

Summary: Effectiveness of Behavioral Interventions to Modify Physical Activity Behaviors in General Populations and Cancer Patients and Survivors

Introduction

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, \geq five days per week OR vigorous intensity activity ≥ 20 minutes per day, \geq 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.

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

1. Is the effectiveness of theoretically based interventions different?
2. Do hypothesized moderators affect the results of these interventions?
3. Do these interventions affect theoretically hypothesized mediators?
4. In these interventions, is there a relationship between changes in theoretically hypothesized mediators and changes in physical activity?

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. 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. For example, it is estimated that there are approximately 9.5 million cancer survivors alive in the United States today.⁴ 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} 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, the second specific aim was to examine whether physical activity is efficacious for improving psychosocial or physiologic outcomes among cancer survivors.

Methods

We synthesized evidence from the scientific literature on the effectiveness of behavioral interventions to increase physical activity in the general population, as well as evidence of the effectiveness of physical activity interventions to improve psychosocial and physiologic outcomes for cancer survivors. The methods used for this process were developed by the project team at the Minnesota Evidence-based Practice Center (EPC), in conjunction with representatives from the National Cancer Institute (NCI) and the Agency for Healthcare Research and Quality (AHRQ) and a Technical Expert Panel assembled for the purpose of this report.

The literature to be reviewed for the first key question was initially identified in two ways. A search of PubMed® (1966 to present) was carried out to identify all trials of physical activity interventions. The second source of references was published reviews of physical activity interventions.⁹⁻²⁹ The titles and, if necessary, the full references were reviewed by an expert in physical activity interventions. All possibly qualifying studies were reviewed by a team of reviewers. Forty-seven studies were identified that met inclusion/exclusion criteria.

The literature for the second key question was identified through two searches of MEDLINE® including all available years (1966 to present), review of the results by an expert in physical activity interventions in cancer survivors, and then by a team of peer reviewers. Twenty-four studies were identified that met inclusion/exclusion criteria.

The included references for both key questions were abstracted by a trained abstractor using a computerized data abstraction form. Results of each of these abstractions were reviewed by a senior member of the study team with expertise in physical activity interventions.

After a careful examination of the included studies, it was concluded that it was not possible to pool outcomes. This conclusion was reached for three reasons. First, the diversity of outcomes reported did not allow for a clear metric to be used across studies. Second, important information that would be necessary to pool studies (such as variance estimates) was missing from many studies. Finally, the diversity of studies (including populations, interventions, followup time, etc.) was not conducive to reasonable pooling. Therefore, we elected for both key questions to present semi-quantitative results including counts of positive and statistically significant studies, calculation of post-intervention differences between groups (effect size) and further descriptive information rather than formal quantitative analysis.

Results

General Population

The 47 studies identified addressed a variety of populations. Forty-one studies included adults exclusively, four exclusively children, and two included both. Three studies focused on older adults. Of the studies of adults, eight included only women, whereas two included only men. In all but two of the studies where race was reported, white subjects were in the majority.

There were 72 interventions in the 47 identified studies. (Many studies tested more than one intervention). The physical activity interventions were undertaken in a wide range of settings, and some in more than one. Twenty-four interventions were in the health care setting, 12 in the

home setting, 17 in the community, 8 in schools, 20 in worksites, and 11 more in a government institution, a religious institution, a sports center, or a child care center. A wide variety of interventions were tested using variations of 27 different theoretical constructs, 12 of which were used by more than 15 percent of the interventions. About half of the interventions had no clear theoretical underpinning and the remainder used one of ten different models. The intensity of the interventions varied widely from a single mailing to multiple contacts per week over years. The length of followup also varied from 3 months (the minimum for inclusion in the review) to over 10 years.

A range of different physical activity outcomes was found in the included studies, and many studies included more than one primary outcome. Eight studies had two physical activity outcomes, 11 had three, one had five, two had six, and one had nine. No one specific outcome was used as the primary outcome across studies. Further, what may have been considered the primary outcome domain in one study (such as a measure of leisure time activity) may have been a secondary domain in another study (where the primary outcome could have been overall activity). Therefore, we elected to include all of the physical activity outcomes reported in the results.

Because national guidelines have targets for moderate and vigorous activities,² we chose to examine whether interventions had different effects on these individual sorts of activities. For these analyses we categorized the outcomes within “outcome groups” as a measure of “total activities,” “moderate activities,” “vigorous activities,” or “other.” Of the 99 outcomes examined in the studies, 23 (23 percent) were classified as “total activities,” 50 (51 percent) were classified as “vigorous activities,” 25 (25 percent) as “moderate activities,” and one (1 percent) as “other.”

The effect of the interventions was examined in two ways. First, for those outcomes where it was possible, we calculated an effect size, otherwise known as a standardized mean difference. In its simplest form this is the difference in effect between groups divided by the variance. This gives a unitless common metric for outcomes that were measured in different units. We also examined whether an outcome was found by the investigators to have a statistically significant positive effect. As many studies reported the effects of multiple outcomes and had more than one intervention, we: (1) examined each outcome separately, (2) pooled all of the outcomes of one intervention and examined it, and (3) pooled all of the interventions in a given study to assess to overall effect of the study.

There were 102 outcomes within the 34 studies for which effect sizes could be calculated. Of these, 7.8 percent (eight) had an effect size greater than .8, and 2.9 percent (three) had an effect size between .5 and .8. An additional 32.4 percent of outcomes (33) had an effect size that exceeded our criteria for a small positive effect of .2. Of the 50 interventions for which we could calculate an effect size, 10 percent (five) had an effect size greater than .8 and 4 percent (two) had an effect size between .5 and .8. An additional 44 percent (22) interventions had an effect size that exceeded our criteria for a small positive effect of .2. Finally on the study level, 5.9 percent (two) studies had an effect size greater than .8 and 5.9 percent (two) had an effect size between .5 and .8. An additional 47.1 percent (16) studies had an effect size that exceeded our criteria for a small positive effect of .2. Overall, 58.8 percent of the studies had an effect size that exceeded our guideline of small (.2).

Approximately one-fourth of the outcomes reached statistical significance. Nearly a third of all interventions had at least one outcome that was significant at the .05 level. When interventions are pooled within studies, nearly half of the studies (44.7 percent) had at least one

outcome that was statistically significantly positive. Again, this is not corrected for multiple tests within studies.

Within the outcome groups, only the moderate activity group and the vigorous activity group had any outcomes that exceeded our guide of a large outcome of .8 (two moderate and one vigorous). Approximately 60 percent of moderate activity outcomes had an effect size greater than our guide of .2, whereas approximately 40 percent of the vigorous activity outcomes and total activity outcomes exceeded that threshold. A greater percentage of moderate activity outcomes was statistically significant compared to total activity outcomes (48 percent versus 13 percent; $p=.008$). The percentage of vigorous activity outcomes that was statistically significant fell between the other two outcome groupings, (28 percent) but was not statistically significantly different from either the “moderate activity” or “total activity” outcome groups.

There was no clear effect of setting on whether studies were positive or statistically significantly positive. Further, there was no clear effect on the use of theory on whether a study was positive. It appeared on examination that more intensive studies may be more likely to be statistically significantly positive. Qualitatively, there did not appear to be an effect on outcome when accessibility to a means to exercise was addressed in a study or when a study addressed diet and smoking as well as physical activity, but the numbers are too small and the studies too diverse to draw firm conclusions.

Too few studies examined outcomes at multiple points in time to provide a clear sense of the changes in physical activity over time after the end of the intervention, although most of those that did provide data showed a decrease in physical activity over time.

Little attention was paid to possible harms in these studies; in all 47 studies, it was mentioned only once. Although many studies examined baseline characteristics of subjects (such as age and gender) that could be considered possible moderators of the interventions, few of the included studies examined these as moderators.

Eleven studies hypothesized mediators.³⁰⁻⁵⁶ Of the studies that hypothesized mediators, all of them intervened on at least one of the hypothesized mediators. Nine of the studies measured the effect of the interventions on the hypothesized mediator, although two did not report any of the mediator results. Statistically significant changes in mediators were seen for greater intention to exercise in one study.³⁹ In the other studies that reported results, there was either no effect or a non-significant effect. Only one study examined whether a hypothesized mediator affected the outcome.³²

Eighteen criteria of study quality were examined using a measure derived from that used by the *Guide to Community Preventive Services*. On average the studies met under half of the quality criteria (average 7.5), but there was a wide range from a low of three criteria met to a high of 16. The quality of studies that randomized individuals was also examined using the scale developed by Chalmers.⁵⁷ On the zero to nine scale (nine best), most of the studies received a rating of two, with the highest rated study receiving a five.

Review of Interventions in Cancer Survivors

Of the 24 studies included in the review, 54 percent conducted interventions during active cancer treatment. The sample sizes were often small, with average group sizes of 22 and 23 in the control and treatment groups, respectively. The most common diagnosis included in the

studies was breast cancer, with 83 percent of the studies reporting inclusion of breast cancer survivors. All included studies had concurrent comparison groups; 83 percent of them were randomized controlled trials. The majority (79 percent) of the interventions were physical activity only interventions. The interventions tended to be supervised exercise programs, of 3 months' duration or less, with no followup after the end of the intervention, and the exercise prescriptions usually focused on aerobic activity. Eighty-three percent prescribed moderate-to-vigorous intensity activity, and 88 percent prescribed exercise three or more times per week. Fifty-eight percent of the interventions prescribed exercise of less than 40 minutes per session.

Dropout rates ranged from 0 to 25 percent with a mean of 10.8 percent. These dropout rates should be viewed in context of the percent of cancer survivors approached regarding study participation who agree to participate or even to be screened for eligibility. The seven studies that provided data regarding the percentage of cancer survivors approached who agreed to participate or to at least be screened for study eligibility reported values of 28, 30.6, 32.5, 43, 68, 75, and 81 percent, with a mean of 51 percent.⁵⁸⁻⁶⁴

In addition to identifying the timing of the interventions with regard to whether they took place during or after treatment, each of the 24 studies has been placed into a category according to the Physical Exercise Across the Cancer Experience (PEACE) framework proposed by Courneya and Friedenreich.⁶⁵ The majority of the studies focus on the time period during or immediately following active cancer therapy (coping and rehabilitation). Included interventions focused on buffering prior to cancer treatment (one study), coping during treatment (13 studies), rehabilitation from treatment (ten studies), health promotion (five studies), and survival (one study). No controlled trials that focused on palliation for survivors with advanced cancer were identified.

Sixteen categories of outcomes were examined: physical activity; physical fitness; cardiorespiratory fitness, strength, and flexibility; fatigue/tiredness; body image/dissatisfaction; quality of life; confusion; difficulty sleeping; self-esteem; other psychosocial outcomes; physiologic outcomes; body size; pain; vigor/vitality; symptoms/side effects; immune parameters; and mental/emotional/psychological well-being. The two most common outcomes examined were cardiovascular fitness and fatigue or tiredness, which were examined in 12 of the 24 studies. Depression, anxiety, and quality of life were also commonly examined (10 studies), as well as body weight or body mass index (BMI) (eight studies).

The criterion for considering an intervention positive was if one or more of the outcomes in a given category was positive. An effect was considered to be statistically significantly positive if any one of the outcomes examined within a category was statistically significant. The intention was to convey a level of positivity of results, not to perform a statistical test. Significance was not corrected for multiple tests. The effect sizes reported a comparison of between group means at post-intervention only, given that pre-post correlations for all 16 outcome categories were not available.

Categories with 100-percent positive findings include strength, flexibility, fatigue/tiredness, confusion, difficulty sleeping, self-esteem, psychosocial outcomes, body size (goal to reduce), vigor/vitality, immune parameters, and mental health quality of life.

The percent of studies reporting statistically significant results within the 16 categories ranged from 0 percent for confusion and body size (goal to gain or avoid muscle loss) to 100 percent for flexibility and difficulty sleeping. There were eight categories with 75 percent of

studies reporting at least one statistically significant finding: cardiorespiratory fitness, flexibility, fatigue/tiredness, quality of life, difficulty sleeping, psychosocial outcomes, physiologic outcomes, and immune parameters.

Mean effect sizes within the 16 outcome categories ranged from -0.055 for immune parameters to 2.93 for physical activity behavior. Outcome categories with effect sizes of 0.20 or greater include physical activity behavior, cardiorespiratory fitness, flexibility, fatigue/tiredness, body image/dissatisfaction, quality of life, confusion, vigor/vitality, symptoms/side effects, depression, anxiety, and the combined multiple constructs section of mental/emotional/psychological well-being.

We examined whether the results of studies would be more likely to be positive during versus post active cancer treatment. The number of studies that fall into each category is small so that no clear conclusions can be drawn regarding timing of the intervention.

Discussion

General Population

Over half of adults and over a third of children do not meet national guidelines for physical activity. Finding interventions that can sustainably increase physical activity is an important public health goal. This review sought to identify those studies that have attempted to increase physical activity in a general population and tested whether there was an effect at least 3 months following the end of the intervention. This is important from a public health standpoint as interventions that increase physical activity during the intervention but for which physical activity is not maintained after the intervention ceases will not bring about long-term changes in the population.

This review focused on studies that examined whether interventions had an effect at least 3 months after the intervention concluded. Because we otherwise included studies of any populations or settings, the literature examined in this review is very diverse. Many different populations are examined in different settings with different interventions with the assessment of different outcomes. Given the great diversity, any conclusions that look across the studies must be viewed with caution. Real effects could be missed because the diversity of the studies masks effects. Similarly, what appear to be possible effects could be the result of confounding by differences between the studies. Nonetheless, with those caveats, a number of conclusions can be drawn from this review:

- It is possible to intervene on subjects to increase their physical activity for at least 3 months after the intervention stopped.
 - We found that overall 45 percent of the studies had at least one statistically significant positive effect on physical activity.
- Although many studies had effects that met the criteria of statistical significance, the overall effect of interventions to increase physical activity is small.
- Although there are no strict criteria of strength of effect, by our guidelines only 5.6 percent of studies (two) had a strong effect (an effect size greater than .8) and 2.8 percent (one) had a moderate effect (effect size between .5 and .8). Outcomes that assessed some sort of moderate activity were more likely to be statistically significantly positive than

those that assessed total activities. This may reflect that a given change in moderate activities in an individual results in a overall smaller magnitude change in that individual's total activities because others that make up the total activities may not be changing.

- The setting did not appear to have an important role in whether an intervention would be successful.
 - In all of the settings at least a quarter of the trials resulted in a statistically significant increase in physical activity on at least one measure three or more months after the end of the intervention. There was no clear pattern of effect sizes within the different setting.
- It is not necessary to have an intensive intervention to get an effect.
 - We found that there were successful interventions at all levels of intensity; in fact, there was not a clear trend that more intensive interactions were more successful.
- It is difficult to assess durability of the effects in these studies because relatively few had tests at multiple points in time. Yet there appears to be some durability to the effects.
 - Over 25 percent of the studies that looked at 1 year or more post-intervention had a statistically significant increase in physical activity.

Because of the issues with the literature, we cannot draw any clear conclusions about the effect of studies that use theory, the effect of studies that address accessibility to exercise, or those that address diet and smoking in addition to exercise compared to studies that did not do those things.

Limitations in the literature did not allow us to address in detail a number of questions we initially sought to answer. There were not sufficient studies that examined moderators or mediators to draw any meaningful conclusions.

Future Research

A number of areas could be addressed in future research to allow the questions addressed in this review to be answered more fully:

- Examine longer outcomes
 - A large portion of the physical activity literature was excluded from this review because there was no followup beyond the end of the intervention period. As the point of physical activity interventions is to change behavior over a long period, more studies should be directed at longer outcomes.
- Standardize followup intervals
 - Even if studies address longer outcomes, it will be difficult to compare the effects of individual studies or groups of studies unless they examine outcomes at similar intervals.
- Standardize the domains of physical activity measured
 - A measure of walking, for example, may or may not be closely correlated with a measure of total activity. So the effect of various interventions can be compared; some attempt at standardization should be undertaken.

- Standardize, if possible, the outcome measures
 - Even where the outcome domain is the same, different measures may do a better or worse job of capturing the domain. It will be easier to compare the effects of interventions if they use standard validated measures
- Use, where possible, blinded measures of outcome rather than self-reporting
 - Given the nature of these interventions blinding of subjects and investigators is impractical. However, the interpretation of some measures such as activity monitors can be blinded to the reader.
- Reduce attrition from studies
 - Many of these studies suffered from attrition that may bias the results. Attention should be paid in future research to reducing this issue.
- Standardize reporting of study results
 - Many of these studies did not report sufficient information, particularly variance estimates, that would facilitate the comparison across studies. Attention should be paid to more complete reporting of the results.
- Use appropriate statistical methodology to examine moderators and mediators of effect
 - None of the studies in this review used appropriate techniques such as Structural Equation Modeling to fully examine the effect of mediators.
- Examine harms
 - To fully understand the risks and benefits of these interventions, more attention needs to be put on possible harms of the interventions as a few people with a moderate or severe harm (such as a fracture) could outweigh the benefits of the intervention.

If these issues are addressed, we may be able to gain a fuller understanding of the overall effectiveness of interventions to increase physical activity in general populations.

Cancer Survivors

The presentation of mean effect sizes for each outcome category allows for discussion of the relative impact on each outcome category of physical activity interventions on cancer survivors. However, because the effect sizes were calculated based on post intervention between group differences only and not adjusted for sample size, interpretive caution is urged. For example, the mean effect size of 2.93 for physical activity behavior is mostly driven by between group differences that existed at baseline and persisted to the end of the intervention.⁶⁶ Given this interpretive caution, the conclusions that can be drawn from a review of the literature on the efficacy of physical activity interventions to positively impact physiologic and psychosocial outcomes are outlined below.

Controlled trials in cancer survivors consistently report a mean effect size > 0.2 and consistent (five or more studies) positive effects of physical activity (usually aerobic exercise) on the following outcomes:

- Vigor and vitality (effect size 0.850).
- Cardiorespiratory fitness (effect size 0.647).
- Quality of life (effect size 0.427).

- Depression (effect size 0.418).
- Anxiety (effect size 0.333).
- Fatigue/tiredness (effect size 0.217).

The outcomes with the greatest consistency across the cancer experience are cardiorespiratory fitness and fatigue/tiredness. The exercise prescription associated with these positive outcomes in cancer survivors was generally moderate-to-vigorous intensity aerobic activity on 3 or more days per week, for 10-60 minutes per session. For many of the other variables, there are too few studies to evaluate whether the findings differ for survivors during compared to post treatment. The findings for some categories, such as cardiovascular fitness, strength, flexibility, body size, and anxiety and depression parallel results reported from exercise interventions in general populations.⁶⁷

Other variables for which there is either consistent evidence that is either less strong or results from fewer studies include:

- Confusion (effect size 0.402).
- Symptoms/side effects (effect size 0.400).
- Psychosocial outcomes (effect size 0.191).
- Body size (goal to reduce) (effect size 0.187).
- Self-esteem (effect size 0.100).
- Mental health quality of life (no effect size available).
- Strength (no effect size available).

Variables for which there is less consistent evidence include:

- Body image/dissatisfaction (effect size 0.310).
- Anger hostility (effect size 0.070).
- Physical activity behavior (no valid effect size estimate available).
- Body size (goal to gain or avoid muscle mass loss) (no effect size estimate available).
- Pain (no effect size estimate available).

The nine studies that measured non-fitness and non-anthropometric physiologic outcomes were placed into one of three categories: immune parameters, symptoms/side effects, or physiologic outcomes. The outcomes from studies with outcomes in these three categories were disparate and reflected goals of evaluating the safety of exercise during active cancer treatment, the efficacy of exercise to prevent muscle loss or assist patients in recovering from active cancer treatment, and two studies specifically interested in whether exercise could favorably alter physiologic parameters hypothesized to be associated with breast cancer etiology.^{68, 69} Given the broad variety of potential physiologic variables that may be of interest for cancer survivors across the cancer experience, nine studies is too few to enable a summary or to draw any conclusions beyond the general statement that the majority of the reviewed studies reported changes in the hypothesized direction. This area of research has just begun to develop.

An overview of 14 physical activity interventions in cancer survivors that were excluded because of the lack of a concurrent comparison group indicated that the conclusions of this report would not have been measurably altered had these studies without comparison groups been included.

For physical activity to be clinically recommended for cancer survivors, it is important to first understand the potential for adverse outcomes. The results of the reviewed studies generally indicate that it is safe for cancer survivors to be physically active, even during bone marrow

transplant procedures and high-dose chemotherapy. Given the small number of studies reviewed, several questions regarding the safety of physical activity across the cancer survivor experience remain, including the potential for bias in self-reported worsening of symptoms or side effects, risk for the development of lymphedema, and worsening of some immune parameters.

Future Research

The process of conducting this review has revealed numerous potential areas for future research on the efficacy of physical activity to positively alter physiologic and psychosocial outcomes in cancer survivors across the cancer experience. The small number of studies for each outcome category underscores the need for an expansion of research on a broad spectrum of cancer control outcomes, across broad timing from the point of diagnosis and through the balance of life. Therefore, rather than focus the need for additional research on specific outcomes, below is a listing of broader themes and methodological issues to be addressed as well as recommendations for efficient forward progress toward greater understanding of the effects of physical activity in cancer survivors.

- Convene researchers with expertise and interest in the efficacy of physical activity to favorably effect physiologic and psychosocial outcomes in cancer survivors to discuss and reach consensus on:
 - Priorities with regard to cancer control outcomes of interest.
 - Priorities with regard to timing of physical activity interventions across the cancer experience.
 - Standardization of measurement tools for cancer control outcomes of interest.
 - Standardization of outcomes reporting for cancer control outcomes of interest.
 - Development of survivor registries from which participants for studies of all types (not just physical activity) could be recruited.
- Increase funding to adequately power studies to examine the effects of physical activity on cancer survivors across the cancer experience.
- Improve reporting of recruitment experiences and demographic description of participants from recruitment to study completion or dropout, for improved assessment of bias and generalizability.

Availability of the Full Report

The full evidence report from which this summary was taken was prepared for the Agency for Healthcare Research and Quality (AHRQ) by the University of Minnesota Evidence-based Practice Center, under Contract No. 290-02-0009. It is expected to be available in June 2004. At that time, printed copies may be obtained free of charge from the AHRQ Publications Clearinghouse by calling 800-358-9295. Requesters should ask for Evidence Report/Technology Assessment No. 102, *Effectiveness of Behavioral Interventions to Modify Physical Activity Behaviors in General Populations and Cancer Patients and Survivors*. In addition, Internet users will be able to access the report and this summary online at www.ahrq.gov or http://dccps.nci.nih.gov/d4d/evidence_report.html.

Suggested Citation

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