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METHODOLOGICAL DEVELOPMENT OF DIETARY FIBER INTERVENTION TO LOWER COLON CANCER RISK

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INTRODUCTION

Increasing dietary fiber intake to lower colon cancer risk has been recommended by the National Cancer Institute (Greenwald 1984), American Cancer Society (ACS 1984) and other organizations committed to cancer prevention/health promotion. However, several methodological concerns need to be considered before dietary fiber intervention can be implemented to achieve the maximum public health benefit with the least cost and risk. In this chapter, dietary fiber intervention issues including risk reduction, cost-effectiveness of intervention method, and safety will be addressed. Two algorithms for decision making in the feasibility and efficacy testing of cancer control interventions will be presented. The dietary fiber intervention will be used to illustrate the sequential steps and the implications of the results.

METHODOLOGICAL ISSUES IN FIBER INTERVENTION

The first methodological concern in dietary fiber intervention is whether significant risk reduction (e.g. lowering colon cancer mortality) can be achieved by increasing certain types of dietary fiber intake in a population currently consuming a low fiber diet. It is well documented that various types of fibers and their fractions exert different physiological and biochemical effects (Vohouny and Kritchevsky 1981). The protective
role of a specific fiber in colon carcinogenesis can only be established by the results of prospective randomized clinical trials or similarly well controlled experiments, the knowledge of which will not be available for at least several years. Meanwhile, suggestions for types of fiber to eat and how much to eat need to be extrapolated from non-experimental epidemiological observations and experimental animal studies. If methodological studies can demonstrate consumer acceptability of the fiber source at a certain dose level, then the particular fiber intervention may be recommended as one of several viable means of dietary fiber intervention, each with estimated risk reduction.

The second concern is the cost-effectiveness of a chosen intervention method. The same nutritional intervention agent and dose can be delivered by a variety of methods to the subjects. Methodological studies which assess perceptions toward each alternative method, estimate operational costs and determine expected units of impact, will provide crucial information for choosing the most cost-effective and feasible intervention method. It is helpful to recognize that the same dietary intervention method used as a therapeutic regimen may have different effectiveness when used as a disease prevention/health promotion practice. A different set of motivations, beliefs, barriers and benefits may even be involved in the compliance behavior of cancer prevention in comparison to cardiovascular prevention.

Third, whenever a single nutrient or nutritional component is used as a disease prevention agent, cautions should be taken to avoid side effects resulting from overdose or from imbalance of the overall nutritional status. Methodologic studies which monitor the severity and distribution of potential side effects, identify subject correlates, and test methods of controlling for the side effects are important for further decision making based on the risk/benefit ratio in the target population.
SEQUENTIAL DECISION MAKING

The five phases of cancer control developed by the National Cancer Institute, including hypothesis generation, feasibility testing, efficacy testing, population trial and community demonstration, provide a framework for a progressive approach to cancer control programs (Greenwald and Cullen 1985). The methodological development discussed in this paper will focus on the decision making process involved in the feasibility and efficacy testing of the fiber intervention (Phases II and III). Two algorithms adapted from Lopez's algorithms for nutrition intervention (Lopez, 1986) will be used to illustrate the essential steps in the sequential series of methodological studies (see Figures 1 and 2). A dietary fiber intervention to lower colon cancer risk in a retirement community will be used to illustrate the steps involved in such an approach.

The initiation of a nutritional intervention study (i.e. Cancer Control Phase II Trial) may be decided by following the algorithm in Fig. 1. Evaluation of the scientific evidence of the protective effect of the intervention agent against a particular cancer is only the first step. Review of the relative significance of the specific cancer problem in terms of morbidity and mortality in the target population will assist in prioritizing various cancer sites for cancer control program planning (Namboodiri et al. 1986). Information on the estimated risk reduction with a specific intervention method is important in predicting its public health impact, given a significant cancer problem. Sometimes an intervention with modest reduction in relative risk may be justified if the cancer problem is severe enough at the community level. Assessment of perceived attitudes, knowledge and behaviors associated with the proposed compliance behavior in the target population provides further crucial information on the feasibility of the intervention. It is desirable to list all feasible intervention alternatives and compare the operational cost per unit of impact. The potential side-effects of an intervention method sometimes outweigh the likely benefit except in populations at high risk for the specific cancer. All of the above factors need to be considered in the initiation of a pilot intervention trial.
Evidence of Protection

Significance of cancer problem

Yes

Sufficient risk reduction achievable by intervention

No

Intervention shown feasible

Attitude

Knowledge

Behavior

Yes

Less effective or higher cost alternatives shown feasible

No

Likely benefit is worth risk and cost

Yes

No

Reevaluate evidence of protection

No

Pilot Intervention is recommended

Yes

Initiation of Pilot Intervention (Phase II)

Measured Efficacy of Intervention

• Recruitment
• Biological effectiveness
• Subject compliance
• Safety
• Cost per unit of impact

No

Yes

Most cost-effective alternative chosen for biological/behavioral outcomes

No

Yes

Outcome worth the costs

No

Yes

Continue or expand the intervention (Phase III)

Reevaluate the initiation decision

Fig. 1 A decision making algorithm for initiation of a nutritional intervention to lower cancer risk (i.e. a cancer control phase II study).

Fig. 2 A decision making algorithm for continuation/expansion of a cancer control intervention (i.e. cancer control phase II to phase III).
The continuation/expansion of a nutritional intervention (i.e. Cancer Control Phase III Trial) may follow the decision making algorithm in Fig. 2. The efficacy of a specific intervention method needs to be measured in terms of subject recruitment, biological effectiveness in cancer risk reduction, behavioral compliance to the regimen and the dosing schedule, safety from toxic or deleterious effects, and acceptable unit cost for future populations based intervention. Not all pilot studies are designed to measure all aspects of the efficacy issue at the same time. In addition, significant demands on human and physical resources may preclude comprehensive studies from taking place even when the research design provides the framework for it. Often the methodological problems involved in developing reliable and valid measures of one aspect of efficacy (e.g. biological markers of cancer risk) would require extensive resources to carry out. Ideally, pilot data from all aspects of intervention efficacy should be acceptable, and cost-effectiveness and cost/benefit analyses performed before the intervention is continued or expanded into a Cancer Control Phase III trial.

It is not uncommon for community cancer prevention programs to skip the decision making steps outlined in the algorithms. Due to the behavioral/educational focus of some programs, it is understandable that the biological effectiveness of each recommended dietary change in lowering cancer risk is assumed rather than tested. However, the intermediate behavioral outcome needs to be measured, the potential nutritional risk in subpopulations monitored, and cost-benefit analyses conducted. Evaluation of existing programs may also utilize the same algorithms to put current activities into perspective, to identify areas of planning needs, and to expand successful components. Two goals directed our approach to methodology development in dietary fiber intervention. One was to develop a clinical trial model with a single fiber source, so the hypothesis of a causal relationship between the specific fiber and colon cancer risk can be tested. The other goal was to develop the "how-tos" for the general public in following the recommendation to double current fiber intake. A description of the process involved for the fiber intervention will follow below.
INITIATION OF FIBER INTERVENTION

Steps in Fig. 1 are used to illustrate the sequential decision making process in the initiation of a fiber intervention.

Review of Evidence, Significance and Risk Reduction

Based on literature review of the cumulative evidence from epidemiological studies, animal experiments and the proposed mechanisms of action, the National Cancer Institute issued the public recommendation of doubling current dietary fiber intake for Americans to lower colon cancer risk (Greenwald 1984). The significance of colon cancer prevention is self-evident: (1) colon cancer continues to be one of the leading causes of cancer deaths in males and females in the U.S., (2) in the 50% of patients who have advanced colon cancer at the time of diagnosis, the 5-year survival rate is poor (GI Tumor Study Group 1984). Dietary modifications will complement screening for high risk individuals with precancerous lesions. The NCI estimated that 50% reduction in cancer of the colon and rectum could be achieved by the year 2000, with dietary modifications emphasizing fiber-rich foods and reducing fats (Greenwald and Sondik 1986). Whether there is sufficient scientific evidence for the policy recommendation remains a controversial issue among scientists and some consumer groups, and is beyond the scope of this paper. Despite the controversy, an array of cancer education and health promotion organizations has started dietary education program nationally.

The older adult was chosen as the target population for our dietary fiber intervention because of their increased risk of developing precancerous colonic polyps with age. Epidemiological data on migrants suggest that it is possible to change the risk of colon cancer in a lifetime (Correa and Haenszel 1978). From the carcinogenesis perspective, a 15 to 20 year latency period is required and the promotional stage is dose and time dependent. With the life expectancy of Americans increasing into the seventies, and the median age of diagnosis and death from colon cancer in the seventies,
intervention starting at early retirement age may have several decades to exert its effect. Therefore, reduction in colon cancer mortality in older adults should be achievable by dietary modifications including fiber intervention.

Evaluation of Alternative Dietary Interventions

Goal oriented literature search focusing on cost benefit/effectiveness ratios of alternative interventions provides the necessary information for this evaluation process.

Fiber vs. Other Dietary Risk Factors. Many dietary components other than fiber have been associated with colon cancer, including fat, B-carotene, Vitamin C, Vitamin E, etc. (NRC 1982). The non-proportional distribution of fiber, fat and micronutrients in foods, and the vast difference in volume of their purified forms, make it necessary to plan for each intervention individually (e.g. a high fiber intake does not follow automatically with a low fat or high vegetable/fruit intake). Feasibility factors such as participant compliance, resource requirements, promptness of behavioral change and generalizability to the public also vary with each dietary intervention. All of these nutritional changes may cumulatively provide a protective effect against cancer.

Fiber Supplementation vs. Changing Total Dietary Fiber. There are various ways of doubling dietary fiber consumption, including increasing intake from various food sources, and supplementation and fortification with a single concentrated source. The chemopreventive approach using a single fiber supplement will require less behavioral change, and is likely to produce better compliance and prompter risk reduction. It is, therefore, an attractive alternative for high risk populations, such as older individuals with history of colonic adenomatous polyps. For the general public it is, of course, desirable to aim at a comprehensive dietary improvement in the long term. In the case of
fiber, the intake of a concentrated source of cereal fiber can be a first step and an integral part of a high fiber diet plan.

Selection of a Fiber Supplement. In the case that supplementation is the selected method of intervention, its selection should be based on (1) scientific evidence of its effectiveness in risk reduction, and (2) long-term consumer acceptability including taste, convenience, cost, and daily dose. Any product that meets the above two criteria may be considered a viable intervention agent. Among the natural sources of fiber, wheat bran fiber has been shown to be associated with reduced colon cancer incidence in rat studies (Reddy and Wynder 1984) and in epidemiologic studies (McKeown-Eyssen and Bright-See 1984). The consumer acceptability of the wheat bran fiber cereal is demonstrated by the availability of commercial products on the market since the 1940’s. In addition, reports of market surveys suggest that, as a food category, commercial wheat bran cereals were used most commonly in older adult households (Sellery 1984). Once the methodology for wheat bran fiber supplementation in a target population is developed, it may be adapted to other sources of fiber (e.g. rye or oat) shown to be protective for different targeted populations.

Feasibility Surveys in Target Population

To gain specific information on attitudes, knowledge, and behavior of a target intervention population, a randomized survey of a probability sample of the population is useful in providing baseline data for program planning. Based upon the knowledge of attitudes, beliefs and behavior associated with the proposed intervention in the target population, the overall participation of the intervention may be projected.

The feasibility of the chosen dietary intervention method is assessed by developing valid and reliable test instruments (Atwood, 1986). Three instruments, Health
Behavior Questionnaire (HBQ), (Atwood et al. 1986), Colon Cancer Prevention Questionnaire (CCPQ), (Ho et al. 1986a) and Dietary Modification for Cancer Prevention Questionnaire (DMCFQ), (Ho et al. 1986b), were developed based on criterion variables in a Health Behavior for Cancer Prevention Model (Atwood et al. 1984), as listed in Table 1. In addition, the format of ethnographic interviews and focus group discussions was developed to further investigate unclear issues or discrepant findings from previous surveys. The instruments and methods described above may be used singularly or in combination as a needs assessment process in community dietary improvement programs.

Table 1: A table of test instruments and their criterion variables (based on Health Behavior in Cancer Prevention Model, Atwood et al. 1985)

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Criterion Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Behavior Questionnaire (Atwood et al. 1986)</td>
<td>efficacy (personal and treatment), health locus of control, health threat (severity and susceptibility), health status (general), personal characteristics (age, sex, education), social support, value orientation</td>
</tr>
<tr>
<td>Colon Cancer Prevention Questionnaire (Ho et al. 1986a)</td>
<td>efficacy (personal and treatment), health status (bowel function, food and medication use), knowledge about colon ca., social support, threat reduction (benefits and barriers)</td>
</tr>
<tr>
<td>Dietary Modification for Cancer Prevention Questionnaire (Ho et al. 1986b)</td>
<td>health status (food intake patterns), efficacy (personal and treatment), threat reduction (benefits and barriers), social support</td>
</tr>
<tr>
<td>Ethnographic Interviews (Benedict et al. 1987)</td>
<td>knowledge about dietary modification, threat reduction (barriers)</td>
</tr>
</tbody>
</table>
In a mail survey of a retirement community in southern Arizona (Ho et al. 1986a), questionnaires were sent out to a probability sample of the population randomly selected from the phone book. Two survey instruments, the HBPQ and the CCPQ, were included in the mail package which was adapted from the personalized method of Dillman (1978). The survey was completed in three months, had a return rate of 48%, and cost about $3,000. Findings directly applicable to the implementation of a fiber intervention trial are summarized below:

Personal Efficacy of the Fiber Intervention. When subjects were presented with a list of alternative methods to increase daily dietary fiber intake, the most favorable choices were overall dietary fiber increase, fiber pills, and fiber cereals. The perceived ability to follow the self selected high fiber plan for a minimum of four years was high (see Table 2). The major reasons given for unwillingness to participate in a fiber intervention were: lack of persuasive scientific evidence, behavioral inconvenience, old age and health barriers.

Table 2: Personal efficacy toward increasing dietary fiber intake by a method of own choice (% of subjects, N=328) (Ho, et al. 1986a)

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
<th>don't</th>
</tr>
</thead>
<tbody>
<tr>
<td>know</td>
<td>76.2</td>
<td>14.7</td>
<td>9.1</td>
</tr>
<tr>
<td>could follow</td>
<td>43.2</td>
<td>41.2</td>
<td>14.6</td>
</tr>
<tr>
<td>want to participate</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Correlates of Personal Efficacy and Implications for Compliance. Knowledge about colon cancer was found to be the best predictor for the subjects' perceived ability and willingness to increase dietary fiber intake to lower colon cancer risk (p 0.001 and p 0.01 for each dependent variable in step-wise multiple regression analysis). Current use of high fiber bran cereals is also a good predictor (p 0.05 for ability and p 0.01 for willingness). The presence of current bowel function problems is associated with the willingness to participate in the intervention (p 0.05), but not the perceived success in such a program. Overall, these findings suggest that educational efforts to increase colon cancer related knowledge may improve participation in and compliance to the fiber intervention.
Perceived Compliance Enhancers and Detractors.

Profiling the relevant compliance enhancers and barriers of a specific intervention is crucial to ensure maximum compliance given the resources available. Table 3 summarizes the subjects's perception toward various compliance related factors observed in the mail survey.

Table 3: Benefits and barriers of increasing dietary fiber intake by a method of own choice (% of subjects, N=328) (Ho et al. 1986a)

<table>
<thead>
<tr>
<th>Benefits</th>
<th>positive effect</th>
<th>negative effect</th>
<th>no effect or don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td>convenience</td>
<td>61.3</td>
<td>7.4</td>
<td>31.3</td>
</tr>
<tr>
<td>improve bowel movement</td>
<td>55.7</td>
<td>2.5</td>
<td>41.8</td>
</tr>
<tr>
<td>effect on health</td>
<td>61.4</td>
<td>1.5</td>
<td>37.0</td>
</tr>
<tr>
<td>effect on bowel cancer risk</td>
<td>54.6</td>
<td>0.3</td>
<td>45.1</td>
</tr>
<tr>
<td>influence of family/friends</td>
<td>12.6</td>
<td>2.5</td>
<td>84.9</td>
</tr>
<tr>
<td>taste</td>
<td>35.4</td>
<td>3.7</td>
<td>60.9</td>
</tr>
</tbody>
</table>

Compliance Enhancement Activities Perceived Helpful.

In designing a cost-effective compliance enhancement program for any specific intervention, a survey of the target population's perceptions of potential activities can provide information on the general interest and its distribution. A list of preferred compliance enhancement activities in the target population was compiled from the mail survey.

Results of other pilot studies using the DMCPQ and qualitative methods also contributed to the decision making process. Pilot testing of the DMCPQ in thirty older individuals from a residential community (Ho et al. 1986b) suggested that dietary fiber is considered good for health in general, but its association with colon cancer risk is not known to many. Different levels of ability and willingness to follow specific dietary recommendations were also observed. Use of whole grain products, fruits and vegetables were viewed as easier and more likely than lowering fat intake. Approximately one third of the participants did not know if they were following a low fat diet in contrast to the three per cent who did not know about a high fiber diet.
Qualitative methods (Spradley 1979) including ethnographic interviews and focus group discussions were used to further investigate the subjects' perceptions within the contextual perspective (Benedict et al. 1987). Measures were taken to ensure the validity and reliability of the results. Areas of knowledge gap and compliance barriers identified complemented findings of quantitative methods. Together, the above qualitative information suggests that individual dietary changes are more likely to be achieved with adequate knowledge of diet and cancer, reasonable estimation of the difficulties of behavioral change, and attitudes conducive to the modification.

Estimation of Cost, Risk and Benefit

Cost/benefit to society and risk/benefit to the individual are additional items to be considered in the development of a nutritional intervention. However, the decision of whether the likely outcome would be worth the cost and risk is the least objective of all steps involved in the algorithm. All benefit estimates for interventions are necessarily based on insufficient or crude data, and the impact on the quality of life is difficult to quantify. Weinstein (1983) had estimated that the cost of nutritional supplementation in the general public would compare favorably with currently accepted costs of cancer screening. The cost per participant and the cost per incremental improvement in outcome varies a great deal with any recommended dietary behavioral change, depending on the delivery model (e.g., professional counseling, group lessons, self-help groups, peer teaching, and mass media campaign).

The acceptability of side effects for an individual needs to be evaluated in light of the degree of cancer risk reduction expected given the initial at-risk level. The general rule is the higher the initial risk level and the more the estimated risk reduction, the more side effects posed by the agent will be tolerable. In the case of doubling fiber intake with supplements or overall dietary increase, some degree of gastro-intestinal symptoms is not uncommon. A upper limit of dietary fiber intake of 35 grams daily has been suggested by the NCI, considering the potential side effects on mineral balance and metabolism of other nutrients, (Light 1987).
EXPANSION OF THE FIBER INTERVENTION

To obtain efficacy information for decision making of a proposed intervention protocol as outlined in Fig. 2, a pilot study of short duration may be used. A comprehensive compliance enhancement program which addresses major compliance enhancers and barriers may be an integral part of the intervention protocol. Variables perceived to affect subject compliance may also be measured before and after the trial to test the specific impact of individual compliance enhancement strategies.

Measuring the Efficacy of Fiber Supplementation

In our pilot intervention study, an experiment was designed to test the hypothesis that the group with the most comprehensive compliance enhancement program, although having a higher operational cost than less intensive programs, would have the most cost-effectiveness in terms of subject compliance. Subjects who returned previous mail surveys were recruited and randomly assigned to one of the following three treatment groups for three months:

- Group A: Fiber Supplement + Education
- Group B: Fiber Supplement only
- Group C: Control

Group C received the minimal amount of compliance enhancement support in the form of information sharing. Subjects in Groups A and B received further compliance enhancement support in the form of free fiber supplements in an effort to improve treatment efficacy. Group A also received a comprehensive educational program developed to meet the needs of general compliance maintenance and individualized problem solving. Results of feasibility surveys in the target population were found to be informative and useful in designing the intervention at this stage. Major findings are summarized below:
Recruitment Methodology. A recruitment technique was developed which used telephone interviews with subjects who returned questionnaires in the previous community mail survey. The interview used a social marketing approach (Novelli 1985) which provided behavioral motivation and emphasized individual contribution. The recruitment of 180 eligible subjects was completed in two months with less than $1,000 expenditure. The combined drop out rate in the three treatment groups was less than 20%. This technique produced an entrant/contact ratio of about 1:4 as compared to ratios between 1:22 to 1:119 in major long-term clinical trials (Tangrea 1984, Hunninghake et al. 1982). The recruitment method validated in this short-term trial may be adapted to be a cost-effective alternative in long-term studies.

Dietary Fiber Intake. Baseline mean daily dietary fiber intake, as estimated by a revised version of the National Cancer Institute's Food Frequency Questionnaire (Block 1986), was similar in the three groups (16.7 +/- 6.9 grams). This consumption level was more than the American mean of 10-15 grams (Murphy and Calloway 1986). The target population could further increase, about 10 grams, daily dietary fiber intake to reach the NCI's goal of 20-35 grams daily. The self-reported mean supplemental dietary fiber intake in subjects staying on the regimen was about 13g in both Groups A and B. At the end of the study, the mean daily dietary fiber intake of these subjects was about 30 grams. In Group C, only four subjects reported increased daily dietary fiber intake of more than two grams. It appeared that a significantly higher level of fiber intake is unlikely to be achieved by dissemination of information alone in the target population.

Compliance Rate and Side Effects. Table 4 lists the compliance rates and side effects of the three treatment groups. "Compliance rate to study participation" refers to the proportion of subjects who completed the study forms before and after the intervention. "Compliance rate to daily regimen intake" designates the proportion of participants who consumed any amount of fiber supplements on a daily basis. In both Groups A and B, subjects who chose to stay on the regimen seemed to self-adjust to a tolerable dose based on convenience and
side effects. It appeared that compliance to study participation, to a daily regimen intake and to the recommended dose of that regimen are different parameters of the compliance behavior likely to be influenced by various combinations of factors.

Table 4: Compliance rate, side effects and operational cost of the three treatment groups in the fiber supplementation study (Ho et al. 1986c)

<table>
<thead>
<tr>
<th>GROUP</th>
<th>Compliance rate to study participation (%)</th>
<th>Compliance rate to daily regimen intake (%)</th>
<th>Rate of intermittent flatulence (regimen compliers only)</th>
<th>Total operational cost ($)</th>
<th>Operational cost per regimen complier ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP A</td>
<td>75%</td>
<td>90%</td>
<td>60%</td>
<td>$3,000</td>
<td>$51</td>
</tr>
<tr>
<td>GROUP B</td>
<td>56%</td>
<td>56%</td>
<td>93%</td>
<td>$2,000</td>
<td>$66</td>
</tr>
<tr>
<td>GROUP C</td>
<td>76%</td>
<td>7%</td>
<td>80%</td>
<td>$360</td>
<td>$91</td>
</tr>
</tbody>
</table>

In Group A subjects who volunteered for blood tests (N=35), there were no observable patterns of change in self-reported body weight, serum cholesterol, triglyceride, high density lipoprotein, CBC, urine analysis and other SMA 20 parameters except for calcium after three months of intervention. The most prevalent gastro-intestinal side effect was intermittent flatulence, diarrhea, and/or constipation. Serum calcium dropped significantly (p < 0.01) at the end of the study in one third of subjects tested. Preliminary analysis did not indicate any significant associations of dietary intake of calcium, fiber and protein with the serum calcium change. Until the interaction of minerals and fiber is understood better, it is important to ensure the adequate intake of calcium and other similarly absorbed minerals (e.g. zinc, copper, magnesium) when recommending a high fiber diet. Findings on side effects from this pilot intervention study are critical for designing protocols that minimize side effects in further fiber intervention at the population level.

Cost-effectiveness of the Compliance Enhancement Program. The results supported the hypothesis that a
well-planned compliance enhancement program for the fiber intervention was most cost-effective for the unit of impact (i.e. compliant subject). Although the total operational cost of the control group was the lowest, the effect on individual behavioral change was also the smallest. The ready availability of the supplements in Group B led to a seven fold leap in compliance. An additional cost of $1,000 (i.e. about an additional $50 per recruited subject) for implementing a comprehensive compliance enhancement program in Group A resulted in almost doubling regimen compliance and a modest decrease in the incidence of gastrointestinal side effects, as compared to Group B.

Pilot Testing the Efficacy of Increasing Total Dietary Fiber Intake. The efficacy of increasing total dietary fiber intake was tested in 46 older volunteers by using a teaching module designed for training of peer counselors. Both low and middle/high socio-economic status participants demonstrated a significant increase in knowledge, and indicated the willingness, capability and intention to carry out the behavioral change. Comparison of dietary data collected with different instruments from the same individuals suggested that repeated 24-hour food records before and after the intervention would be less subject to participant reporting bias than food frequency checklists.

IMPLICATIONS

The decision making strategy in the initiation and continuation/expansion of a nutritional intervention to lower cancer risk (Figs. 1 and 2) was demonstrated to be practical in our sequential approach of dietary fiber intervention for colon cancer prevention. It is applicable to general cancer control strategy and community health promotion programs. Techniques used in this process, including goal oriented literature search focusing on cost/benefit ratios of alternative interventions, development of valid and reliable instruments to assess health behavior related to intervention methods in the target population, survey of the feasibility of the proposed intervention and potential enhancers and detractors to compliance, and pilot studies to assess different aspects of the efficacy
of the intervention also have general implications for cancer control programs.

Results from the feasibility studies and the intervention study have been used by the Cancer Prevention and Control Program at the Arizona Cancer Center to (1) develop the clinical protocol for a Phase II cancer control chemoprevention trial (i.e. using wheat bran fiber supplementation in patients with adenomatous colonic polyps and (2) develop a cost-effective delivery model of community-wide nutritional intervention for cancer prevention/health promotion.

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