGURE 2. OVERVIEW OF INTERVENTION COMPONENTS AND THEIR RELATIONSHIP TO THE CONCEPTUAL FRAMEWORK**



**C.4b Intervention Components**

A synopsis of the intervention goals and personalization strategies is given in Table 3. Further

**C.4c Self-help Manual**

The self-help manual will be an updated version of the "Help-

**TABLE 3. SYNOPSIS OF INTERVENTION COMPONENTS, GOALS, AND PERSONALIZATION STRATEGIES**

Material	Primary Intervention Goals	Personalization Strategies
Introductory letter	(1) Acknowledge participants' stated interest/involvement in changing diet; (2) highlight and reinforce reasons for dietary change; (3) give positive feedback on current healthful dietary habits.	Different computer-generated letters based upon participants' stage of change reasons for changing diet, and current dietary habits.
Help Yourself Manual	(1) Provide information about short-and long-term benefits of decreasing fat and increasing fiber; (2) provide suggestions for ways to modify specific meals to reduce fat/increase fiber; (3) teach general skills for implementing and maintaining dietary changes (e.g., label reading, grocery shopping, dining out, recipe modification.)	Stickers placed on sections of the booklet that are most relevant to participant based on stage of change, and food autonomy
Specialized Dietary Change Materials: "Tips Packet"	(1) Provide more visually-oriented messages on basic intervention components (reasons to change, simple changes to reduce fat and increase fiber); (2) provide detailed information, e.g., eating away from home (scripts for requesting low-fat entrees); (3) provide recipe cards.	Yellow highlighting in Table of Contents of tip sheets related to flagged sections of Help Yourself Manual

Food Frequency Questionnaire	(1) Provide analysis of amount of fat and fiber consumed; (2) provide positive feedback on current intake of lower fat/higher fiber foods; (3) provide suggestions for specific, gradual changes that will reduce fat and increase fiber.	Computer-generated feedback on primary sources of dietary fat, fiber in current diet, suggested modifications given current eating patterns (e.g., suggestions for higher fiber cereals for participants who eat cereals).
Motivation Telephone Call	(1) Encourage completion/return of FFQ; (2) encourage use of self-help materials; (3) answer questions, reinforce goals/changes that have been made.	Introductory statement by health educator will be tailored to participant's stage of change; different "scripts" will be followed by health educator according to participant's stage of change.
Newsletters	(1) Maintain salience of dietary change; (2) provide additional information on food preparation strategies; (3) enhance and reinforce motivation through use of "Personal Stories" or Profiles.	"Tear out" coupons to request additional materials will be included in newsletter

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**TABLE 4. EXAMPLE OF PERSONALIZING ALGORITHMS FOR INTRODUCTORY LETTER, HELP YOURSELF MANUAL, AND TIPS PACKET**

(Personalized Contents)	Introductory Letter (4 paragraphs)	HYM (5 colored flags)	Tips Packet (Highlighted Cover Sheet)
<u>Stage of Change</u>			
Precontemplation	1st paragraph: version a	"Why change my diet" "Self-evaluation"	"Diet and Good Health" (visually-oriented health messages)
Contemplation/ Preparation	1st paragraph: version b	"Self-evaluation" "Goal Setting"	"Five Simple Changes" (visually-oriented diet tips)
Action/Maintenance	1st paragraph: version c	"Recipe modification" "Dining Out"	"New Recipes"
<u>Food Autonomy</u>			
Complete	2nd paragraph: version a	"Grocery shopping"	Pantry inventory
Partial/None	2nd paragraph: version b	"Involving the cook"	"Great Snacks — Without Cooking or Cleaning"
<u>Type of Motivation</u>			
Self-Improvement	3rd paragraph: version a, b, or c — depending on stated motives	"Why change my diet"	N/A
Medical	3rd paragraph: version d, e, or f — depending on stated motives	"Why change my diet"	"Science Update: Diet and Health"
<u>Food Habits</u>			
Positive fat behavior	4th paragraph: version a, b, or c — depending on FFB <sup>+</sup>	Meal section most appropriate to good behavior (a=breakfast, b=lunch, c=dinner)	More great fat-saving ideas for... (a=breakfast, b=lunch, c=dinner)
Positive fiber behavior	4th paragraph: version d, e, or f — depending on FFB <sup>+</sup>	Meal section most appropriate to good behavior (d=breakfast, e=lunch, f=dinner)	More great ways to add fiber to... (d=breakfast, e=lunch, f=dinner)

<sup>+</sup>FFB = Fat-and-Fiber Habits Questionnaire

**C.4d Introductory Letter:** The introductory letter will be designed to motivate participants to...

**C.4e Dietary Assessment with Behavioral Feedback:** Each intervention packet will include a..

**C.4f Follow-up Phone Call:** A health educator will call PSH participants approximately three.

**C.4g Follow-up Mailings:** Every months and continuing for six months, we will mail PSH...

**C.4h Usual Care Follow-Up:** We will offer usual care participants the "Help Yourself" manual and Tips Sheets Packet after...

**C.4i Vanguard Group:** The protocols described above are sufficiently complex to support the use of a small vanguard...

## C.5 EVALUATION

### **Background: Can We Measure Small Dietary Change?**

There are no simple solutions to the problems inherent in evaluating *public health* nutrition...

#### **Overview**

Table 5 gives: 1) the measures of dietary change; 2) measures used in the Intensive Assessment..

### **Data Collection Instruments - Overall Study Evaluation**

**Nutrient Intake:** The principal endpoint measures of diet change will be mean, intervention-group level changes in percentage of energy from fat and grams of fiber, based on a single 24-..

**Fat- and Fiber-Related Dietary Habits:** We will measure fat- and fiber-related dietary habits..

**Stages of Dietary Change:** A participant's readiness to change or their active involvement in the..

**Covariates:** We will collect data on factors, in particular those related to socioeconomic status,..

**Additional Data:** We will collect limited data on three key psychosocial constructs: motivation..

**Sequence of Overall Study Evaluation:** Baseline assessments, including the 24-hour recall, FFB..

### **Data Collection Instruments--Intensive Evaluation**

**Nutrient Intake:** At each assessment point we will collect three, unannounced 24-hour dietary..

**Psychosocial Questionnaire:** To support one of our secondary aims, to better understand the..

**Sequence of Intensive Assessment:** The timing of intensive assessments parallel those for...

### **Data Management and Tracking...**

### **Phone Counselor Training and Supervision...**

**Table 5. Evaluation Measures**

<b>Instrument Name</b>	<b>Construct(s) Measured</b>	<b>Month(s) Administered</b>
<b><i>All Study Participants</i></b>		
24-hour dietary recall	Treatment group-level estimates of: Percentage energy from fat Grams of fiber	0, 12
Fat and Fiber Behavior <sup>31,38,47</sup>	Low-fat diet habits High-fiber diet habits	0, 3, 12
Stage of Change <sup>39</sup>	Movement from pre-contemplation through maintenance of new dietary behavior ...	
	adopting lower-fat diet	0, 3, 12
	adopting higher-fiber diet	0, 3, 12

A Different Sort of Approach...From an Alternative Medicine Proposal  
Note the imbedded “Research Hypotheses” section, that for many grants would be the Specific Aims.

## **RESEARCH DESIGN AND METHODS**

### **Overview**

This study will be conducted at Group Health Cooperative of Puget Sound, a large health maintenance organization in western Washington state. Group Health consumers between 20 and 70 years of age who have visited a primary care provider for low back pain will be identified through review of automated visit data and referrals by primary care physicians. About 5 weeks after their back pain visit, potential participants identified by clinic staff and visit data will be mailed letters describing the study (Figure 1) and informed consent forms. Enrollees interested in participating will be asked to sign and return the informed consent form. Enrollees returning signed consent forms will then be telephoned by a Research Assistant who will confirm eligibility, collect baseline data and randomize participants to begin acupuncture treatments (n=100), massage treatments (n=100) or to be mailed a new, innovative and relatively inexpensive book and videotape on the self-management of chronic low back pain (n=100). All study subjects will continue to have their usual access to conventional medical care for their back pain.

Using the treatment protocol drafted by Drs. Eisenberg and Kaptchuk in conjunction with the national Acupuncture Association as a starting point, Karen Boyd, LAc, current board member and immediate past President of the Acupuncture Association of Washington, and her colleagues will work with the research team to make any modifications that may be necessary to reflect the specific form of traditional Chinese acupuncture used in Washington and local standards concerning number of treatments, duration of treatment and cointerventions (e.g., exercise recommendations, massage, heat/cold) that will be permitted. In addition, Ms. Boyd and her colleagues will help identify acupuncturists appropriate for the study.

In a similar fashion, the massage treatments will follow the nationally-developed massage treatment protocol. Because the Washington massage therapy consultants (Houston Lebrun and Laurie Bielinski), as Vice Presidents of the national organization, are familiar with the protocol, few, if any, revisions in the national protocol to accommodate local standards will be necessary. The massage consultants will help identify massage therapists (called “licensed massage practitioners” in Washington state) appropriate for the study. Efforts will be made to ensure that the upper limits on numbers of visits and treatment duration will be the same for both acupuncturists and massage therapists. Thus, it will be up to each provider to determine the number of treatments they provide recognizing that cost as well as effectiveness will be measured. This will allow individual providers to treat patients as many times (up to a limit) as they and their patient believe is worth the cost of an additional visit, thereby avoiding the imposition of a fixed number of visits on all patients irrespective of a perceived need. This approach was used successfully in the chiropractic vs. physical therapy trial.

Patient outcomes will be assessed through telephone interviews (3 and 6 weeks after randomization) and by mailed questionnaire with telephone follow-up (12 and 52 weeks after randomization). Interviewers will be blind to the treatment group that study participants were assigned to. The short-term (less than 3 months) outcome measures will be symptom relief, functional status, days of restricted activity and patient satisfaction. The long term (one year) outcomes of primary interest will include additional treatments for back pain, costs of care for low back pain, symptom severity and functional status. Data on health care utilization for low back pain will be collected from follow-up interviews as well as from automated Group Health data systems in order to ensure that "out of plan" utilization (e.g., massage, acupuncture) as well as in-plan utilization is captured.

The data collected in the course of this study will permit analysis of the relationship between patient expectations of benefit from a specific intervention (i.e., acupuncture, massage or self-care materials) and actual outcomes. Prior to randomization, study subjects will be asked to rate how helpful they believe each of the study interventions (acupuncture, massage and educational materials) will be for their current back problem. The relationship between the expected benefit of a treatment and the actual benefit (in terms of amount of symptom reduction or improvement in function) will then be calculated.

### **Research Hypotheses**

This study will test three hypotheses which follow directly from the specific aims:

- 1) During the first three months, those randomized to acupuncture and massage will be more satisfied with their care and will report greater symptom relief than those receiving the self-care materials. There will be no differences between the acupuncture and massage groups in any outcomes, including costs. Differences among the groups in functional status will not be significant.
- 2) After one year, the three groups will not differ in terms of symptom severity or functional status. After the treatment period, there will be no differences among the groups in use or cost of services for low back pain.
- 3) Patients believing the treatment they receive will be very helpful will have better outcomes than patients believing the treatment will be of little value. This finding will persist even after controlling for patients' general expectations for improvement.

### **Study Sites**

The subjects used in this study receive their medical care from Group Health Cooperative of Puget Sound (GHC)....

### **Patient Recruitment Strategies/Informed Consent**

The target population for this study is GHC enrollees with chronic low back pain, (i.e., back pain that has.....

### **Eligibility and Exclusion Criteria**

Group Health enrollees between the ages of 20 and 70 with low back pain of at least 3 months duration will be eligible for the study. Enrollees determined to have any of the following characteristics during the.....

### **Randomization Procedures**

The Research Assistant will randomize the participants by opening sealed, sequentially numbered opaque envelopes each containing a slip of paper indicating either "acupuncture," "massage," or "self-care...."

### **Treatments**

Determining the specific types of acupuncture and massage to be was a very difficult but critically important issue. Our team decided that it would be best to study the types of acupuncture and therapeutic.....

#### Acupuncture

As noted above, the specific details of the acupuncture treatment protocol will be finalized before the beginning of the treatment phase of the study and after discussions between the researchers and the leadership...

#### Massage

The treatment protocol developed by the American Massage Therapy Association (AMTA) in conjunction with Drs. Eisenberg and Kaptchuk will be modified if necessary to accommodate local standards of practice in western Washington. Dr. Cherkin will meet with the local massage consultants (Lebrun and Bielinski), both of whom happen to also be Vice Presidents of the AMTA. This protocol will.....

#### Self-Management Book

The Principal Investigator has been working with Drs. Michael Von Korff (Group Health Center for Health Studies), James Moore (Department of Rehabilitation Medicine, Virginia Mason Medical Center), Kate Lorig (Stanford University Patient Education Research Center) and Richard Deyo (University of Washington Schools of Medicine and Public Health) to develop and evaluate educational materials for persons with chronic low back pain. That research, which was funded by the National Institutes....

### **Outcome Measures**

Several measures will be used to evaluate the conceptually distinct outcomes of care for back pain. These will include measures of symptom relief, physical function, restricted activity days, patient evaluations of their care, and use and cost of services (Figure 2). Both short-term (less than 3 months) and....

#### Primary Outcome Measures

The primary outcome measures include symptom relief, functional status, restricted activity days and use of services. Subjects will be asked at baseline and during all follow-up interviews to rate how "bothersome....."

### Secondary Outcome Measures

Secondary outcome measures include subjects' evaluation of the interventions they received and of their back pain care at Group Health, their worry about their back problem and their perceived ability to care for future back problems without professional help. We are aware that subjects' ratings of the care they have.....

### Additional Variables

Data on prognostic and sociodemographic variables will be collected during the baseline interview. Prognostic variables will be measured to permit an evaluation of the extent to which randomization succeeded in creating comparable treatment groups, and if necessary, to permit statistical adjustment of any.....

### Sample Size and Power Calculations

The primary goal of the sample size calculations is to ensure an adequate number of subjects per group to detect a clinically significant difference in key outcomes with an acceptable level of power. One month outcome data from our chiropractic versus physical therapy trial were used to determine the d...

### Statistical Analysis

The power calculation is based on simple comparisons of the follow-up scores at a single point in time. This is a simplification of what may actually be done. We will first test the success of the randomization by comparing the three groups at baseline. Even if they are not statistically different, we might consider adjustment....

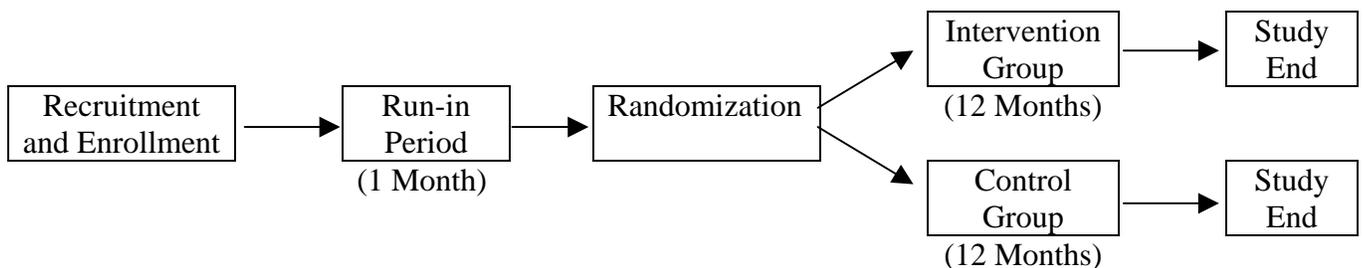


Table 5. Enrollment in the Barrett's Esophagus Study by Year and Diagnosis

Category	2001	2002	2003	2004	2005
Metaplasia-Indefinite/low-grade dysplasia <i>without flow abnormalities</i>	235	242	242	238	236
Metaplasia-Indefinite/low-grade dysplasia <i>with flow abnormalities</i>	23	25	27	28	29
High-grade dysplasia	67	58	56	59	60
Total	325	325	325	325	325

Table x. Number of prostate cancer cases diagnosed in King County, WA, 1994-1998, by age\*

Age	1995	1996	1997	1998	Avg./Yr
40-49	12	17	19	21	17
50-59	130	149	129	181	147
60-69	312	311	337	352	328
70-74	193	194	206	187	195
Total	647	671	691	741	687

Table x. Interview completion rates for eligible cases in prior case-control studies conducted within the Epidemiology Program, FHCRC

Study	Percent
Breast cancer in middle-aged women	92.0
Male breast cancer	89.6
Hodgkin's disease	90.0
Adenocarcinoma of the esophagus/gastric cardia	87.6
Prostate cancer in middle-aged men	85.2

<b>Instrument Name</b>	<b>Construct(s) Measured</b>	<b>Month(s) Administered</b>
<b><u>All Study Participants</u></b>		
24-hour dietary recall	Treatment group-level estimates of: Percentage energy from fat Grams of fiber	0, 12
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Stage of Change <sup>39,31</sup>	Movement from pre-contemplation through maintenance of new dietary behavior ...	
	adopting lower-fat diet	0, 3, 12,18
	adopting higher-fiber diet	0, 3, 12,18
Psychosocial Questionnaire <sup>30,33</sup>	Motivation for change Self-efficacy Nutritional knowledge and skills <i>Family Involvement</i>	0, 3, 12,18
<b><u>Intensive Assessment Participants</u></b>		
Repeat (3 total) 24-hour dietary recalls	Individual-level estimates of: Percentage energy from fat Grams of fiber	0, 3, 12
Comprehensive Psychosocial Questionnaire <sup>30,33</sup>	Nutritional knowledge and skills Self-efficacy Motivation for change Belief in diet-disease connection Perceived norms Barriers to change Benefits to change Intentions to change Family Involvement	0, 3, 12