Evidence Report

Chapter 1. Introduction

Purpose

This report has two primary purposes, both of which were identified by the National Cancer Institute's Division of Cancer Control and Population Sciences. The first purpose was to conduct a systematic review of the scientific literature to assess the evidence that behavioral interventions are an effective means to help the general population meet current aerobic physical activity recommendations or to maintain or increase their level of aerobic activities in interventions that had a minimum of three months of non-intervention followup time. By specifically examining results of interventions with a minimum of three months of non-intervention followup time, the intent is to focus on the sustainability of the physical activity changes produced by behavioral interventions.

Further, in reviewing the effectiveness of physical activity interventions in the general population, there were several more specific goals stated, including examining whether the effectiveness of theoretically based interventions differed from non-theoretically based interventions, whether hypothesized moderators affect results of these interventions, whether the interventions affect theoretically hypothesized mediators, and whether there is a relationship between changes in theoretically hypothesized mediators and changes in physical activity.

The second primary purpose of this study was to conduct a systematic review of the scientific literature to assess the evidence that physical activity interventions are efficacious for producing improvements in psychological and physiologic outcomes in cancer survivors.

Healthy People 2010 places physical activity in the top ten leading indicators of health of Americans.[1] Yet 54.6 percent of U.S. adults report levels of physical activity that fall below the following two guidelines: moderate intensity activity ≥ 30 minutes per day, ≥ five days per week OR vigorous intensity activity ≥ 20 minutes per day, ≥ three days per week.[2] Further, 2001 Youth Risk Behavior Survey data indicate that 64.6 percent of high school students meet the Healthy People 2010 goal for vigorous activity (three or more days per week for 20 or more minutes per occasion), and 25.5 percent of high school students meet the Healthy People 2010 goal for moderate intensity activity (at least 30 minutes on five or more of the previous seven days).[1, 3] Clearly, there is a need to understand how to sustainably increase and maintain physical activity behaviors in children, adolescents, and adults.

In addition to the importance of physical activity in general populations, physical activity may play a special role in the experience of cancer survivors from the point of diagnosis through the balance of life, regardless of the outcome of treatment. Understanding the impact of cancer and its treatment on individuals living years beyond a cancer diagnosis is increasingly important, especially as the population of long-term cancer survivors continues to grow. It is estimated that there are approximately 9.5 million cancer survivors alive in the United States today[4] and the population of long-term cancer survivors continues to grow. As children and adults with a history of cancer are living longer, the challenges that face survivors will gain increasing attention. Current cancer treatments, although increasingly efficacious for preventing death, are toxic in numerous ways and produce negative long-term physiological and or psychological effects. Because physical activity has been shown to improve well-being in healthy people,[5] it has been proposed as a possible intervention to combat the early and late effects of treatment in

cancer patients.[6,7] Further, the American Cancer Society now recommends that cancer survivors perform regular physical activity toward the goal of maintaining a healthy body weight, reducing risk of recurrence, and reducing risk for other common chronic diseases.[8] Therefore, to repeat, our second goal was to conduct a systematic review of the scientific literature to assess the evidence that physical activity interventions are efficacious for producing positive psychological and physiologic outcomes in cancer survivors.

Key Questions

The specific aims of this review were to examine the evidence that physical activity interventions, alone or combined with diet modification or smoking cessation, are effective in helping:

1. Individuals in the general population sustainably increase their aerobic physical activity or maintain adequate aerobic physical activity. Further, within this first portion of the review, there were four sub-aims:
    a. Is the effectiveness of theoretically based interventions different?
    b. Do hypothesized moderators affect the results of these interventions?
    c. Do these interventions affect theoretically hypothesized mediators?
    d. In these interventions, is there a relationship between changes in theoretically hypothesized mediators and changes in physical activity?
2. Cancer survivors improve their psychosocial outcomes or physiologic outcomes

Definitions: Physical Activity, Exercise, Fitness, General Population, Cancer Survivor, and Effect Size

In order to understand this report, it is important to first define what we mean by physical activity, exercise, health related physical fitness, general population, cancer survivors, and effect size. The following definitions of physical activity, exercise, and physical fitness were first published in 1985.[9]

Physical activity is defined as any 'bodily movement produced by the contraction of skeletal muscle that increases energy expenditure above the basal level.' All domains of activity are included in this definition, including leisure time physical activity, occupational activity, activity to transport oneself from one place to another, household chores, self-care, other-care, volunteer work, or any other activity other than complete body stillness.

Exercise is defined as 'physical activity that is planned, structured, repetitive, and purposive in the sense that improvement in one or more components of physical fitness is the objective.' Exercise can refer to a single bout or multiple bouts over a period of weeks, months, or years. The latter is commonly termed exercise training. This distinction between single bouts (acute exercise) and exercise training (chronic exercise) is important because the effects of acute and chronic exercise differ (e.g., blood pressure increased during acute exercise but resting blood pressure is lowered by chronic training). Exercise does not occur in all domains of physical activity. Exercise is confined to leisure time activities.

Health-related physical fitness is defined as 'the ability to carry out daily tasks with vigor and alertness, without undue fatigue, and with ample energy to enjoy leisure pursuits and to meet unforeseen emergencies.' This includes cardiorespiratory endurance, muscular strength, power,

speed, flexibility, agility, balance, reaction time, and body composition. Participation in many domains of physical activity is affected by one's physical fitness.

General population is defined as individuals without chronic or acute diseases, with one exception. With guidance from the Agency for Healthcare Research and Quality (AHRQ) and the National Cancer Institute (NCI), it was decided that studies with diabetic or obese participants would be included. The rationale was that the impact of behavioral interventions on individuals with the excluded diseases might differ from the impact on included individuals.

Cancer survivors are defined as 'any individual that has been diagnosed with cancer, from the time of discovery and for the balance of life', as suggested by the National Coalition for Cancer Survivorship.[10]

Effect size is defined as the standardized mean difference between the treatment and control group(s) and was calculated using the software ES.[11]

Negative Health Outcomes Associated with Physical Inactivity

There is consensus that regular physical activity is associated with decreased risk for a number of negative health outcomes, including coronary heart disease, cardiovascular disease, stroke, Type 2 diabetes, obesity, several forms of cancer, osteoporosis, depression, fall related injuries in the elderly, and all-cause mortality.[12] This consensus underscores the need for effective interventions for sustainable increases in physical activity. A review of the literature on the topic of physical inactivity and negative health outcomes is beyond the scope of this report. Readers interested in this research evidence are referred to the Surgeon General's Report on Physical Activity and Health.[12]

Physical Activity and Issues Facing Cancer Survivors

The number of cancer survivors is growing annually and is expected to continue to grow.[4] This makes a compelling case for the need to understand the unique needs of this population. A framework for examining physical activity across the cancer experience (Framework PEACE) has been proposed[13] based on the cancer control perspective. The proposed framework includes six possible cancer control outcomes after the point of cancer diagnosis, including buffering prior to treatment, coping during treatment, rehabilitation immediately post treatment, health promotion and survival for those with positive treatment outcomes, and palliation for those without positive treatment outcomes.

Buffering prior to treatment refers to the potential to improve cancer treatment outcomes by preparing the body through physical activity prior to cancer treatment. The outcomes of interest during this point in the cancer experience will likely be physiologic and fitness related, though psychological buffering may also be useful. For those coping with cancer treatment, primary outcomes of interest are likely to include physiologic fitness and quality of life indicators as well. The numerous possible adverse outcomes that can result from cancer treatments include reduced quality of life, depression, anxiety, fatigue, reduced cardiovascular function, bone and muscle wasting, and lymphedema. Exercise interventions for those who have completed treatment during the past year seek to assess whether these adverse outcomes may be favorably altered by physical activity. If cancer treatment is successful, physical activity becomes of interest for health promotion purposes after the rehabilitation stage is over, to reduce risk of chronic diseases

which may be more prevalent among cancer survivors, such as cardiovascular disease, diabetes, and osteoporosis.[8] Further, there is strong epidemiologic evidence that physical activity may prevent some types of cancer,[14, 15] so the potential for physical activity to serve as a modifiable risk factor for secondary prevention of cancers is of great interest as well. For those with advanced stage cancers that are untreatable or that do not respond to treatment, palliation of fatigue and pain may be an appropriate cancer control outcome for physical activity interventions.

One goal of this report is to present a balanced view of the outcomes related to cancer control in survivors who have volunteered to participate in a physical activity intervention at some point during the cancer experience. The goal of such interventions would be to improve physiologic and psychologic outcomes, yet the potential for harm must be acknowledged and examined. The cancer survivor portion of the report is informed by Framework PEACE, developed by Courneya and Friedenreich.[13]

Uniqueness of the Present Report

General population. There are several excellent recent reviews of the efficacy of behavioral interventions to alter physical activity behaviors in particular populations or settings.[16-27] The Agency for Healthcare Research and Quality (AHRQ) sponsored one such review on the efficacy of counseling by primary care physicians for improving physical activity.[16] The November 1998 issue of the *American Journal of Preventive Medicine* was devoted entirely to understanding the efficacy of behavioral interventions to promote physical activity. A recent systematic review of the literature on the effectiveness of interventions to increase physical activity by the Task Force on Community Preventive Services[17] formed an excellent starting point from which to develop unique goals for the present report. The Task Force on Community Preventive Services review concluded that there were two informational, three behavioral and social, and one environmental approach to promoting physical activity that could be recommended. These are listed below.

Recommended informational approaches to increasing physical activity:

- ‘Point of decision prompts’ for stair use
- Community-wide campaigns

Recommended behavioral and social interventions for increasing physical activity:

- School-based physical education
- Community-based social support
- Individually adapted health behavior change

Recommended environmental approach for increasing physical activity:

- Creation of or enhanced access to places for physical activity, combined with informational outreach

This same review found there was insufficient evidence to assess a variety of other intervention types.[17]

A review of prior systematic reviews on the efficacy of behavioral interventions to increase physical activity in general populations was undertaken.[17, 20-38] Based on this review, it became clear that several aspects of this literature have received less attention in prior reviews. First, the sustainability of increases in physical activity resultant to behavioral intervention has only been addressed in two prior reviews. In the Dishman and Buckworth 1996 review[30] it was noted that

only about 25 percent of the 127 intervention studies located reported effect sizes for followup. The mean effect was non-significant for the followup effects for self-reported physical activity and fitness; whereas effects for objective measures of attendance or observation were large. Similarly, in the Dishman et al., 1998 review[23] it was reported that eight of 26 worksite intervention studies located had effects at followup exceeding three months. The mean effect was small and not different from the effects of interventions without followup, but interventions using variations of exercise prescription yielded larger effects. Sustainability is of vital importance for physical activity behavior change interventions. Therefore, for the portion of the review that focuses on the general population, we chose to focus exclusively on interventions that had at least three months of followup data on physical activity behavior beyond the end of any intervention activities.

Second, it has been proposed that theoretically-based interventions would be more efficacious than nontheoretical interventions. Yet only one prior systematic review has examined whether this claim is supportable.[39] This review focused on older adults and reported that the seven of ten studies with theoretical frameworks showed improvements in physical activity behavior. This was compared to three of seven studies without theoretical frameworks. There has also been little focus on which theories are most commonly used. Therefore, in the context of this report, we outline which theories were applied (as reported by the authors), which theoretical constructs have been applied, and whether theory-based interventions are more efficacious at increasing physical activity than nontheory-based interventions.

Finally, only one prior review has examined the variables that mediate change in physical activity in the context of intervention studies. This review included only 12 studies.[35] This seems to indicate that few intervention studies examine the mediating variables for physical activity behavior change. Therefore, in the context of this report, we gathered data from the included intervention studies on mediators proposed, measured, and whether there was any analysis to examine whether the proposed, hypothesized mediators were influential in any observed change in physical activity behavior.

To guide our review process we worked with a Technical Expert Panel (TEP) to develop a logic model (Figure 1). The figure illustrates that intervention components can sometimes increase physical activity behavior directly, or through one to three targets for change: environmental, social or cultural, or personal factors. For this review, mediators are defined as constructs that are hypothesized by the interventionist to fall in the causal pathway between the intervention components (at any of the three levels labeled 'targets for change') and behavior. For example, provision of education to explain how to exercise or what it should feel like to exercise could be an intervention component that would mediate changes in physical activity or exercise behavior. Moderators are defined, for this review, as variables not targeted by the intervention and, in most cases, not expected to change, but which could influence the outcomes or interact with the intervention to change study outcomes. For example, if the intervention effect differed across gender, gender would be defined as an intervention moderator.

Cancer survivors. Reviews on the topic of physical activity in cancer survivors have also been conducted.[7, 13, 40-42] Some reviews have focused on specific outcomes, such as weight loss in breast cancer survivors[43] and fatigue[42] and include studies with a variety of interventions, not just physical activity. In the review on weight loss,[43] the review authors indicated that the effects of physical activity on weight change were mixed. A review on effects of physical activity interventions on fatigue indicated that physical activity may be a feasible intervention

‘even for patients with advanced disease.’[42] Other reviews focus more specifically on physical activity and examine a broad variety of outcomes from physical activity interventions in cancer survivors.[7, 13, 40] All of these reviews noted that though completed studies consistently report improvements in quality of life, as well as variables related to physiological and psychologic well-being, many of the physical activity studies in cancer survivors suffer from methodologic weaknesses.[7, 40] In particular, the review authors felt that additional controlled trials were needed, preferably randomized. In an attempt to focus the present report on the best quality research, included studies were required to have a concurrent comparison group with results presented separately for treatment and comparison groups. However, because we acknowledge that some important studies in this area were conducted as pilot or feasibility studies with no control group, the discussion section includes a brief summary of results from fourteen studies excluded on the basis of not having a concurrent control group.