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Health-Promotion Behaviors That Promote Self-Healing

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ABSTRACT

A large body of evidence has shown that health-promotion programs in smoking cessation, stress management, fitness, nutrition, weight control, and medical self care have been successful in helping people improve their health practices and related health conditions. However, the impact of these programs on promoting self-healing among people with acute and chronic diseases is mixed. The purpose of this paper is to identify research opportunities important to fostering a better understanding of health promotion behaviors that promote self healing. To provide context, the health-promotion concept is discussed, as is the literature on workplace health-promotion programs provided to overtly healthy people. Next, examples of the literature on health-promotion programs for people with chronic illness are provided. Finally, a research agenda and opportunities for research are presented.

INTRODUCTION

Positive health behaviors such as regular exercise, eating nutritious foods, managing stress, and avoiding toxic substances such as tobacco, have a well-established relationship with well-being and reduced levels of morbidity and mortality. Furthermore, a large body of evidence (see below) has shown that health-promotion programs have been successful in helping people improve their health practices and health conditions. However, the impact of health-promotion programs and the behaviors they instill on promoting self-healing among people with acute and chronic diseases is less well established.

The purpose of this paper is to identify research opportunities important to fostering a better understanding of health promotion behaviors that promote self-healing. To provide context, the health-promotion concept is discussed, as is the literature on workplace health-promotion programs provided to overtly healthy people. Next, examples of the literature on health-promotion programs for people with chronic illness are provided. Finally, research challenges and a framework for future research are presented.

In the context of this paper, healing is defined as "the dynamic process of recovery, repair, restoration, renewal and transformation that increases resilience, coherence and wholeness. Healing is an emergent process of the person's whole system: physical, mental, social, spiritual and environmental. It is a unique personal and communal process and experience that may or may not involve curing."[1]

BACKGROUND ON HEALTH PROMOTION

The *American Journal of Health Promotion* defines health promotion as "the science and art of helping people change their lifestyle to move toward a state of optimal health. Optimal health is defined as a balance of physical, emotional, social, spiritual, and intellectual health. Lifestyle change can be facilitated through a combination of efforts to enhance awareness, change behavior and create environments that support good health practices. Of the three, supportive environments will probably have the greatest impact in producing lasting change."[2] This definition applies equally well to overtly healthy people and people with acute and chronic diseases.

The evidence supporting health promotion must be examined from two perspectives. First, what is the relationship between health practices and health outcomes? Second,

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what is the impact of health-promotion programs on health outcomes?

Lifestyle practices and health outcomes

There is an abundance of high-quality epidemiologic evidence supporting the relationship between health practices and heath outcomes. There is little question or disagreement that health behaviors have a huge impact on health outcomes. Approximately 40% of all premature deaths in the United States, at least 900,000 deaths annually, are the result of unhealthy lifestyle choices such as tobacco use, poor diet, sedentary lifestyle, misuse of alcohol and drugs, and accidents. Other contributors to early death include genetic predisposition (30%), social circumstances (15%), poor access to quality medical care (10%) and environmental exposures (5%).[3] Furthermore, unhealthy lifestyle is the primary contributor to the six leading causes of death in the United States: heart disease, cancer, stroke, respiratory diseases, accidents, and diabetes, which collectively account for almost 75% of all deaths.[4,5] Almost two thirds of American adults are overweight or obese,[6] more than 60% do not get enough physical activity, 25% are completely inactive, and only 23% eat recommended amounts of fruit and vegetables.[7] People with healthier lifestyles live an average of 6 to 9 years longer,[8] postpone disability by 9 years, and compress disability into fewer years at the end of life.[9]

The devastating impact of lifestyle on the population is clear, and the burden is made worse by the fact that lifestyle diseases disproportionately effect racial and ethnic minorities and poor people,[10] as well as older adults.[11]

Although the recent research cited above has provided a rich pool of data to describe the current status, the impact of lifestyle on health has been well established for decades. In fact*, The Surgeon General's Report on Health Promotion and Disease Prevention,* published in 1979, called for "a second public health revolution in the history of the United States" to address problems related to lifestyle.[12] The revolution never occurred, the federal government invested minimal resources in this area, and thousands of health-promotion programs emerged in the private sector.

Impact of health promotion on health outcomes

Although encouraging, the evidence supporting the impact of health-promotion programs on health outcomes is not as strong as the evidence supporting the link between health behavior and health outcomes. Low-cost, short-term programs have been successful in changing knowledge, attitudes, behavior, and health conditions on a short-term basis for a wide variety of behaviors. More intensive, longer term programs have produced greater and longer lasting changes. The biggest weaknesses in these programs have been low participation rates, challenges in attracting people of color, low income and low education, children and older adults, failure to address long-term changes, low budgets, and short duration. These programs also tend to focus on educational interventions and the individual as a unit of change, without sufficient attention to the impact of social and cultural norms on health practices and change processes.

The workplace offers a unique environment in which to provide programs because people spend a large portion of their waking hours at work, and the employer has a financial incentive to keep its employees healthy and medical utilization low. As such, approximately 90% of employers with 50 or more employees have offered some type of health-promotion program.[13] Many of these programs are minimal in scope and impact, but hundreds of employers, especially large employers, have developed more comprehensive programs.

A comprehensive systematic review of the literature published in 1996 identified 378 studies published in peer-reviewed journals on the impact of workplace health-promotion programs on health outcomes.[14] This review examined health-promotion programs designed to address alcohol and drug abuse, exercise, human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), hypertension, hypercholesterolemia, nutrition, seat belt use, smoking control, stress management, weight control, and health risk appraisals. The quality of research and the impact of the programs varied by subject area. Approximately 29% of the studies utilized randomized controlled designs, 26% utilized quasiexperimental designs and the remainder were performed in nonexperimental designs. Positive results occurred in 75% of the experimental studies, 88% of the quasiexperimental studies and 100% of the nonexperimental studies. Most programs were successful in changing knowledge, attitudes, behaviors, and health conditions on a short-term basis. Long-term impacts were typically not measured. Success rates were encouraging in hypertension, stress management, smoking control, nutrition, hypercholesterolemia, exercise, and seat belt use, but discouraging in weight control and alcohol and drug abuse. There were too few studies to draw conclusions for programs in HIV/AIDS and health risk appraisals.

There have been no comprehensive reviews published since 1996, but the general trend has been to improve success rates. The biggest weaknesses in these programs have been participation rates ranging from 20% to 30% and the absence of programs offered by small employers. Programs also tended to have low budgets in the $30–$60 per employee per year range, and frequent program closures during economic downturns.

Understanding the impact of programs on financial outcomes is important because funds will be scarce for programs that cost more and more available for programs that save money. A comprehensive review of the financial impact of workplace health-promotion programs found 16 studies that used absenteeism as an outcome and 24 that used medical costs as an outcome. Eighty-seven percent (87%) of the studies found that health-promotion programs reduced

absenteeism, and 88% reduced medical costs. For the 8 medical cost studies that included cost benefit analysis, the range of savings was $2.30 to $5.90 per dollar invested, with a mean of $3.35. For the 5 absenteeism studies that included cost benefit analysis, the range of savings was $25.50 to $10.10 per dollar invested, with a mean of $4.90. Given that the majority of studies did not include cost benefit analyses, it is difficult to draw broad conclusions. However, it is safe to say that some programs have been able to show strong cost savings.[15]

There are no standard guidelines for high-quality programs, but there is widespread agreement that education on the benefits of healthy lifestyle is not enough. More successful programs also offer opportunities to engage people in behavior change processes that include health assessment, goal setting, ongoing opportunities to acquire knowledge and build skills and receive feedback on progress. There is increasing recognition of the importance of creating supportive environments that encourage good health practices. These environments provide smoke-free air, access to nutritious foods, opportunities for physical activity as part of the routine day as well as fitness facilities, and protection from stress inducing situations and safety hazards.[16]

HEALTH-PROMOTION PROGRAMS THAT PROMOTE SELF-HEALING AMONG ILL PEOPLE

An important early step in identifying research opportunities and gaps on health-promotion programs for ill people would be conducting a comprehensive, systematic review of this literature. Such a review might examine health-promotion programs offered to people suffering from all the major causes of death related to lifestyle factors, and be organized by disease, outcome measure within each disease (e.g., functionality/disability, symptoms, quality of life, medical care utilization, recovery, mortality), intervention focus (e.g., exercise, stress management, smoking cessation, nutrition, weight control), and degree of illness/wellness of program participants. Such a review is beyond the scope of this paper, and similar reviews have not been conducted to my knowledge.

However, there is at least one ongoing effort to review the impact of a wide range of preventive services from a clinical standpoint. The U.S. Preventive Services Task Force was convened by the Public Health Service in 1984 to perform this function; it published its first *Guide to Clinical Preventive Services* in 1989.[17] The second edition was published in 1996.[18] The content examines the efficacy of screening for 53 different health conditions organized under major categories including cardiovascular diseases, neoplastic diseases, metabolic, nutritional and environmental diseases, infectious diseases, vision and hearing disorders, prenatal disorders, congenital disorders, musculoskeletal disorders, mental disorders and substance abuse. For each of the 53 screenings, there is a summary comment on the quality of evidence supporting a recommendation to conduct the screening, burden of suffering, accuracy of screening tests, effectiveness of early detection, recommendations of other groups and a brief description of the screening protocol. The *Guide* also examines the efficacy of physician counseling in 17 different areas including tobacco use, physical activity, healthy diet, and more. The *Guide* also provides a summary comment on each for the quality of evidence supporting a recommendation, the provision of counseling, the burden of suffering, efficacy of risk reduction, issues specific to special populations when relevant, effectiveness of counseling, recommendations of other groups and a brief summary of the clinical intervention. The third edition[19] is published in booklet form and online as installments are completed. Two installments have been completed. This series of guides is an excellent resource, but provides insufficient information on the literature to give a clear sense of the most important research priorities.

RESEARCH DISCUSSION

My recommendation is that a complete review of the literature in this area be conducted as a first step in developing a research agenda. As an interim step, examples of selected studies on three of the most prevalent chronic diseases in the United States are provided: type 2 diabetes mellitus, coronary artery disease (CAD), and breast cancer.

HEALTH PROMOTION FOR TYPE 2 DIABETES MELLITUS

Research discussion

Diabetes mellitus, the sixth leading cause of U.S. mortality,[20] reached an overall prevalence of 10.8 million or 5.4% of the U.S. population in 1999.[21] This excludes undiagnosed cases that are estimated to increase the prevalence by approximately 35%.[22] The early 2003 estimate of 6.2% diabetes mellitus prevalence,[23] a 14.8% increase over the last 4 years, represents a largely preventable epidemic among the 90%–95% of diabetics classified as type 2.[22] Thus, lifestyle interventions that reduce the incidence of type 2 diabetes mellitus among those with impaired glucose tolerance (IGT), promote glucose control and cardiovascular risk factor reduction in diagnosed type 2 diabetics, and benefit the long-term vascular complications of type 2 diabetes mellitus in established diabetics offer significant opportunities for self-healing.

Substantive evidence supports the effectiveness of health-promotion behaviors in reducing the incidence of type 2 diabetes mellitus among those with IGT and improving glu-

cose control and cardiovascular risk factors in diagnosed type 2 diabetics. Considerably less evidence suggests that health promotion behaviors support self-healing of macrovascular complications, such as CAD, stroke and peripheral vascular disease which account for 80% of diabetic mortality,[24] or microvascular complications such as retinopathy, nephropathy, and neuropathy.

Some large clinical trials demonstrated that lifestyle interventions decrease the incidence of type 2 DM in those with IGT. The Da Qing IGT and diabetes study in China was the first randomized, controlled trial to show that interventions of diet alone, physical activity alone, or diet and physical activity reduced the incidence of type 2 DM among those with IGT by 25%–50% in a group of 110,660 participants over 6 years.[25] The Finnish Diabetes Prevention Study Group conducted a randomized, controlled trial of 522 subjects with IGT followed for an average of 3.2 years, and showed a 58% reduction in the incidence of type 2 DM using a diet with 30% total fat, 10% saturated fat, and 15 grams of fiber per 1000 kcal, plus 30 minutes of daily physical activity to increase muscle strength and aerobic fitness.[26] These results were consistent with those of the Diabetes Prevention Group, which followed patients without diabetes with IGT for an average of 2.8 years in a randomized, controlled trial showing a 58% reduction in type 2 DM incidence with lifestyle intervention, including a minimum of 7% weight loss and 150 minutes of weekly physical activity, versus a 31% reduction using metformin compared to the control group.

A second group of observational and experimental studies examined the effects of diet, physical activity, smoking behavior, and stress management on glycemic control, cardiovascular risk factors, and long-term vascular complications in newly diagnosed and/or established type 2 diabetics. In a meta-analysis of 14 controlled clinical trials involving type 2 diabetics, Boule et al.[27] found that physical activity with and without diet changes significantly decreased hemoglobin A_{1c} (HbA_{1c}) by approximately 0.66%, which was near the average 0.9% difference between the conventionally treated control and intensive pharmacologically treated intervention groups in the United Kingdom Prospective Diabetes Study (UKPDS). Although the UKPDS metformin arm showed only a 0.6% decrease in HbA_{1c} compared to the control group, there was a 32% reduction in diabetes-related complications.[27]

The prospective cohort of 2896 participants with diabetes in the 1990 and 1991 National Health Interview Survey followed for 8 years demonstrated a 34% lower cardiovascular mortality rate with 2 hours of weekly walking after controlling for gender, age, race, body-mass index, smoking and comorbid conditions.[28] The prospective cohort Nurses' Health Study subgroup of 6547 women with type 2 diabetes followed for 20 years showed a 7.7 times greater risk for developing CAD among women with diabetes who smoked 15 or more cigarettes daily than women without diabetes who never smoked, and the relative risk for CAD among diabetic women 10 years after smoking cessation was comparable to women with diabetes who had never smoked.[29]

The Japan Diabetes Complications Study currently in progress is the first randomized, controlled trial of 2205 subjects with established type 2 diabetes to examine the effects of comprehensive lifestyle intervention directly on the long-term macrovascular and microvascular disease complications. During the initial 3 years, the intervention group showed small but significantly increased glycemic control. This study will proceed for a minimum of 10 years and will include analysis of an extensive lifestyle survey after 5 years and an evaluation of the development of long-term complications after 10 years.[30] Surwit et al.[31] have also demonstrated small but significant glycemic control improvements in the first randomized study using a simple, cost-effective group stress management program in 108 subjects with type 2 diabetes over 1 year.

A third category of studies investigated the effects of community-based diet, physical activity and stress reduction interventions, alternatively referred to as diabetes self-management education,[32] on glycemic control, cardiovascular risk factors and long-term vascular complications in subjects with type 2 diabetes. Barnard et al.[33] conducted a study of 652 subjects with type 2 diabetes that demonstrated both significant decrease in fasting serum glucose levels and reduction of cardiovascular risk factors, including serum total cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides and resting blood pressure ($p < 0.001$), during the Pritikin Longevity Center 26-day residential program using a high complex carbohydrate, high-fiber, low-fat, low-sodium diet, and aerobic physical activity.[33]

Gilliland et al.[34] studied 104 Native Americans with type 2 diabetes in New Mexico using a culturally specific lifestyle education intervention through either a family-and-friends or one-on-one format compared with standard education in the control group. They found small statistically significant improvement in HbA_{1c} ($p = 0.02$) and weight ($p = 0.05$) in the combined intervention arm compared to the control group over 1 year.[34] Galper et al.[35] have suggested adding thermal biofeedback to community-based diabetes self-management interventions after considering preliminary evidence found by Rice et al.[36] of the improved ulcer healing rate, sensory nerve function and patient activity using biofeedback-assisted relaxation for chronic foot ulcers in a small, randomized, controlled study, including subjects with type 2 diabetic neuropathy, conducted over 3 months.

Research questions

This sampling of the substantive research on type 2 DM stimulates questions about how to maximize the effectiveness of health promotion behaviors in treating this disease. What is the optimal dietary composition[37] to reverse IGT and maximize healing in subgroups of newly diagnosed and

established subjects with type 2 diabetes? Is dietary pattern more important than specific macronutrients to healing?[38] What are the critical components of successful physical activity programs that optimize insulin sensitivity and functional capacity in various target diabetic subgroups, including high-risk ethnic groups like Native Americans, African Americans, and Hispanics?[39] Because DM is an independent predictor of using complementary and alternative medicine such as meditation and lifestyle diets such as those designed by Pritikin and Ornish, what is the efficacy of the broad range of these treatments?[40] How effective is progressive relaxation training in improving glycemic control for various target subgroups and levels of stress?[41] Because many people with diabetes seem to be less responsive to medical treatments which have been effective in managing cardiovascular disease in the general population, how can comprehensive lifestyle intervention best address this increased cardiovascular morbidity and mortality seen in people with type 2 diabetes?[37] How effective is biofeedback-assisted relaxation training in reversing the accelerated atherosclerosis seen in people with type 2 diabetes?[37] Because diabetes education has been more successful in promoting glucose monitoring than lifestyle self-management, how effective are brief, customized, practical self-management interventions in improving compliance and sustaining lifestyle changes?[42] What is the optimum method for recruiting subjects with type 2 diabetes to community-based interventions? Who are the optimum providers? What is the ideal intensity and duration for community-based interventions? What is the optimum way to coordinate community-based and primary care?[32]

HEALTH PROMOTION FOR CAD

Research discussion

In 1999, heart disease, the foremost cause of U.S. mortality,[20] affected 21.5 million or 11.0% of the U.S. population, including 10.7 million or 5.4% of the U.S. population with CAD.[21] Thus, health promotion behaviors that support CAD healing through risk factor reduction, reversal or prevention of atherosclerotic stenosis progression and/or decreased morbidity and mortality have the potential to significantly impact this major public health burden.

The relatively few studies with coronary patients are difficult to compare secondary to methodological and intervention differences,[43] but rigorous evidence supports the effectiveness of health promotion behaviors in healing CAD. Some of the clinical trials examining the effects of comprehensive lifestyle change on CAD have shown less dramatic results[44] than those demonstrated by Ornish and colleagues, whose work demonstrates the possibilities, though not necessarily the practicality, for CAD reversal using comprehensive lifestyle changes.[45–47] When Ornish and colleagues studied 23 intervention and 23 control patients with ischemic heart disease in a randomized, controlled trial using stress management and a vegan diet for 24 days, they found a 21% mean plasma cholesterol decrease, a 44% mean exercise capacity increase and a 91% mean decrease in the frequency of anginal episodes.[45] Their subsequent Lifestyle Heart Trial was the first randomized, controlled trial to successfully demonstrate the possibility of atherosclerotic stenosis regression in selected free-living, highly motivated CAD patients over 1 year using comprehensive lifestyle modifications, including low-fat vegetarian diet, smoking cessation, stress management, and moderate physical activity.[46] The intervention group mean percentage diameter stenosis decreased from 40.0 to 37.8 while the control group lesions enlarged from 42.7 to 46.1. Lipid-lowering drugs were not used, and 82% of the intervention group showed an average change towards regression. Further 5-year follow-up showed continuing significant differences between the intervention group lesion regression and control group lesion progression ($p = 0.001$).[47]

Manchanda et al.[48] have also demonstrated significant atherosclerotic stenosis regression and prevention of lesion progression in a small, randomized, controlled trial of 42 male participants using a comprehensive yoga diet, physical activity, and stress management intervention over 1 year without lipid-lowering drugs. The severity of disease was greater in this study than the Lifestyle Heart Trial since 81% of the participants had triple vessel disease. Participants were also asked to pursue a more liberal diet with 50 mg cholesterol per day and 15% of calories from fats versus the Lifestyle Heart Trial's 5 mg cholesterol per day and 10% of calories from fats. There were significantly fewer cardiac events such as revascularization procedures in the intervention versus the control group, a finding Ornish and colleagues also reported during their five year follow-up ($p < 0.001$), but no data were available for the 1-year Lifestyle Heart Trial. The report by Manchanda and colleagues does not indicate how smoking behavior was treated in their study.

Other researchers have investigated the effects of comprehensive lifestyle changes on specific cardiac event outcomes. Wallner et al.[49] recruited 60 patients after successful percutaneous transluminal coronary angioplasty (PTCA) for a randomized, controlled trial testing the effect of comprehensive lifestyle changes, including American Heart Association (AHA) step II diet, physical activity and smoking cessation, on the rate of clinical restenosis and necessity for revascularization procedures. Although this study cannot claim the prevention of angiographic restenosis through comprehensive lifestyle intervention at the end of the one year trial since repeat angiography was not performed, a 0.26 relative risk was found for revascularization procedures in the intervention compared to the conventionally treated group and overall 74% reduction in necessary revascularization procedures for clinical restenosis through comprehensive lifestyle modification.

A second category of lifestyle intervention study uses clinical trials to examine the effects of variations in single factors such as diet, physical activity, and stress reduction on CAD. Singh et al.[50] conducted a randomized, controlled trial of 406 patients with suspected myocardial infarction that demonstrated a significantly lower occurrence of cardiac events ($p < 0.001$) and all-cause mortality ($p < 0.001$) over 1 year when a low-fat, high-fiber diet with abundant fruits and vegetables was started within 72 hours after acute myocardial infarction (AMI).[50] Hambrecht et al.[51] showed significant angiographic regression of CAD without lipid-lowering drugs in a randomized, controlled trial of 62 male patients with stable angina who utilized an average of 2200 kcal per week, or the equivalent of 5–6 hours per week of physical activity, over 1 year. Through a meta-analysis of 23 randomized, controlled trials Linden et al.[52] found that certain psychosocial interventions, such as relaxation therapy, can boost the effects of standard cardiac rehabilitation programs by decreasing risk factors, psychological stress and morbidity and mortality, especially in the initial two years. Consistent with these findings, Morris[53] more recently reported results from a less rigorous case-control study examining the relationship between spirituality and CAD in 14 previous participants in the Lifestyle Heart Trial 4 years after the study's completion. Based on a spirituality questionnaire, the study showed tentative results suggesting that the highest spirituality well-being scores correlated significantly with the most atherosclerotic stenosis regression.

A third category of lifestyle intervention study uses community trials to examine the effects of comprehensive lifestyle changes on CAD. Although no angiographic documentation or separate data were available for the 32% of total 304 free-living participants with CAD enrolled in the initial Coronary Health Improvement Project (CHIP), Diehl[54] found significant coronary risk factor improvement over one month in total cholesterol, LDL cholesterol, high-density lipoprotein (HDL) cholesterol, blood pressure, weight and body–mass index ($p < 0.001$). These results were obtained using a low-cost 40-hour hospital-based educational program to improve dietary habits, physical activity, smoking cessation, and stress management in combination with 30 minutes of daily walking and adherence to the Optimal Diet focusing on complex carbohydrates. CHIP's goal was to enroll 5% of the community's adult population and to promote community ownership of the program through its alumni plus grocery stores and restaurants that offer foods on the CHIP diet.

Research questions

This brief discussion of some of the health promotion literature related to CAD healing elicits many research questions including: How do we define and differentiate the effects of single health promotion behaviors in comprehensive lifestyle changes with patients with CAD? Considering the limited angiographic results in some studies using comprehensive lifestyle changes, how radical must individual changes such as in diet be to have positive effects on coronary risk factor reduction, atherosclerotic luminal narrowing and morbidity and mortality in various target subgroups such as patients after AMI, PTCA, coronary artery bypass grafting (CABG), and those with angiographically documented CAD? Furthermore, what is the relationship between outcome variables such as the predictive value of luminal narrowing reduction for significantly decreased morbidity and overall mortality for patients with CAD?[43] Although we have evidence that physical activity has independent positive effects on atherosclerotic stenoses,[55] does physical activity also significantly decrease the risk of reinfarction and/or extend the lives of patients with CAD?[43] Although we have evidence of a significant decrease in cigarette consumption after myocardial infarction among patients who exercise,[56] what are the critical components involved in this change and do they apply to other subgroups of coronary patients such as patients after CABG?[43] Considering the diversity of psychosocial interventions with positive effects for coronary patients such as provider, length and target behavior, what are the critical components making them successful?[52] In general, what are the effects of health promotion behavior on less studied healing outcome variables like quality of life for various subgroups of coronary patients? And how do we sustain these positive health promotion behaviors in individual coronary patients and their communities such as the healthy community subculture initiated by CHIP?[54]

HEALTH PROMOTION FOR BREAST CANCER

Research discussion

The 1999 prevalence of malignant neoplasms, the second leading cause of U.S. deaths,[20] was 13.0 million or 6.5% of the U.S. population. This includes 2.2 million or 1.1% of all women who are diagnosed with breast cancer[21] the second leading cause of cancer deaths among women after lung cancer.[57] Thus, health promotion behaviors that support self-healing among cancer survivors have unique opportunities to influence an important burden of illness through impacting the lives of individuals who are often highly motivated to make lifestyle changes.[58–60] The considerable research on lifestyle change and cancer includes more studies on primary prevention than survival,[58,61,62] and many of the few studies on the effects of lifestyle change on cancer survival have focused on breast cancer.[60]

There are cohort studies supporting an association between body weight and breast cancer prognosis. When Rock and Demark-Wahnefried[58] reviewed 40 published epidemiologic studies, they found moderate evidence that obesity at

the time of diagnosis is associated with recurrent breast cancer and/or decreased survival. The studies supporting this association indicated that the risk of death increased by 30%–540% for higher levels of obesity, and that the effect may be magnified in patients first diagnosed with early stage breast cancer and women with estrogen receptor-positive disease.[58,61] When Tretli et al.[59] followed 8427 breast-cancer survivors from the Cancer Registry of Norway for a mean of 4.3 years, they found a 1.7 relative risk of all-cause death for stage I and 1.4 for stage II disease in both premenopausal and postmenopausal women in the highest quintile versus the lowest quintile of body mass. No similar associations were seen for stage III and IV participants.[58,61,62]

Some studies also suggest that postdiagnostic weight gain is associated with poorer outcomes.[58,61] In an exploratory study of weight change over 60 weeks of chemotherapy, Camoriano et al.[64] monitored post-treatment weight changes in 646 node-positive breast-cancer survivors over a median of 6.6 years. They found that premenopausal women who gained more than the treatment median of 5.9 kg during follow-up had a 1.5 relative risk of recurrent disease and 1.6 relative risk of breast-cancer death.[58,61,64]

Nutrition studies have focused on investigating the relationships between nutritional factors and breast-cancer recurrence and survival.[58,61] Although cancer survivors have used many types of diets, such as the macrobiotic diet, scientific evidence is lacking on the effectiveness of these diets in extending survival in cancer patients. However, controversial evidence using self-reported intakes suggests that postdiagnostic dietary fat, unadjusted for energy intake in many studies, may be associated with recurrence or decreased survival in breast-cancer patients.[58,61,65] When Rohan et al. followed 412 breast-cancer survivors from the South Australian Central Cancer Registry for a median of 5.5 years, they found a 1.4 relative risk of breast-cancer death for those in the highest quintile compared to the lowest quintile of fat intake after energy intake adjustment.[58,61,65] In contrast, Holmes et al.[66] found no survival differences for postdiagnostic low-fat intake after energy intake adjustment during the average 13-year follow-up of 1982 breast-cancer survivors from the Nurses' Health Study cohort.[58,61] In addition, although the evidence is variable, some studies suggest that vegetable-related intake may have a modest protective effect in breast-cancer survivors.[58,61] In the study noted above by Rohan et al., the investigators also found a 0.78 relative risk of death for β-carotene and corresponding 0.76 for vitamin C among those in the highest quintile of beta-carotene and vitamin C intakes.[58,61,65]

A second category of experimental studies investigates the effects of physical activity and stress reduction on quality of life for breast-cancer survivors. According to a review by Courneya and Friedenreich, preliminary evidence from efficacy studies shows that physical activity may improve functional quality of life in breast-cancer survivors. In the 14 studies reviewed, physical activity to increase cardiovascular and/or muscle strength showed overall beneficial effects on quality of life indicators, including improvements in cardiovascular function, pulmonary capacity, muscular strength, loss of lean muscle mass, nausea, fatigue and sleep problems.[60] In one of the larger physical activity intervention studies to date, Mock et al.[67] randomly assigned 46 stage I and II university hospital patients with breast cancer using a two-group pretest and post-test design. They found improved functional capacity and diminished fatigue, anxiety, and sleep problems compared to the usual care control group using a home-based, self-paced walking program for 20–30 minutes 4–5 times weekly over 6 weeks of radiation therapy.[67]

A limited number of stress reduction interventions have also demonstrated improved quality of life in patients with breast cancer. When Carlson et al.[68] studied 49 patients with breast cancer through pre-intervention and postintervention assessments using an 8-week mindfulness-based stress reduction (MBSR) program including relaxation, meditation, gentle yoga, and daily home practice, they found significant improvements in quality of life, stress symptoms, and sleep quality, as measured by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, the Symptoms of Stress Inventory and a Health Behaviors Form. An internet support group entitled "Bosom Buddies" has also been moderately effective in decreasing depression, perceived stress and cancer-related trauma as demonstrated by Winzelberg et al.[69] in a randomized, clinical trial of 72 breast-cancer survivors over 12 weeks.

There are two noteworthy studies currently in progress that examine the effects of nutrition on breast-cancer recurrence and survival. The Women's Intervention Nutrition Study (WINS) began in 1987 and includes 2500 postmenopausal stage I and II breast-cancer survivors with resected disease who are testing the effect of a 15% or less dietary fat intake on breast-cancer recurrence and survival over a mean of at least 6 years of follow-up. The basis for conducting WINS comes both from laboratory data suggesting that dietary fat promotes breast-cancer progression and cross-cultural data indicating an association between levels of fat intake and breast-cancer survival. The Women's Healthy Eating and Living (WHEL) Study began in 1995 and tests the effect of a plant-based, high-fiber, low-fat diet on recurrence and survival over a mean of 6 years for 3100 breast-cancer survivors diagnosed with stages I, II and IIIA within 4 years prior to study entry and previously treated with conventional therapy. The WHEL intervention diet provides 2–3 fruits per day, 3–5 vegetables per day with 16 ounces of vegetable juice/day, 30 g of dietary fiber and 15%–20% of daily energy from fat. Both WINS and WHEL outcomes data are expected after 2005.[57–61]

Research questions

These studies point to some important research questions including the following: Does diet and/or physical activity

promote postdiagnostic weight loss in overweight women and improve prognosis?[58,61] Does diet and/or physical activity prevent postdiagnostic weight gain, particularly in the first year, and improve prognosis?[58,61] What are the optimum healing diets for target subgroups such as early stage, adjuvant chemotherapy and metastatic breast-cancer survivors?[70] Do macrobiotic diets promote quality of life and/or prolong survival after breast-cancer diagnosis?[71] Do specific foods such as soy promote breast-cancer healing?[58,66] Because the study investigators consider the WHEL diet to require "radical" changes, how much dietary change is necessary for the minimum degree of breast-cancer healing?[59] What is the minimum level of dietary intervention needed to attain and sustain any degree of breast-cancer healing?[67] What is the minimum exposure necessary for a protective effect from any dietary changes that promote healing?[72] Does physical activity and/or stress reduction improve breast-cancer survival?[61] What is the optimum type of physical activity intervention for various target subgroups of breast-cancer survivors?[60] Is the best physical activity intervention time during treatment or immediately after treatment?[60] Is physical activity intervention more effective in a supervised or unsupervised, institutional or home-based, group or individual setting?[60] What factors promote enrollment in, and maintenance of, physical activity regimens after breast-cancer diagnosis?[60] Which components of the MBSR intervention are most effective for breast-cancer healing and how do these critical components compare to similar stress reduction programs?[68,73] Are Internet support groups effective for ethnically diverse breast-cancer survivor groups?[69]

RESEARCH CHALLENGES

Conducting research on the impact of health promotion interventions on health outcomes among people with chronic and acute diseases presents some methodological challenges.

Design

The gold standard in medical research is a placebo-controlled, double-blinded study. Blinding the intervention from either the patient or the clinician is probably impossible in health promotion research. Randomizing at the unblinded level also presents both subject selection and ethical problems.

Ethical problems occur if the gold standard treatment is withheld from an ill patient, even on a short term basis, with or without their consent. It might be possible to identify patients that would prefer the experimental treatment, especially in situations in which the usual care treatment has low efficacy rates or high risks. However, this would destroy the random assignment of the study and result in a quasiexperimental design, because the patient's motivation could not be controlled for in interpreting the study results.

One strategy to overcome the ethical problem of withholding the gold standard treatment might be to assign patients to a usual care intervention and a usual care plus experimental intervention. The problem with this strategy is that it masks the interaction effect of combining the two interventions. The interaction effect may be competing, destructive, enabling, or complementary in effectiveness. The ethical problems might be reduced as the level of acuity decreases, or as the patient progresses along the recovery path. For example, if there were no commonly recommended treatment after surgery, patients might be randomly assigned to usual care (of no intervention) or an experimental condition consisting of nutrition, exercise, stress management, or other lifestyle interventions. If the experimental intervention produced better results than the usual care intervention, those assigned to usual care could then be scheduled to receive the experimental intervention.

Another problem related to study design is lack of understanding of the mechanisms through which recovery and self-healing occur. Thus, it is impossible to know what intervention to provide, when in the recovery process to provide it, what outcome variables to measure, when and how often to measure and what types of subjects to recruit.

Measures

Research in these areas spans many diseases, levels of acuity, stages of recovery, interventions and outcome goals. Validated measures are required for each of these combinations of conditions, but because of the relatively elementary stage of much of this research, few validated measures now are available.

Another measurement-related challenge is including measurement of enough factors to understand the mechanism of healing fully. For example, if involvement in a support group after breast cancer surgery results in improved longevity, is it because of the emotional benefits of the social connections, the coping skills learned that reduce stress at the biochemical level, the increased motivation and sense of hope that somehow helps the women will themselves to live longer, greater knowledge of nutritional, medicine, or physician resources that result in procuring a new interventions, or something else? The answer would be obscured unless measurements are made of changes in biochemistry, behavior, knowledge, emotions, and motivations, in addition to mortality.

The level of biochemical factors to measure is yet another issue. Such measurements could range from basic blood chemistry levels to examination of receptor sites, mitochondrial changes, new protein complexes and RNA analysis.

Research subjects

There is an abundance of sick people, many of whom are highly motivated to do whatever is necessary to regain their health. However, there are also many people who are not willing or able to change their health behaviors before, during, or after a health crisis. Therefore, attracting a large number of subjects may be difficult for some studies. For ex-

ample, Medicare provided funding for large-scale (1600 patients) testing of the Ornish heart disease reversal program approximately 4 years ago. The study was almost canceled because an insufficient number of patients had been recruited for the study by the third year.

Attrition is also a common problem in any longitudinal study that requires ongoing performance of activities and data collection. For example, in a study of 100 patients, if annual attrition was a respectable 5%, there would be 77 patients left after 5 years, and 60 after 10 years. If the annual attrition were 10%, there would be 59 left after 5 years and 35 after 10 years. With this level of attrition, a randomization would be assumed to have broken down and the controlled trial would need to be considered a quasiexperimental design.

Interventions

Conducting health promotion interventions with acutely sick patients may be difficult if the patient is unable to perform the required tasks. For example in a nutrition intervention, if a patient has no appetite, it would be difficult to make sure he or she eats the quantity and combination of food required for the study. This would be true even if the food is prepared for and provided to the patient. The same patient might also have difficulty performing the physical activities required in an exercise intervention. Using the food example, collecting accurate data can be a challenge, even when food is provided to a patient in a hospital setting. A normal method of measuring the amount of food eaten is to examine the patient's tray when it is collected after the meal. If an attendant is not present at all times, it is not unusual for visiting family members to eat some or all of food the patient does not eat, especially if they are spending long hours with the patient.

Providing high-quality health-promotion interventions to nonacutely ill patients also presents challenges because of quality and cost issues. The Ornish program was successful in actually reversing heart disease, something medical science has never achieved. It produced these results at a cost of approximately $25,000 per patient over the 5 years of the study. This is less expensive than many heart disease-related procedures, especially open heart surgery or heart transplant, but more than 100 times more costly than most high-quality health promotion interventions. The Ornish program included food prepared by some of the best chefs in San Francisco, stress management programs by charismatic psychologists, exercise programs lead by attractive and talented exercise physiologists and trainers, medical care provided by nationally prominent physicians, and the opportunity to meet with a fascinating group of motivated fellow participants during a 5-year period. Duplicating these conditions, even with sufficient funds, would be a challenge.

Analysis

Many health-promotion intervention studies conducted in clinical settings have small sample sizes because of the challenge of attracting subjects, the relatively high cost of conducting controlled studies, and the shortage of qualified people to provide the interventions. As a result, sample sizes are often too small to detect experimental differences when effect sizes are not dramatically large, or to conclude there is no experimental effect when statistically significant results are not produced.

When the mechanism of recovery is multistaged and complex (as in the breast cancer example above), detecting and understanding change requires complex analyses such structural equation modeling. Unfortunately, too many researchers do not understand how to conduct such analyses, and most readers do not understand how to interpret them.

FRAMEWORK FOR CONSIDERING RESEARCH OPPORTUNITIES

I believe the next step in preparing the research agenda should be conducting a comprehensive review of the research literature of all published studies of health promotion interventions for overtly ill subjects. The subsequent step would be to identify the factors that should be considered in constructing an overall research agenda framework:

1. Which health problems should be addressed? Lifestyle is the primary contributor to the six leading causes of death in the United States—heart disease, cancer, stroke, respiratory diseases, accidents and diabetes—that collectively account for almost 72% of all deaths, and is at least a secondary factor for seven of the next nine causes, including Alzheimer's disease, kidney diseases, suicide, liver disease, essential hypertension, and assaults, which account for an additional 9% of deaths.
2. What stage of illness should be studied? Study subjects could be overtly healthy, but have risk factors for disease, terminally ill or any where between these two ends of the spectrum.
3. What outcome goals should be measured? Possible outcome goals might include quality of life or quality of dying; improved physical, mental, and emotional functioning; reduced risk factors; clinical recovery or cure based on medical measures; reduced morbidity or mortality; or reduced utilization or cost.
4. What interventions should be studied? Health-promotion interventions might include any of the dimensions of optimal health including physical (exercise, nutrition, weight control, smoking cessation), emotional (including stress management), social (including building social support and relationship training), spiritual, or intellectual interventions.
5. What is the mix of research to refine techniques in developed areas, explore new territory, and understand basic mechanisms? It is important to determine the level of intensity required for success, methods to attract a larger portion of eligible participants and expand efficacious interventions to larger groups, and to conduct more complex studies appropriate to uncover the underlying mech-

anism of lifestyle change and recovery from disease. For many diseases, an early step will be to determine if lifestyle interventions can have any impact, and if so, at what point in the progression of the disease the greatest impact can occur.

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