COMMENTARY

Diet and Lifestyle Intervention among Patients with Colorectal Adenomas: Rationale and Design of a Malaysian Study

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Abstract

Comprehensive evaluation of the large body of consistent evidence from laboratory, epidemiologic and clinical studies has led to the conclusion that modification of the dietary and lifestyle patterns of populations has considerable potential for reducing cancer risk. This paper describes a randomized-controlled trial involving a diet and lifestyle intervention for patients with history of colorectal adenomas. The primary aim of this trial is to evaluate the effectiveness of the intervention with reference to recurrence of adenomatous polyps over a two year period - the first year being the intervention period and the second year of the study allowing for post-intervention follow-up. Subjects found to fit the inclusion criteria are recruited and randomized to two groups: the intervention group and the control group. The intervention group subjects will attend a monthly lecture-discussion session for 10 months and small group counseling on modification of lifestyle behavior and diet as well as receive educational materials which were adapted from the WCRF Diet and Health Recommendations for Cancer Prevention. Control subjects will be provided with the usual care given to such patients. One hundred and sixteen patients who were diagnosed with colorectal adenomatous polyps in the previous twelve months at the Hospital Kuala Lumpur have already been enrolled in this trial. Baseline data collection is on-going.

Key Words: Maleysia - colorectal adenomas - diet - lifestyle - intervention

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Introduction

Malaysia has been experiencing rapid economic growth and unprecedented increase in affluence during the post-independence era of 45 years. The 2020 policy of the government has propelled the pace of industrialization and urbanization resulting in tremendous changes in diet and lifestyle practices of Malaysians. As in all cultures, diet plays a central role in the social and cultural aspects of the life of Malaysians. The ethnic variation in the Malaysian population and the on going diet transition from a traditional rice-fish-vegetable base to a Western style has resulted in partial fusion of dietary habits of Malaysians today. Changes in food preferences and food preparation methods have modified the dietary patterns of urban Malaysians in particular. The increase in the incidence of and mortality from coronary heart disease, diabetes mellitus, cancers and other chronic diseases in the past 3 decades have paralleled significant increase in Malaysians' intake of total calories, meat, animal fat and refined carbohydrate intake while the consumption of fruits and vegetables has not changed substantially.

Colon and rectal cancers rank among the most common cancers worldwide with almost 1 million new cases being reported annually. According to the first National Cancer Registry (NCR) Report of Malaysia (2002), colon cancer ranked third among cancers reported in males (7.8%) and in females (5.6%) and cancer of the rectum ranked fifth and eighth among cancers reported in males (6.4%) and females (3.4%) respectively.

Given that colorectal cancers usually arise from adenomatous polyps, which are treatable precursor lesions, attention should be clearly be directed towards preventive strategies in affected patients. It has been shown that removal of adenomas in the colon and rectum or removing any that reappear will prevent colorectal cancer (Winawer et.al., 1997; Atkin et. al., 1993 and Atkin et. al., 1992). However, patients after removal of colorectal adenomas or polyps are still at risk for recurrence of colorectal adenomas and developing colorectal cancer eventually. Approximately 10% of individuals who have an adenoma removed will develop

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recurrence in the following year (Schatzkin and Gail, 2002). Thus adenomas are feasible surrogate markers for colorectal cancer prevention and thus could be a potential target for primary prevention. Hill et al. (1978) proposed the notion that the adenoma-carcinoma sequence is a multistep process and that cancer could be prevented at the stage of adenoma appearance, growth, or transformation into carcinoma.

Dietary habits are highly relevant to the health of the colon and rectum, but most people believe that if they make a significant effort to change not only their diet but overall lifestyle as well, it may ultimately prevent or delay recurrent rate (Young, 2000). Thus these individuals may be extremely receptive towards improving their diet and physical activity behaviors and this offers the researcher a captive or " teachable moment" to promote behavioral change which may ultimately prevent cancer or delay recurrence. Few such studies have capitalized on this opportunity (McTiernan et al., 1999)

Diet Intervention

Compelling evidence from laboratory, nutritional and epidemiological studies have indicated that dietary factors are involved in the pathogenesis of cancer at several sites. It is roughly estimated that about 32% of all cancers may be avoidable by changes in the diet (Willet, 1995). Colorectal cancer is the cancer for which there is strongest documented evidence that diet is involved where up to 80% of the cancers may be preventable by dietary changes (Cummings and Bingham, 1998).

The international variation in the incidence of and mortality from colorectal cancer and the rapid increase in the incidence of colorectal cancer in several developing countries in economic transition run parallel to the nutrition transition that is occurring rapidly in these populations. Excessive consumption of red meat, barbecued, smoked and preserved meat; low intake of vegetables, fruit and total fiber, and high fat intake have been implicated (Cummings et. al., 1998). This evidence forms a strong basis for cancer prevention through dietary changes. Results from several observational studies have suggested that three main dietary factors are protective against cancer of the large bowel, i.e. low fat intake, high fiber intake and high fruits and vegetables intake (Schatzkin et al., 2000). The overwhelming epidemiological evidence for the role of diet in the occurrence of cancer have resulted in recommendations for a more plant-based diet suggesting a higher intake of vegetables and fruits, grains and pulses to prevent cancer, by a number of leading scientific centers such as The American Institute for Cancer Research (2003), World Cancer Research Fund (2003) and American Cancer Society (2004). These recommendations not only may serve as a basis for dietary advice for the promotion of health but also provide the investigator with an attractive hypothesis for a preventive approach.

Increasingly, behavioral research is being conducted which examine the role of dietary and lifestyle changes in cancer reduction. Table 1 lists various interventional studies that have investigated the effect of fibre and calcium in particular. Two diet intervention studies have provided some evidence of a protective effect of calcium alone (Baron et. al., 1999) or with antioxidants on adenoma recurrence (Greenberg et. al., 1994), but findings of trials on the effect of a low-fat, high-fiber and wheat-bran supplement were not significant (MacLennan et. al., 1995). In a press release by the International Agency for Cancer Research (IARC, 2003), it was reported that high intake of dietary fiber from cereals, vegetables and fruits were associated with a significant lower risk of adenoma based on evidence from two large population based studies, The European Prospective Investigation on Cancer (EPIC) and The Prostate, Lung, Colorectal and Ovarian Cancers Screening Trial (PLCO)

Lifestyle Intervention

There are considerable observational data which have linked physical activity to reduced risk of several cancers. The most definitive epidemiological evidence for an association between physical activity and cancer exists for colon or colorectal cancer. To date, nearly 30 published studies have examined the association between physical activity and risk of developing colon cancer alone. A single study of colorectal adenomatous polyps has reported an inverse relationship between risk of adenomas and level of total physical activity (Sandler et. al., 1995). Another study of colorectal adenomas also found an inverse association, but only for running or bicycling, and only with one of two different comparison groups (Little et al. 1993).

Several biological mechanisms have been indicated beneficial for the role of physical activity in cancer etiology. The main mechanisms that influence several cancer sites include modifications of sex and metabolic hormone levels, growth factors, decreased body fat and possibly enhanced immune function. Metabolic hormones and growth factors have been suggested as being influenced by increased activity levels. Exercise significantly lowers insulin, glucose, triglycerides, and raises HDL cholesterol, which may also be associated with decreased cancer risk (Nakamura et al., 1983).

Several randomized clinical trials have shown a beneficial outcome of physical activity in reducing fasting insulin level in normoglycemic and insulin-resistant populations, with the most benefit observed for those individuals who lose weight and increase physical activity level. More specifically, exercise may affect cancer risk through its effects on IGFs and their binding proteins (IGFBPs). High levels of circulating IGF-I and low levels of IGFBP-3 are associated with an increased risk of colorectal, breast, prostate and lung cancers (Slattery et al., 1990).

Lifestyle risk factors, including high-energy diets and low physical activity, may increase IGF-I levels. Increases in physical activity can confer reduced risk of colorectal

cancer through effects on prostaglandin, colon peristalsis, which in turn decreases the time that dietary factors, toxic and carcinogenic components reside in the colon. In addition it is been shown that exercise might also improve insulin homeostasis and reduce the proliferative drive of tumor cells (Young and Leu, 2002). In summary, it appears that physical activity is not merely a marker for healthier lifestyle but that it also confers an independent protective effect.

To date, no clinical trials of physical activity as a means for the primary prevention of cancer have been published. However, two major randomized controlled trails are currently on going. McTiernan et al. (1999) are conducting a one-year randomized controlled trial that is examining the effect of moderate intensity physical activity intervention in two study populations. The first trial, the Physical Activity for Total Health Study (PATH), is examining postmenopausal obese women for the prevention of breast cancer. The second trial, known as the Colon Polyp and Exercise Study, which include male and female adenomatous colon polyp patients, is being carried out to decrease cell proliferation in the upper part of the colon and rectal crypts.

A large study conducted in USA and Puerto Rico found that tobacco smoking might increase the risk of colon polyps, which will be transformed into colorectal cancer if were not removed on time (Kahn et. al., 1998). Besides smoking, the same study had also found alcohol consumption to be positively correlated with colon cancer. The study also suggests that smoking may act as an initiator of polyp formation, where else alcohol may act later as the growth promoter of these cancerous cells. A case-control study conducted among men in three hospitals in Japan revealed that the risk for colorectal adenomas increased with increasing levels of cigarette exposure, and the trend was highly significant (Todoroki et. al., 1995).

Follow-up data from two Japanese prospective cohort derived from middle-aged and elderly Japanese men and women was analyzed by Otani et. al. (2003). Both alcohol consumption and smoking were associated with colorectal cancer in men after adjusting for age, family history of colorectal cancer, BMI and exercise. The risk was similar in women, although the trend was not significant.

From the study, it was further substantiated that regular heavy drinking is associated with increased risk for colorectal cancer in men compared to non-drinkers. On the contrary, regular alcohol consumption was not associated with colorectal cancer risk in women. Combined analysis of the effect of smoking and alcohol consumption estimated that colorectal cancer risk increased by three-folds in current smokers who consume 300g/week or more ethanol compared to nondrinkers among nonsmokers in men. As a conclusion, the authors estimated that colorectal cancer attributable to alcohol consumption or smoking to be 40%, which may be preventable by tobacco and alcohol control in the population. Based on the existing positive evidence for the role of a healthy diet and appropriate lifestyle behavior change for disease prevention, we plan to investigate the effect of a 2-year structured educational intervention in patients with history of colorectal adenomas on dietary, lifestyle, physical and biochemical parameters and on further development of new adenomas with approaches that would be successful in promoting healthy eating and healthy lifestyle behavior. In addition the Transtheoretical Model of Behavior will be used to understand how people change diet and health behavior. Initially, this model was applied to smoking behavior change and other addictive habits. Subsequently, the application of this model has been extended to diet and physical activity behavior (Prochaska et. al., 2000).

Methods

Study Design

A 2-armed randomized control trial will be carried out with quantitative and qualitative techniques to measure primary and secondary outcomes (Figure 1).

Subjects: Eligibility and Exclusion Criteria

Men and women who are at least 30 years old and who have had one or more histologically confirmed colorectal adenomas removed within the previous six months and free from other chronic diseases will be invited to participate into the study.

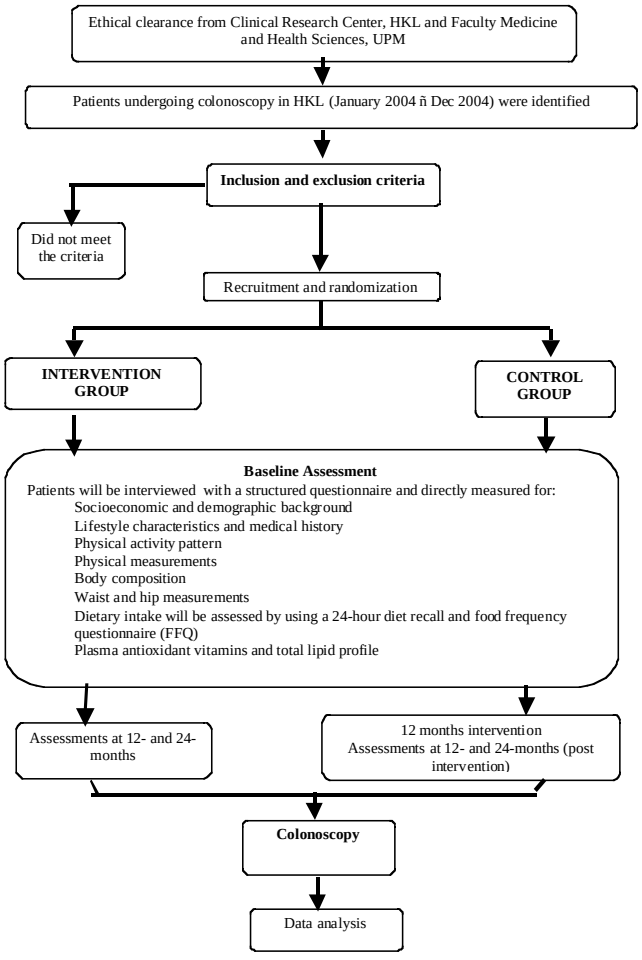

Figure 1. Study Design Flow Chart

Exclusion criteria include: participants who have a history of colorectal and/or any other cancers or, bowel resection, polyposis syndrome, or inflammatory bowel disease, weigh not more than 150% of the desired weight for height, take cholesterol-lowering drugs and have chronic medical conditions or dietary restrictions that would substantially limit their ability to complete the study requirements.

After the eligibility screening, subjects will be invited to participate with written informed consent. Patient information sheet and consent forms will be prepared in Malay Language and English. Kuala Lumpur General Hospital will serve as the clinical center and the source of participants for this study.

Subjects are randomly be assigned to one of 2 study groups:

1. Control Group: This is group will receive the usual care given to cancer patients; they will be also provided with educational materials on diet and exercise.

2. Intervention Group: This group will receive an intensive diet and lifestyle intervention in the form of lecture-discussions, educational materials including new recipes, individual counseling and motivational sessions that will be reinforced at regular intervals through phone calls during the intervention period.

Data Collection

All data will be collected during a face-to-face interview with the subjects. A pre-tested, structured questionnaire will be used to record the information obtained during the interview. The questionnaire consists of four major parts:

a) Sociodemographic information

This section consists of questions on the subject's personal particulars, educational status, occupation, personal and household income, family size and number of years residing in the Klang Valley, a highly urbanized environment.

b) Lifestyle Characteristics

Included are smoking habits, alcohol consumption, eating out pattern, physical activity and exercise as well as intake of nutritional supplements.

c) Physical Measurements

Weight, height and waist and hip circumferences will be determined using standard procedures. Blood pressure and resting heart rate will also be recorded. The OMRON body fat monitor will be used to obtain subjects' body fat percentage and total body fat.

d) Dietary pattern

a) 24-Hour Dietary Recall: Three day 24-hour dietary

Table 1. Study Design, Endpoints and Results of Chemoprevention Trials with Fiber and Calcium for Colorectal Carcinogenesis

Study	Subjects	Intervention	Number of subjects	Duration	Endpoints
De Cosee et. al., New York, 1989	Familial polyposis	Wheat bran 22.5 g/d + vitamin C 4 g/d + vitamin E 400 mg/d	58	4 years	Non significant reduction in the number of rectal adenomas
MacKeown-Eyssen et. al., Canada 1994	Previous adenoma	Diet high in fiber and low in fat	201	2 years	No effect on adenoma recurrence
MacLennan et. al. Australia, 1995	Previous adenoma	Wheat bran 11 g/d	378	4 years	No effect on adenoma recurrence
Alberts et. al., Arizona, 2000	Previous adenoma	Wheat bran 13.5 g/d	1400	5 years	No effect on adenoma recurrence
Bonithon-Kopp et. al., Europe 2000	Previous adenoma	Ispaghula husk	656	5 years	Significant increase in adenoma recurrence
Schatzhin et. al., USA, 2000	Previous adenoma	Diet high in fiber, fruits vegetables, low in fat	2079	4 years	No effect on adenoma recurrence
Hofstad et. al. Oslo, 1998	Previous adenoma	Calcium 1.8 g/d + β-carotene 15 g/d + vitamin E 75 mg/d+ vitamin C 150 mg/d + Se101 mg/d	116	3 years	No effect on adenoma growth, Significant reduction in adenoma recurrence
Baron et. al. USA, 1999	Previous adenoma	Calcium 1.2 g/d	930	3 years	Significant decrease in adenoma recurrence
Bonithon-Kopp et. al., Europe, 2000	Previous adenoma	Calcium 2.0 g/d	656	3 years	Decrease in adenoma recurrence

recall data will be obtained from the subjects, with details of foods and drinks taken each day recorded. A food album on commonly consumed food is used to help subjects recall the portion size of their food and drinks consumed.

The FFQ consists of 250 food items categorized into 15 food groups including beverages beverages. Food intake frequencies were classified into five categories to which weights or points were assigned: everyday (5 points), 4-6 times per week (4 points), 1-3 times per week (3 points), 1-2 times per month (2 points) and never or seldom (1).

A score was calculated for each food item using the equation of Reaburn et. al. (1979).

$$\text{Score} = \frac{R1S1 + R2S2 + R3S3 + R4S4 + R5S5}{5}$$

where S1-S5 were scale ratings and R1-R5 were the percentage of respondents selecting a rating, with 5 as the maximum scale rating.

Collection and Centrifugation of Blood Samples

Venous blood will be collected on five occasions by a trained and qualified nurse or doctor at baseline, at 12, and 24 month post – randomization. Fifteen ml (15ml) of fasting blood sample will be drawn each time into EDTA (1.6g/L) – containing tubes. Tubes will be protected from light with aluminum foil, and centrifuged within three hours after collection at 2100 xg at 4^0C for 15 minutes. Plasma will be separated, transferred into polypropylene micro centrifuge tube, and stored at -80^0C until further analysis.

Plasma Antioxidants

The plasma concentrations of carotenoids (α-carotene, β-carotene, β-cryptoxanthin, lycopene and lutein), vitamin A (retinol) and α-tocopherol will determined using high pressure liquid chromatography (HPLC) as described by Lee et. al. (1992). Plasma vitamin C was determined using method of Chung et. al. (2001).

Plasma Lipids and Lipoproteins

Plasma lipids and lipoproteins will be determined by the method described by Stark et al. (2000). Triglycerides and total cholesterol concentrations will be quantified enzymatically, following the manufacturer's guide (Sigma, USA). HDL – cholesterol concentrations will be quantified after precipitation of the serum (Sigma, USA) and LDL – cholesterol will be determined by Friedwald's equation.

All the measurements described will be carried out at baseline, after intervention (12 months) and at 24 months.

Intervention

This is a two-year educational intervention with follow-up assessments at 12-month interval. The intervention program comprises 4 key elements i.e nutrition skill building, behavior modification, self-monitoring, and the provision of standardized nutrition behavior modification materials. The intervention educational modules will be developed based on the guidelines of the World Cancer Research Fund (WCRF) for cancer prevention (Table 2). These guidelines will be modified to suit the local context. The intervention will comprise lecture-discussions and individual counseling sessions, which will be scheduled according to lesson plans or modules. Each lesson is an adaptation of the information that is contained in "The Power of Prevention" booklet of the WCRF.

Table 2. WCRF Cancer Prevention Guidelines

1.	Choose a diet rich in a variety of plant-based foods.
2.	Eat plenty of vegetables and fruits.
3.	Maintain a healthy weight and be physically active.
4.	Drink alcohol in moderation, if at all.
5.	Select foods low in fat and salt.
6.	Prepare and store foods safely.

Handouts and brochures are being developed for each lesson plan in simple understandable form in two languages ie. Bahasa Malaysia (the Malay language) and English. At each group-counseling session, the participants will receive these learning materials. The duration of each lesson will be around 45 minutes, which will include time for questions and answers.

The counseling and educational materials for the intervention group will focus on goal setting, which is to increase vegetables and fruits consumption to at least a total of 8 servings per day with a secondary emphasis on increasing the intake of β-carotene-rich vegetables and fruits, and reducing energy intake from dietary fat to <30% Research assistants trained in nutrition and community health will conduct the teaching sessions.

Patients who are assigned to the control group will receive the usual care provided to patients with history of adenomas and will also be given the same educational materials as those given to the intervention group. This group, however, will not in any way receive the intervention, talks and the regular reinforcement of messages given to the intervention group.

Post Intervention Evaluation

This will be carried out one year after the final evaluation. All the measurements taken during the intervention period will be taken again. In addition, a final colonoscopy will be carried out. This is important to assess the possible recurrence of colorectal adenomas.

Colonoscopy

Subjects will be required to undergo a colonoscopy to observe recurrence of the adenomas at the end of the first year of intervention and at the end of the third year of the study ie at the post intervention evaluation. In addition information on the size, number and location of all polyps will be determined.

Data Analysis

As this a prospective RCT involving repeated measures, the ANOVA repeated measures model would be applied to observe significant differences between study groups at 95% confidence interval. Associations between stages of change,

fruit and vegetable intake, physical activity level, demographic, psychosocial factors and plasma biomarkers will be examined through linear regression analyses. All data analysis will be conducted using SPSS 12.0.

Results

Enrollment of study subjects commenced on 1st March 2004 and ended on 30th April 2005. A total of 343 patients' medical records were screened according to the inclusion and exclusion criteria. Of the 343 patients, 157 responded to the mailed invitation. Upon obtaining confirmation via telephone, the participants were randomized into intervention or the control group. They were invited to a "meet the researcher session" with the investigators who then explained to the participants the objectives of the study and their role in the study. Informed consent was obtained and 74% of those who attended the briefing session, agreed to participate.

There were 59 (42 males versus 17 females) subjects in the intervention group and 57 subjects (33 males versus 24 females) subjects in the control group. The majority of the respondents were more than 50 years with a mean age of 58.96 $\pm$ 9.96 years in the intervention group and 55.13 $\pm$ 1.18 years in the control group. About 85% of participants in each group were married and majority of them have had at least 9 years of education. At the time of recruitment, most of the respondents (60.3%), 39 subjects in intervention group and 31 in control group were either retired or unemployed.

The socio-economic and demographic backgrounds of the participants were considered when the intervention package was being developed. The talks around which the group discussion and counseling are centered were developed to suit the comprehension level of the group. Simple terms and language were used in developing the talks as well as the brochures as this was not a very highly educated group. As the majority of the participants were married, they were even encouraged to bring their spouses for the group counseling sessions, as we believe that support from the partner is one of the essential elements in encouraging behavior change.

Discussion

Colorectal cancer is multifactorial in its etiology and is postulated to result from a composite of host, diet and other lifestyle factors that may occur over many years. It is likely that there are key pathways to this disease and that factors that increase the risk for colorectal cancer do not work in isolation from other factors.

Adenomatous polyps are benign growths that protrude from inner walls of the colon or rectum (National Cancer Institute, 2002). More than 70% of the colorectal cancer develop from sporadic adenomatous polyps and a review of some postmortem studies have shown the incidence of adenoma to be 30-40% in the Western population (Hardy et. al., 2000). However, the incidence of colorectal adenomas in the Malaysian population is not known. Dietary and lifestyle risk factors have been implicated in the development, progression and transformation of these polyps to cancerous cells or tissues. This is the basis of our intervention, which focuses on diet as well as lifestyle characteristics such as physical activity pattern, alcohol consumption and tobacco use to reduce the risk of recurrence of colorectal adenomas and subsequently reduce the risk of colorectal cancer.

Diet, implicated as the prime risk factor for developing colorectal cancer remains an area of active investigation. Modification of dietary risk factors is the central theme of this intervention trial, wherein we will provide intensive dietary counseling to the patients, besides motivational talks on other lifestyle risk factors. Although the exact relationship between diet and the risk for colorectal cancer remains unclear, many case-control, cohort and intervention trails have indicated close association between dietary intake and incidence of colorectal cancer. As dietary factors such as types of foods, food preparation methods, portion sizes, food variety and overall calorie balance may affect cancer risk (American Cancer Society, 2004), we will gather all these information from the participants at baseline, during and after the intervention.

Since adenomatous polyps are precursors to most colorectal cancers, studying these polyps might allow one to measure the diet of relatively asymptomatic subjects closer to the time of the initial neoplastic process. A case-control study conducted between 1991 and 1993 revealed an inverse relationship between consumption of high carotenoid containing vegetables, cruciferous vegetables, high vitamin C fruits, garlic and tofu, and adenomatous polyps (Witte el. al., 1995). This finding supports the hypothesis that high intake of vegetables, fruits and grains may decrease the risk of developing recurrent colorectal adenomas. This study utilizes this finding together with recommendations by international organization such as WCRF in providing education for the subjects with history of colorectal adenomas in order to reduce the risk of developing polyps again in the future.

Besides diet, the study also focuses on other lifestyle measures. Physical inactivity is a prime suspect in the etiology of colorectal cancer. Convincing evidence exists on the inverse relationship between physical activity and risk for colorectal cancer. Increased level of physical activity can confer a reduced risk of colon peristalsis that in turn, decreases the time the dietary factors, toxic and carcinogenic components reside in the colon. In addition, it will probably influence insulin homeostasis and increase the proliferate drive for tumor cells as well (Young et. al., 2002).

Other lifestyle-associated factors that we address here include alcohol consumption, overweight and obesity, and tobacco smoking. There is accumulating evidence, which strongly supports the addition of colorectal cancer to the list of tobacco-related malignancies, and there is a possibility that up to 1 in 5 colorectal cancer cases in USA is related to this habit (Giovannuci et. al., 2001). Tobacco smoking was

found to increase the risk of developing colon polyps in a large study conducted in USA and Puerto Rico (Kahn et. al., 1998). The same study also found alcohol consumption to be positively correlated with colon cancer. The researchers hypothesized that smoking may act as an initiator of polyp formation while alcohol may act later as the growth promoter of these cancerous cells.

In addition to smoking and consumption of alcoholic beverages, obesity-related factors also have shown to be strong risk factors that are associated with promotion and progression of adenomas towards colorectal cancer. In a large study on male health professionals, positive association was found between BMI and colorectal adenomas (Giovannuci et. al., 1995). Similar findings were observed among women where the relative risk for overweight was 2.2 for large adenomas and 1.4 for smaller adenomas (Giovannuci et. al., 1996).

The difference one can observe in this trial will be the incorporation of various lifestyle factors in its intervention program. This study also utilizes various plasma antioxidants in order to assess the feasibility and effectiveness of the intervention. Biomarkers may be valuable in diverse aspects of both the investigation and treatment of this disease. Plasma values of antioxidant vitamins, such as various carotenoids, vitamin C, retinol and _-tocopherol as well as total lipid profile may serve as indirect markers of colorectal cancer risk.

Recruitment of study subjects for a randomized controlled trial usually is time-consuming and challenging. In order to improve participation rate of the patients, we had decided to randomize the subjects first and then seek their consent. With this strategy, we could discuss their role in the research, be it as participants in intervention or control group, and the discussion had actually improved the number of participants consenting to their study group.

During the intervention, talks will be given based on guidelines that we had adopted from WCRF. However, we modified the guidelines according to local needs and provided various dietary options for the participants to follow. When options are given and the guidelines are not too rigid, we hope the participants will find it easier to adhere to the intervention.

The participants of the study were not charged any fees for the monthly intervention session as well as for the blood sample collection. The participants were in fact paid a small sum of money to cover their transportation fees as a token of appreciation for each session they attend which is seen as another motivating factor for continued participation and retention.

Conclusion

This study is the first of its kind in Malaysia. Although the recruitment of subjects was fraught with difficulties and often time-consuming, several measures were taken to reduce the drop out rate and maintain the interest of the participants. We anticipate that this intervention trial, which focuses on behavior change, will at least lower modifiable risk factors for colorectal adenomas in this high-risk group. The baseline data is on going and the first batch of participants' one-year intervention will be completed by December 2005.

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