EVIDENCE REPORT AND EVIDENCE-BASED RECOMMENDATIONS

Exercise Programs for Older Adults: A Systematic Review and Meta-analysis

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Executive Summary

The Centers for Medicare & Medicaid Services (CMS), as part of its Healthy Aging initiative, requested an evidence-based systematic review of physical activity interventions to better assess the potential benefits of physical activity as it relates to older adults. For this report, CMS asked us to provide evidence in response to the following questions:

- What are the benefits of physical activity for seniors? What is the impact of physical activity on health status, health outcomes, functional status, quality of life, mental health and ability to maintain independence?
- How are seniors motivated to engage in physical activity?
- What is the role of family and social support?
- What is the role of the physician?
- What are barriers and how can they be reduced?
- What is known about adherence to programs?
- What are the best strategies for promoting physical activity - by public health, medical model, social services or a combination of these approaches?
- What are the key messages for seniors?
- Is there an infrastructure that promotes senior exercise—if not, what are recommendations for building the infrastructure?
- What is the range of public policy responses towards this intervention (e.g., Centers for Disease Control and Prevention (CDC), Administration on Aging (AoA) programs)? Are there any programs/benefits that could be expanded to include these additional interventions? (e.g., could senior center programs be

improved and expanded to include appropriate exercise programming?) What is the interaction between falls prevention and physical activity?

- Are different strategies needed for different cohorts (e.g., functional status levels)?
- Cost effectiveness or cost savings—does the intervention appear to reduce health care costs by reducing disease, physician office visits, hospitalizations, nursing home admissions, etc?

Methods

We conducted a systematic review and meta-analysis of controlled clinical trials of the effects of exercise on health and related outcomes for seniors. To be included, studies had to report outcomes on strength, cardiovascular fitness, physical function, or depression. Other outcomes were not reported sufficiently often to justify meta-analysis. Strength was usually measured by large muscle (knee, quadriceps) strength, while cardiovascular fitness was measured by VO_2 max. Function was measured by the Activities of Daily Living (ADL) scale, the Sickness Impact Profile (SIP), and the SF36. Depression was measured using the Beck Depression Inventory (BDI) or CES-D.

To identify existing research and potentially relevant evidence for this report we searched a variety of electronic databases including the Cochrane Library (containing both a database of systematic reviews and a controlled-trials register), Medline, HealthSTAR, Ageline, and EMBASE. We exchanged reference lists with a group at the University of Illinois which had received a grant from the Centers for Disease Control and Prevention (CDC) to prepare an evidence report on what types of physical activity have demonstrated robust health benefits among seniors and what types of strategies promote adherence in this population. In addition, RAND had many articles on hand from a recent evidence report on the prevention of falls among older adults; exercise was one focus of that report. We also contacted experts in the field and asked for any studies that were in press or undergoing review. Finally, we combed the reference lists of all review articles. Article selection, quality assessment, and data abstraction were done in standard fashion by two trained physician reviewers working independently. Disagreements were resolved by consensus or third-party adjudication.

The research questions regarding efficacy were addressed with meta-analysis. We conducted separate meta-analyses for each of the outcomes. We included all controlled trials that assessed the effects of an intervention or interventions relative to either a group that received usual care or a control group. The majority of our outcomes were continuous and we extracted data to estimate effect sizes for these outcomes. For each pair of arms, an unbiased estimate of Hedges' g effect size and its standard deviation were calculated. A negative effect size indicates that the intervention is associated with a decrease in the outcome at follow-up as compared with the control or usual care group. Because follow-up times across studies can lead to clinical heterogeneity, we excluded from analysis any studies whose data were not collected within a specified follow-up interval chosen based on clinical knowledge.

We also conducted a stratified analysis on each outcome where it was possible. We categorized each exercise intervention as primarily endurance or primarily strength, and then pooled the effect sizes within the endurance and strength strata. (A trial with more than one intervention group could contribute to the analyses in both strata. If an intervention could not be classified as either primarily endurance or primarily strength, the trial was dropped from the stratified analysis.)

We assessed the possibility of publication bias by evaluating a funnel plot of effect sizes for asymmetry, which can result from the non-publication of small trials with negative results.

Results

Key Question #1

- What are the benefits of physical activity for seniors? What is the impact of physical activity on health status, health outcomes, functional status, quality of life, mental health, and ability to maintain independence?

We were able to conduct meta-analysis to determine effects on strength, cardio-vascular fitness, function, and depression. We identified 47 trials that reported strength outcomes, of which 32 could be included in a meta-analysis. The pooled effect size was 0.48, (95% CI: 0.29, 0.67); this is equivalent to an increase in strength of about 7 kilograms in knee extension. Considering only the interventions aimed primarily at strength, the pooled effect size was 0.66 (95% CI: 0.38, 0.94), or an increase in knee extension strength by almost 10 kilograms. Stratifying studies by the duration of the intervention, there were statistically significant pooled effect sizes for all three time strata**,** with effect sizes of 0.65 and 0.22 at 0-3 months and 3-6 months, respectively, increasing to an effect size of 0.95 at a follow-up of 6-12 months. From these data, we conclude that interventions aimed at improving strength in sedentary older adults result in statistically significant benefits as early as 1-3 months after beginning the intervention and persisting at least through 12 months.

For endurance and cardiovascular fitness, we identified 18 studies that could be included in a meta-analysis of VO_2 (max). With only two exceptions, these RCTs studied subjects at least 70 years of age. The pooled effect size of 17 studies that assessed endurance exercise interventions was an increase of VO_2 (max) of 0.41, (95% CI; 0.23, 0.59). This effect size is equivalent to an increase in VO_2 (max) of about 10 $ml/kg/m^2$, meaning the average VO_2 (max) of participants after endurance training was about 30 $ml/kg/m^2$, or about 8.5 mets. Clinically, this means the participants could now engage without difficulty in activities such as walking upstairs, pitching softball, or general gardening that previously had been the limit of their exertion, and their new limit of exertion (8.5 mets) is equivalent to engaging in activities such as climbing hills (with a 21-42 pound load), running a 12 minute mile, or playing singles tennis.

The six studies that measured physical function using the SF36 had a pooled effect size of 0.15 (95% CI: -0.03, 0.34). For the Sickness Impact Profile, the pooled effect size of three studies was 0.08 (95% CI: -0.22, 0.38). For the outcome Activities of Daily Living (ADL), the pooled effect size of five studies was 0.40 (95% CI: -0.07, 0.87 p = 0.09). We were able to pool ten studies that reported depression outcomes. The pooled effect size was -0.21 (95% CI: -0.46, 0.04), an effect that was not statistically significant. However, the trends in effect for all these outcomes were in a beneficial direction.

Key Questions #2, #5, #6, #10

- How are seniors motivated to engage in physical activity?
- What are the best strategies for promoting physical activity – by public health, medical model, social services or a combination of these approaches?
- What is the role of the physician?
- What is the role of family and social support?

These four key questions are interrelated and will be dealt with together. The data on the efficacy of counseling by physicians or other clinicians to improve physical activity in adults were recently reviewed for the US Preventive Services Task Force (USPSTF) by the University of Oregon. The review found that the evidence is inconclusive regarding whether counseling adults in primary care settings to increase physical activity is effective. In contrast to the mixed and modest results reported for clinician-based counseling, a review done for the Guide to Community Preventive Services was more supportive of various behavior, social, and environmental approaches to improving physical activity. Both randomized and observational studies were included in the review, which focused on all age ranges. Among the interventions assessed that were relevant to older adults, the study reported that several interventions had sufficient evidence that they are effective, including: point of decision prompts (i.e. signs placed by elevators to motivate people to use stairs); community-wide campaigns; social support interventions in community settings (i.e. setting up a "buddy" system or walking groups); individually adapted health behavior change programs, which are those tailored to the individual's readiness for change based on established health behavior change models; and the creation of or enhanced access to places for physical activity.

Key Question #3

- What are the barriers and how can they be reduced?

The previously mentioned Guide to Community Preventive Services noted substantial barriers to implementing these interventions. For example, stairways in buildings may be difficult to find or poorly lit making point of decision prompts less effective. Community-wide campaigns require careful planning and sufficient resources to implement, and individually adapted health behavior change programs also require careful planning and coordination, well-trained staff members and resources sufficient to carry out the program. Furthermore, several recommended interventions involve policy and environmental approaches, not within the usual domain of health care.

Key Question #4

- What is known about adherence to programs?

In 1996, Dishman and Buckworth published a quantitative synthesis of 127 studies examining interventions for increasing physical activity among adults. To be included, each study had to report an amount of physical activity as an outcome or a measure of fitness that is a surrogate of amount of physical activity. The analysis suggests that large effects were associated with those interventions based on behavior modification principles delivered to healthy people in a community setting. Effects were particularly strong when the interventions were delivered to group (as opposed to individuals) and involved leisure physical activity of low intensity. They found an absence of effects for interventions using health risk appraisals or health education.

Key Question #5

- What are the best strategies for promoting physical activity – by public health, medical model, social services, or a combination of these approaches?

A combination approach that includes encouragement from public health education, exercise prescriptions from physicians, and widely publicized available programs in senior centers and other social service locations seems to have the best chance of success.

Key Question #7

- What are the key messages for seniors?

Messages should emphasize that exercise improves many aspects of health and function for seniors, including strength, cardiovascular conditioning and endurance, fall prevention, as well as mood. The choice to begin an exercise program is perhaps the most difficult step, but that once it is begun, the benefits become apparent within a short time period.

Key Question #8

- Is there an infrastructure that promotes senior exercise? If not, what are the recommendations for building the infrastructure?

The current infrastructure for senior exercise has multiple components, but they are not well coordinated (either between or within types). Most common are the senior center programs, funded by a combination of Older American's Act federal funds, state funds, and local funds and facilities. Many Medicare HMO programs offer an exercise benefit, often through health clubs or franchised "Silver Sneakers" programs, in an attempt to recruit more health-conscious enrollees as well as to keep enrollees as healthy as possible. Formal exercise programs provide supervised exercise programs for short periods of time. Several states are attempting to overcome the poor coordination of services through statewide planning. If successful, these programs could be emulated by other states.

Key Question #9

- What is the range of public policy responses towards this intervention? Are there programs/benefits that could be expanded to include additional interventions?

The above existing programs should be encouraged to expand through greater outreach to a larger population. While few data exist on what proportion of the older population are using these programs, it is estimated as relatively small. Thus, there is much room for growth. More medically oriented programs for frailer populations should be encouraged as well, perhaps with an expanded Medicare benefit for longer-term rehabilitation-oriented exercise programs, possibly tied to specific diagnoses. The HMO health club benefit (e.g. Silver Sneakers) could be considered as a general Medicare benefit to non-HMO Medicare enrollees.

Key Question #11

- What is the interaction between falls prevention and physical activity?

Our meta-analysis from a recent report on falls prevention showed that exercise interventions yielded a statistically significant decrease in a person's risk of falling at least once by 12% and the number of falls by 19%. While several types of exercise programs were included, there were insufficient data to identify the most effective exercises. Falls prevention programs using exercise typically included one or more of the following: cardiovascular endurance, muscular strength, flexibility, and balance. Differences in effectiveness between exercise types were not consistent and not statistically significant.

Key Question #12

- Are different strategies needed for different cohorts?

Exercise needs are different for different individuals, depending on medical conditions and baseline level of exercise and conditioning. Strategies for healthy community living individuals, who can probably be beneficially served by non-medical exercise professionals, will be very different from those for more frail or disabled individuals, who will likely need more medical supervision and tailoring. Additionally, some persons respond to social motivations more than individual motivations, so recruitment and adherence strategies should be tailored to individual psyches and readiness to change as much as possible.

Key Question #13

- Cost effectiveness vs. cost savings – does the intervention appear to reduce health care costs by reducing disease, physician office visits, hospitalization, nursing home admissions, etc.

There is very limited evidence in randomized clinical trials regarding the economic impact of physical activity programs for older adults. One study estimated it might cost more than $5,000 to move a person from sedentary to a recommended level of physical activity. (No direct health or utilization benefit was assessed in this study.) Another trial reported short-term exercise might have beneficial effects on health care use in some subgroups of older adults, although no significant health improvement was found.

Conclusions

The strongest evidence supporting a beneficial effect of exercise in older adults exists in fall reduction. Our evidence report on fall prevention indicates a physician-based intervention targeted at high risk individuals can be highly cost effective and possibly even cost savings.

There are sufficient data to conclude that exercise can modestly to moderately improve strength and cardiovascular performance among previously sedentary older people. The benefits in endurance are equivalent in a change in maximal exertion from pitching softball to playing singles tennis.

There is a trend in the appropriate direction supporting modest benefits of exercise on function and depression.

There have been no long term randomized controlled trials of exercise in older persons, therefore, there is no evidence supporting or refuting any long term health effects of exercise. The significant beneficial effects of exercise have lasted at least as long as the periods of study.

Extrapolating the results from these relatively short-term trials to a longer term could lead to conclusions qualitatively similar to the conclusion of longer term cohort studies with respect to strength, function, and mood. Thus, there is room to be optimistic about possible longer-term benefits.

The existing evidence is inconclusive regarding the efficacy of physician-based intervention to increase physical activity. The evidence is more encouraging regarding community-based interventions.

Introduction

Increased physical activity has been reported to be associated with a variety of health benefits. Cohort studies have reported mortality benefits in both men[1] and women,[2] coronary heart disease reduction in both men and women,[3] and stroke reduction in both men and women.[4] Some of the other reported health benefits of physical activity include reductions in the risk of hip fracture,[5] pancreatic cancer,[6] colon and breast cancer,[7] the risk of cholecystectomy,[8], glucose intolerance, depression and even dementia[9] Increasing physical activity is a stated goal of US public health policy.[10] Despite this, the majority of US adults do not engage in recommended levels of activity, with only about one quarter of adults self-reporting moderate intensity physical activity of at least five times per week for at least 30 minutes each time, or vigorous intensive physical activity at least three times per week for at least 20 minutes each time, or both during the preceding month.[11] Furthermore, data from the 1995 National Health Interview Survey reported that only about one-third of patients were counseled about exercise at their last physician visit.[12]

In light of these data, the Centers for Medicare & Medicaid Services (CMS), as part of its Healthy Aging Project, requested an evidence-based systematic review of physical activity interventions to better assess the potential benefits of physical activity as it relates to older adults. For this report, CMS asked us to provide evidence in response to the following questions:

- What are the benefits of physical activity for seniors? What is the impact of physical activity on health status, health outcomes, functional status, quality of life, mental health and ability to maintain independence?
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- What is the interaction between falls prevention and physical activity?
- Are different strategies needed for different cohorts (e.g., functional status levels)?
- Cost effectiveness or cost savings—does the intervention appear to reduce health care costs by reducing disease, physician office visits, hospitalizations, nursing home admissions, etc?

Methods

We conducted a systematic review and meta-analysis of the effects of exercise on health outcomes in seniors as part of the CMS Healthy Aging initiative. We synthesized evidence from the scientific literature on exercise programs, using the evidence review and synthesis methods of the Southern California Evidence-Based Practice Center, an Agency for Healthcare Research and Quality - designated center for the systematic review of literature on the evidence for benefits and harms of health care interventions. Our literature review process consisted of the following steps:

- Develop a conceptual model (also sometimes called an evidence model or a causal pathway).
- Identify sources of evidence (in this case, sources of scientific literature).
- Identify potential evidence.
- Evaluate potential evidence for methodological quality and relevance.
- Extract study-level variables and results from studies meeting methodological and clinical criteria.
- Synthesize the results.

<u>Identification of Literature Sources:</u>

We used the sources described below to identify existing research and potentially relevant evidence for this report.

<u>RAND Evidence Report on Falls Prevention:</u>

Numerous interventions have been studied in the prevention of falls among older adults. Results have been mixed, yielding uncertainty as to which interventions are most clinically effective or cost-effective, or what kind or combination of interventions should be included in a program to prevent falls. To gain a better understanding of which interventions may be beneficial in the Medicare population, the Centers for Medicare and Medicaid Services (CMS), as part of its Healthy Aging Project, commissioned an evidence-based systematic review of interventions in the prevention of falls. RAND completed this review in October 2002. All articles regarding exercise interventions were screened for inclusion in the current report.

Cochrane Collaboration:

The Cochrane Collaboration is an international organization that helps people make well-informed decisions about health care by preparing, maintaining, and promoting the accessibility of systematic reviews on the effects of heath care interventions. The Cochrane Library contains both a database of systematic reviews and a controlled-trials registry. The library receives additional material continually to ensure that reviews are maintained through identification and incorporation of new evidence. The Cochrane Library is available on CD-ROM, by subscription. The Cochrane files contained 61 articles on exercise; we obtained all studies referenced therein.

Centers for Disease Control and Prevention Project:

In 2000, the University of Illinois at Chicago received a grant from the Centers for Disease Control and Prevention (CDC) to prepare an evidence report on what types of physical activity have demonstrated robust health benefits among seniors and what types of strategies promote adherence in this population. We exchanged reference lists; theirs contained 2,262 citations.

Library Search:

We searched the library databases MEDLINE, HealthSTAR, Ageline and EMBASE from the inception of each database through 2000. Table 1 describes our search methodology and the number of documents retrieved.

Table 1. Search Methodology

SEARCH #1

DATABASES SEARCHED AND YEARS OF COVERAGE:
MEDLINE 1966-2000
HealthSTAR 1975-1999
Ageline 1965-1999
EMBASE 1974-2000

SEARCH STRATEGY:

NOTES:
AN EXCLAMATION POINT AFTER A TERM INDICATES THAT THE TERM WAS "EXPLODED" – I.E. NARROWER TERMS IN THE HIERARCHY WERE ALSO INCLUDED. THIS FUNCTION IS USED IN MEDLINE, HEALTHSTAR, AND EMBASE.

A QUESTION MARK AFTER A TERM INDICATES TRUNCATION

TERMS FOR AGED WERE OMITTED FROM THE AGELINE DATABASE SEARCH

AGED! OR GERIATRIC ASSESSMENT OR AGING! OR ELDERLY CARE! OR GERIATRIC? OR GERONTOL?

AND

EXERCISE! OR PHYSICAL FITNESS OR FITNESS OR PHYSICAL ACTIVITY OR RUNNING OR WALKING OR SPORTS OR SWIMMING

AND

CLINICAL TRIALS! OR CLINICAL TRIAL! OR CONTROLLED STUDY! OR CONTROLLED CLINICAL OR META ANALYSIS OR METAANALYSIS OR SINGLE BLIND? OR DOUBLE BLIND? OR RANDOMI? OR DOCUMENT TYPE=CLINICAL TRIAL OR DOCUMENT TYPE= RANDOMIZED CONTROLLED TRIAL OR DOCUMENT TYPE=META-ANALYSIS

AND

HEALTHY OR PREVENT? OR PREVENTIVE HEALTH SERVICE(S)! OR PREVENTIVE MEDICINE! OR PREVENTION!)

NUMBER OF ITEMS RETRIEVED: 1935

SEARCH #2

DATABASE SEARCHED AND TIME PERIOD COVERED: MEDLINE 1966-2000

SEARCH TERMS:

DECONDITIONING

AND

AGED (65+)

NUMBER OF ITEMS RETRIEVED: 88

Previous Reviews and Background Articles:

We identified 122 other previously completed reviews or background articles relevant to this project (see Appendix).

Each review discusses, among other things, at least one exercise intervention aimed at exercise prevention. We retrieved all relevant documents referenced in these publications.

Evaluation of Potential Evidence:

We reviewed the articles retrieved from the literature sources against exclusion criteria to determine whether to include them in the evidence synthesis. We created a one-page screening review form that contains a series of simple questions (Figure 1). After evaluation against this checklist, each article was either accepted for further review or rejected. Two physicians, each trained in the critical analysis of scientific literature, independently reviewed each study, abstracted data, and resolved disagreements by consensus. The Principal Investigator resolved any disagreements that remained unresolved after discussions between the reviewers. Project staff entered data from the checklists into an electronic database that was used to track all studies through the screening process.

Since we were searching primarily for data relevant to the Medicare population, studies were restricted to those reporting data on persons age 60 years and older. To be accepted for inclusion, a study had to be either a randomized controlled trial or a controlled clinical trial. We defined the study types according to the criteria described below.

Randomized controlled trial (RCT). A trial in which the participants (or other units) are definitely assigned prospectively to one of two (or more) alternative interventions, using a process of random allocation (e.g., random number generation, coin flips).

Controlled clinical trial (CCT). A trial in which participants (or other units) are either:

a) Definitely assigned prospectively to one of two (or more) alternative interventions using a quasi-random allocation method (e.g., alternation, date of birth, patient identifier),

OR

b) Possibly assigned prospectively to one of two (or more) alternative interventions using a process of random or quasi-random allocation.

Following these restrictions on study design, we excluded studies that employed a simple pre/post design (i.e., a study design in which an intervention is administered to providers, patients, or communities, and the outcome of interest is recorded once before and once after the intervention). Such a study design has no control group; therefore, it cannot account for temporal effects unrelated to the intervention.

Figure 1. Exercise Screening Form

1. Article ID:

2. First Author:

   (Last name of first author)

3. Reviewer: ________________________________

4. Subject of article: **Check all that apply**
   - Falls prevention .... ☐
   - Exercise .... ☐
   - Both falls prevention and exercise .... ☐
   - Neither falls prevention nor exercise......... ☐ **(STOP)**

**** If neither falls prevention nor exercise, then STOP ****

5. Study design: **Circle one**
   - Descriptive (editorial etc. Do not obtain) ..0 **(STOP)**
   - Review/meta-analysis (obtain article) ....1 **(STOP)**
   - Randomized Clinical Trial 2
   - Controlled Clinical Trial 3
   - Controlled Before and After........................4
   - Interrupted Time Series 5
   - Simple Pre-Post 6
   - Cohort...7
   - Other (specify:____________________)..8
   - Unsure 9

   **** If descriptive, then STOP ****

6. Ages of study participants: **Circle one**
   - **Excludes** over 65 1
   - **Includes** over 65 ....2 **(Answer #7)**
   - Unsure 9

7. If study **includes** persons 65 and older, are the results reported separately for this group? **Circle one**
   - Yes 1
   - No..2
   - Not applicable 8
   - Unsure 9

8. Outcomes: **Check all that apply**
   - Falls, primary .... ☐ **(Answer 9)**
   - Falls, intermediate .... ☐
     (strength/endurance; psychological/ functional status; proprioception/ balance; environment; general activity level; quality of life; fear of falling)
   - Falls, utilization/costs............................... ☐ **(Answer 9)**
   - Exercise, primary .... ☐
   - Exercise, intermediate .... ☐
     (disease-specific measures BP/cholesterol/BMI/VO_2Max mood/depression/affect, risk of fracture)
   - Exercise, utilization/costs......................... ☐ **(Answer 9)**
   - Unsure .... ☐
   - None of the above .... ☐

9. If primary falls outcomes or utilization/costs outcomes were measured, was there a follow-up time of 3 months or more?
   - Yes 1
   - No..2
   - Not applicable 8
   - Unsure 9

10. Was the population of the study selected because of a specific disease (excluding "geriatric syndrome", frailty, functional impairment, deconditioning, etc.)
    - Yes 1
    - No..2
    - Not applicable 8
    - Unsure 9

Notes:

Extraction of Study-Level Variables and Results:

Using a specialized Quality Review Form (QRF) displayed as Figure 2, we abstracted data from the articles that passed our screening criteria. The form contains questions about the study design; the number and characteristics of the patients; the setting, location, and target of the intervention; the intensity of the intervention; the types of outcome measures; the time from intervention until outcome measurement; and the results. We selected the variables for abstraction, with input from experts. Two physicians, working independently, extracted data in duplicate and resolved disagreements by consensus. A senior physician resolved any disagreements not resolved by consensus.

We collected information on the study design, withdrawal/dropout rate, agreement between the unit of randomization and the unit of analysis, blinding, and concealment of allocation. To pass to the meta-analytic stage of the review, the studies had to report cardiovascular, physical function, depression, or strength outcomes, as these were the outcomes that were measured sufficiently often to support a meta-analysis.

To evaluate the quality of the studies, we aggregated the elements of design and execution (randomization, blinding, and withdrawals) into a summary score developed by Jadad.[13] The Jadad score rates studies on a 0 to 5 scale, based on the answer to three questions:

- Was the study randomized?
- Was the study described as double-blind?
- Was there a description of withdrawals and dropouts?

One point is awarded for each “Yes” answer, and no points are given for a “no” answer. Additional points are awarded if the randomization method and method of blinding were described and were appropriate. A point is deducted if the method is described but is not appropriate. Empirical evidence has shown that studies scoring 2 or less show larger apparent differences between treatment groups than do studies scoring 3 or more.[14] We note that in the clinical situation of evaluating exercise, double-blinding is not possible. Thus the Jadad scores for all studies in this report will necessarily be 3 or less.

Figure 2. Exercise Article Quality Review Form

Article ID: ______________ Reviewer:____________

First Author: ________________________________
(Last Name Only)

Study Number:____of _____ Date of Publication:_______
(Enter '1of 1' if only one)

Description (if more than one study):____________________________

1. What was the **principal** focus of this study? (circle one)
   - Physical activity....................1
   - Falls....................2
   - Both physical activity and falls....................3
   - Other (specify: ________________)....................4 **(STOP)**

2. Does the study include results (data) on participants ages 60 and older? (circle one)
   - Yes....................1
   - No....................2 **(STOP)**
   - Not reported....................8 **(STOP)**

3. Design: (circle one)
   - RCT....................1
   - CCT....................2

   (If not RCT or CCT, change study design on cover sheet and STOP)

4. What is the geographic setting of the study (circle one)
   - Rural....................1
   - Urban/Suburban....................2
   - Mixed....................3
   - Other (specify: ________________)....................4
   - Not specified....................8

5. In what country was the study conducted? (circle one)
   - US....................1
   - Other (specify: ________________)....................2
   - Not specified....................8

6. Is the study described as randomized? (circle one)
   - Yes....................1 **(ANSWER #7, #8, #9)**
   - No....................2 **(SKIP to #10)**

7. If the study was randomized, what was the unit of randomization? (circle one)
   - Patient....................1
   - Provider....................2
   - Organization (practice, hospital, HMO)....................3
   - Community....................4
   - Other (specify: ________________)....................5
   - Not reported....................8
   - Not applicable....................9

8. If study was randomized, did the method of randomization provide for concealment of allocation? (circle one)
   - Yes....................1
   - No....................2
   - Concealment not described....................8
   - Not applicable....................9

9. If the study was randomized, was method of randomization appropriate? (circle one)
   - Yes....................1
   - No....................2
   - Method not described....................8
   - Not applicable....................9

10. Is the study described as: (circle one)
    - Double blind....................1 **(ANSWER #11)**
    - Single blind, patient....................2 **(SKIP to #12)**
    - Single blind, outcome assessment....................3 **(SKIP to #12)**
    - Open (not blinded)....................4 **(SKIP to #12)**
    - Blinding not described....................8 **(SKIP to #12)**
    - Not applicable....................9

11. If reported, was the method of double blinding appropriate? (circle one)
    - Yes....................1
    - No....................2
    - Method not described....................8
    - Not applicable....................9

12. Are refusal rates (the number of refusals) reported? (circle one)
    - Yes....................1
    - No....................2
    - Not applicable....................9

13. Are inclusion/ exclusion criteria described? (circle one)
    - Yes....................1
    - No....................2
    - Not applicable....................9

14. Are the numbers of and reasons for withdrawals/dropouts reported? (circle one)
    - Yes....................1
    - No....................2

15. Is this a cross-over study design? (circle one)
    - Yes....................1
    - No....................2
    - Not described....................8
    - Not applicable....................9

Figure 2. Exercise Article Quality Review Form (continued)

16. What best describes the reimbursement system in which the study occurred: (check all that apply)
    - FFS ❑
    - HMO ❑
    - MCO (not HMO) ❑
    - Mixed (not specified) ❑
    - Other (specify: ____________________________) ❑
    - Not sure ❑

17. Are data reported separately for or primarily on any of the following populations? (check all that apply)
    - African-Americans ❑
    - Hispanic ❑
    - Low-income populations ❑
    - Nursing home ❑
    - Veterans ❑
    - Women (> 66%) ❑
    - Men (> 66%) ❑
    - Other (specify:__________________________) ❑
    - None of the above ❑

18. Types of comorbidities described in the groups: (check all that apply)
    - Healthy elderly ❑
    - Specific problem:
      - Deconditioning ❑
      - Arthritis (OA/ RA) ❑
      - Balance/ Falls/ Gait ❑
      - Other Geriatric syndromes (incontinence, poly-pharmacy, etc.) ❑
      - Cognitive Impairment ❑
      - Functional decline/ ADL ❑
      - Depression ❑
      - Vision ❑
    - Other:
      - Neuromuscular ❑
      - Musculoskeletal ❑
      - Cardiovascular ❑
      - Pulmonary ❑
    - Other (specify: ______________________________________
      ____
      ____________________________________) ❑
    - Not described ❑

Figure 2. Exercise Article Quality Review Form (continued)

If study has a control group, then enter data for that group in the first arm.
Otherwise, enter data for each group in order of first mention.
Arm 1 of ____ Description: ______________________________

19. What was the sample size in this intervention arm?

___ ___ ___ , ___ ___ ___ ___ ___ ___ , ___ ___ ___

Entering Completing
(Enter 999, 999 if not reported.)

20. Are adherence rates for the intervention described? (circle one)
- Yes 1
- No 2
- Not applicable 9

21. Setting of the intervention(s) (check all that apply):
- Community .... ❑
- Physician's office .... ❑
- Outpatient, clinic .... ❑
- Rehabilitation hospital .... ❑
- Hospital (inpatient) .... ❑
- Nursing Home .... ❑
- Patient's home .... ❑
- Not described .... ❑
- Not applicable .... ❑
- Other (specify:___________________________) .... ❑

22. Types of providers performing the intervention(s): (check all that apply)
- Physicians .... ❑
- Physical/occ. therapists .... ❑
- Nurses .... ❑
- Trainer .... ❑
- Social workers .... ❑
- Family .... ❑
- Not described .... ❑
- Not applicable .... ❑
- Other (specify:______________________________) .... ❑

23. Intervention. Required data indicated by an *
Each reviewer to use individual map to define Intervention component (Grant use numbers, Walter use letters) Fill in a number and units.

			Means				Duration of Session		Session Parts	Number of Sessions		Duration of Component/Intervention	
	Component*	Localization	Intervention* performed/ executed by	Motor	Quality	Quantity	Number*	Units*	Warm Up Rest Cool Down	Number*	Units*	Number*	Units*
1									W R C ND NA				
2									W R C ND NA				
3									W R C ND NA				
4									W R C ND NA				
5									W R C ND NA				
6									W R C ND NA				
7									W R C ND NA				

Use these codes for duration or number:
97 : varies **98**: Not described **99**: Not applicable

Use these abbreviations for units: **MI** minute **HR** hour **DY** day **WK** week **MO** month **YR** year
NA: Not applicable **ND**: Not described

.

Figure 2. Exercise Article Quality Review Form (continued)

Outcomes

24. Type of outcomes measured:

Outcome*	Localization	Measurement Observed/ Recorded by*	Quantity measurement presented in	Class of Outcome: Dichotomous Categorical Continuous
				CA ND CO NA
				CA ND CO NA
				CA ND CO NA
				CA ND CO NA
				CA ND CO NA
				CA ND CO NA
				CA ND CO NA
				CA ND CO NA
				CA ND CO NA
				CA ND CO NA
				CA ND CO NA
				CA ND CO NA

(97 : varies, **98**: Not described, **99**: Not applicable**)** **(ND =** not described**, NA =** not applicable**)**

Evaluation

25. When, relative to the start of the intervention, were outcomes measured?

Enter the number and letters in the appropriate box.

	Number	Unit
1st follow-up		
2nd follow-up		
3rd follow-up		
4th follow-up		
5th follow-up		
Additional follow-ups:		

Use the following abbreviations for units:

MI minute
HR hour
DY day
WK week
MO month
YR year
ND not described
NA not applicable

26. Which adverse effects were reported?

	Reported & measured	Mentioned only	Not Mentioned
Increased musculoskeletal problems	❑	❑	❑
Increased injuries (not fracture)	❑	❑	❑
Increased number of fractures	❑	❑	❑
Increased falls	❑	❑	❑
Other complications	❑	❑	❑
Other (specify: __________________)	❑	❑	❑

None described ....❑

27. Is an unreferenced scale used? (circle one)

Yes 1
No 2
Not described 8
Not applicable 9

28. If an unreferenced scale is used, is its validity/ reliability described? (circle one)

Yes...................................1
No....................................2
Not described....................8
Not applicable...................9

29. Did the analysis include intention-to-treat analysis (explicitly described and all dropouts accounted for)? (circle one)

Yes...1
No 2
Not described 8
Not applicable 9

Our summary of the evidence is both qualitative and quantitative. We used meta-analytic pooling to address as many questions as possible, but for several questions the evidence was insufficient to support a quantitative synthesis. For these questions, our summary of evidence is qualitative. Our quantitative methods are described in detail below.

Meta-Analysis:

Trials were considered for meta-analysis if they assessed the effects of an intervention or interventions relative to either a group that received usual care or a control group. In addition, they had to provide outcome data on strength, cardiovascular fitness, function, and/or depression within pre-specified follow-up intervals and in sufficient detail to allow the calculation of an effect size as described below. Based on clinical guidance, we chose measures in each outcome domain that were clinically relevant and sufficient comparable to extract data for. Those measures were strength; endurance or cardiovascular fitness measured as VO_2 (max); function based on the Activities of Daily Living (ADL) scale, the SF36, and/or the Sickness Impact Profile (SIP), and depression. Our meta-analytic methods were similar across outcome domains.

For some trials, several publications presented the same outcome data. In these cases, we picked the most informative of the duplicates; for example, if one publication was a conference abstract with preliminary data and the second was a full journal article, we chose the latter. The publications dropped for duplicate data do not appear in the evidence table. We note that multiple citations of the same article were removed at the title screening stage of the project.

Trial Effect Sizes:

All of our measures across the outcome domains were continuous. For each outcome, we extracted the follow-up means and standard deviations for the intervention and control or placebo groups respectively. If a study did not report a follow-up mean, or a follow-up mean could not be calculated from the given data, the study was excluded from analysis. For studies that did not report a standard deviation or for which a standard deviation could not be calculated from the given data, we imputed the standard deviation by using comparable studies and groups that did report a standard deviation and weighting all groups equally.

The summary statistic we calculated for all outcome domains was an effect size. The effect size is the difference in follow-up means (intervention mean minus control or placebo mean) divided by the pooled standard deviation. This summary statistic is unitless and indicates the number of standard deviations by which the treatment and control or placebo group means differ. We estimated an unbiased estimate[15] of Hedges' g effect size[16] and its standard deviation. A positive effect size indicates that the intervention is associated with an increase in the outcome at follow-up as compared with the control or usual care group, and a negative effect size indicates the intervention is associated with a decrease.

Each trial contained one control or placebo group. Some trials contained more than one intervention group. In order not to double-count patients, in each analysis we chose the most clinically relevant intervention group, in some cases combining intervention groups together to produce one group. When we stratified by type of intervention as described below; a trial with more than one intervention could enter both strata analyses.

Stratification of Trials:

We performed two stratified analyses in all outcome domains when possible. In the first, we categorized each intervention as primarily endurance or primarily strength, and then pooled the effect sizes within the endurance and strength strata. As noted above, a trial with more than one intervention group could contribute to the analyses in both strata. In addition, a trial's intervention may not be classifiable as either primarily endurance or primarily strength, in which case this trial was dropped from the stratified analysis.

In the second stratified analysis, we pooled effect sizes for different intervals of follow-up: 0-3 months; 3-6 months, and 6-12 months. Due to a paucity of data, this latter stratified analysis was only possible for the strength outcome.

Performance of Meta-Analysis:

For those settings that contained trials that were determined to be clinically comparable and for which there were at least three trials, we estimated a pooled random-effects estimate [17] by combining effect sizes across trials. We also report the chi-squared test of heterogeneity p-value for the effect sizes.[15]

Forest plots were constructed for each setting. Each individual trial effect size is shown as a box whose area is inversely proportional to the estimated variance of the effect size in that trial. The trial's confidence interval is shown as a horizontal line through the box. The pooled effect size estimate and its confidence interval are shown as a diamond at the bottom of the plot with a dotted vertical line indicating the pooled effect size. A vertical solid line at zero indicates no intervention effect.

Publication Bias:

We assessed the possibility of publication bias by evaluating a funnel plot of effect sizes for asymmetry, which can result from the nonpublication of small trials with negative results. These funnel plots include a horizontal line at the fixed-effects pooled estimate and pseudo–95% confidence limits.[18] If bias due to nonpublication exists, the distribution is asymmetric or skewed. Because graphical evaluation can be subjective, we also conducted an adjusted rank correlation test[19] and a regression asymmetry test[18] as formal statistical tests for publication bias. The correlation approach tests whether the correlation between the effect sizes and their variances is significant, and the regression approach tests whether the intercept of a regression of the effects sizes on their precision differs from zero; that is, both formally test for asymmetry in the funnel plot. We acknowledge that other factors, such as differences in trial quality or true study heterogeneity, could produce asymmetry in funnel plots.

Interpretation of the Results:

To aid in interpreting the pooled effect size, whenever possible we back-transformed each statistically significant pooled estimate to a specific metric. In order to do this, we multiplied the pooled estimate by an average standard deviation. To obtain this standard deviation, we calculated a simple average of the standard deviations in all groups, placebo or treatment. We note this back-transformation requires assuming a particular underlying standard deviation in each outcome domain. Readers may wish to apply their own standard deviation, based on the particular patient population to which they wish to apply the results.

We conducted all analyses and drew all graphs using the statistical package Stata.[20]

Results

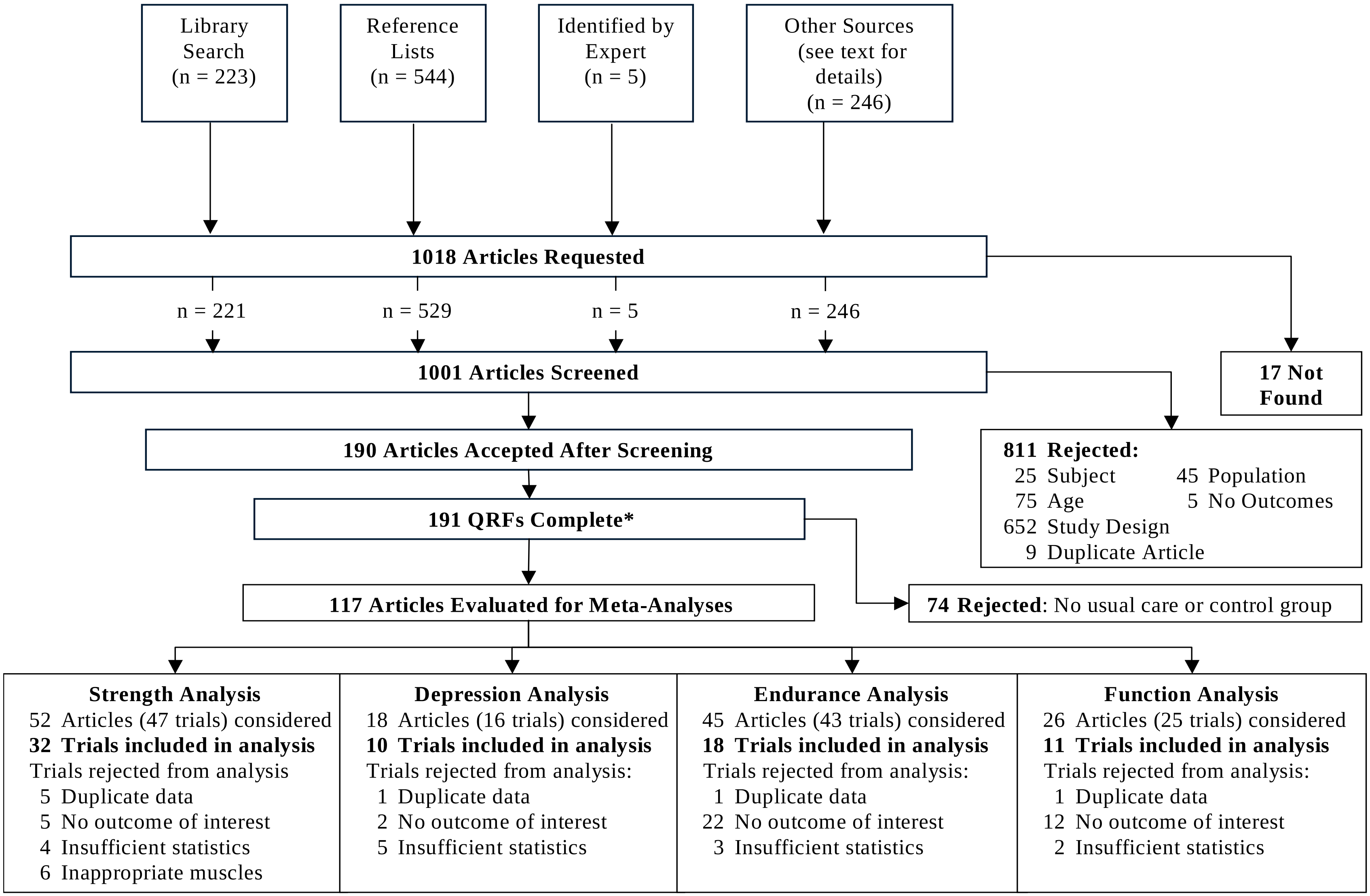
Identification of Evidence:

Figure 3 describes the flow of evidence from the original sources to final acceptance for our review. We retrieved 246 articles from previous reviews (e.g., Cochrane Collaboration) and specialty societies (e.g. American Geriatric Society). A library search yielded 223 articles not previously noted; 544 additional articles were found by examining the reference lists of all articles we obtained. Five additional articles were obtained from experts. In total, the above sources yielded 1,018 articles, but we were unable to obtain 17 of these. This left 1,001 articles for the screening process.

Of the 1,001 articles screened, 25 did not discuss exercise programs. 652 others were rejected because they were not randomized controlled trials (RCTs) or controlled clinical trials (CCTs). Another nine articles were duplicates of articles already on file.

Five others did not include outcomes; i.e. they were simply descriptions of exercise programs. Forty-five articles did not study healthy subjects. Seventy-five articles studied exercise in adolescents or children. This left 190 articles for quality review. No long-term studies were found: the maximum duration of follow-up was one year.

Figure 3. Article Flow



*** One article (#2981) presents data on two trials.**

The outcomes most commonly assessed were strength, balance, psychosocial measures, functional measures, activity level, and cardiovascular health.

Synthesis of Evidence:

We next report our results, grouped according to the questions given us by CMS.

Key Question #1

- What are the benefits of physical activity for seniors? What is the impact of physical activity on health status, health outcomes, functional status, quality of life, mental health, and ability to maintain independence?

As indicated in the Introduction, there is a vast wealth of observational data that relate increased physical activity to a wide range of health outcomes, including mortality, functional status, quality of life, and mental health. These data have been reviewed extensively by others. While observational data can sometimes reach the same conclusions as subsequent randomized trial data on the same topic,[21] in other instances, randomized trials have not supported the conclusions of observational studies, no matter how well executed and analyzed the observational studies were.[22] Therefore, for this key question, we chose not to review observational data, but instead to assess randomized evidence of physical activity interventions in older adults to answer the following policy-relevant question: "What benefits may we expect to gain if we attempt to increase physical activity among existing sedentary older adults?"

Description of Evidence:

We identified 140 articles describing 130 trials that reported data specific to adults aged 60 or over. The maximum duration of these studies was 12 months. As such, these studies did not have a sufficient duration of evaluation to assess the potential effect of physical activity on many of the outcomes reported in long-term cohort studies, such as mortality or the prevention of cancer. The outcomes that were measured in the randomized controlled trials in quantities sufficient for statistical pooling included measures of strength, cardiovascular fitness, function, and depression. The effect of exercise interventions on the prevention of falls is the subject of a separate evidence report.[23] This section will now consider each outcome in turn.

Strength:

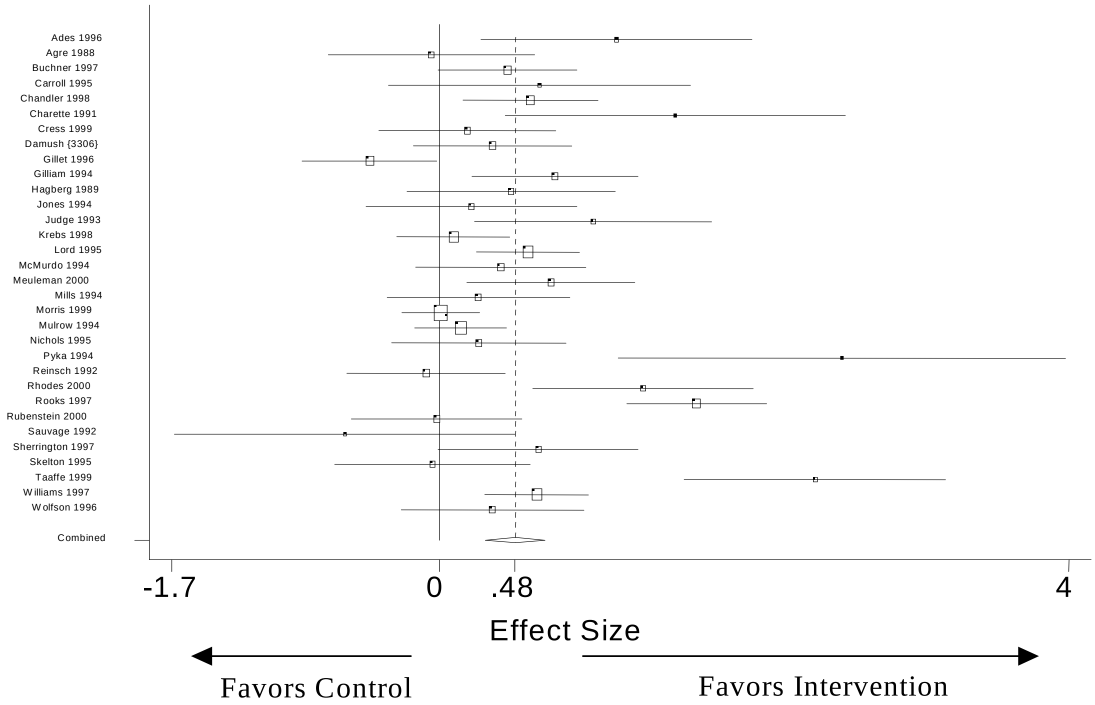
We identified 47 trials that reported strength outcomes, of which 32 could be included in a meta-analysis. Follow-up time ranged between one month and 12 months, and the sample sizes varied from as few as 14 patients to as many as 248. We pooled studies using leg strength outcomes. Combining all 32 studies, the pooled effect size was 0.48, (95% CI: 0.29, 0.67; $p < 0.001$) (see Table 2 and Figure 4), with a chi-squared heterogeneity $p < 0.001$, indicating significant heterogeneity between studies. This effect size is equivalent to an increase in strength of about 7 kilograms in knee extension.

Table 2. Strength for all studies

Trial	Total n	Effect Size	95% CI
Ades 1996	24	1.13	(0.26, 1.99)
Agre 1988	47	-0.05	(-0.71, 0.60)
Buchner 1997	96	0.43	(-0.01, 0.87)
Carroll 1005	35	0.64	(-0.32, 1.59)
Chandler 1998	87	0.58	(0.15, 1.01)
Charette 1991	19	1.50	(0.42, 2.58)
Cress 1999	49	0.18	(-0.38, 0.74)
Damush 1999	62	0.34	(-0.16, 0.84)
Gillet 1996	100	-0.44	(-0.87, -0.01)
Gilliam 1994	59	0.73	(0.21, 1.26)
Hagberg 1989	47	0.45	(-0.21, 1.12)
Jones 1994	42	0.20	(-0.47, 0.88)
Judge 1993	31	0.98	(0.22, 1.73)
Krebs 1998	120	0.09	(-0.27, 0.45)
Lord 1995	151	0.56	(0.24, 0.89)
McMurdo 1994	55	0.39	(-0.15, 0.93)
Meuleman 2000	58	0.71	(0.18, 1.24)
Mills 1994	47	0.25	(-0.33, 0.83)
Morris 1999	248	0.01	(-0.24, 0.26)
Mulrow 1994	180	0.14	(-0.16, 0.43)
Nichols 1995	57	0.25	(-0.30, 0.80)
Pyka 1994	14	2.56	(1.14, 3.98)
Reinsch 1992	95	-0.08	(-0.59, 0.42)
Rhodes 2000	38	1.29	(0.59, 1.99)
Rooks 1997	106	1.63	(1.19, 2.08)
Rubenstein 2000	52	-0.02	(-0.56, 0.53)
Sauvage 1992	14	-0.60	(-1.68, 0.48)
Sherrington 1997	40	0.63	(-0.01, 1.26)
Skelton 1995	40	-0.04	(-0.66, 0.58)
Taaffe 1999	44	2.39	(1.56, 3.22)
Williams 1997	149	0.62	(0.29, 0.95)
Wolfson 1996	50	0.34	(-0.24, 0.92)
Pooled Random Effects Estimate		0.48[1]	(0.29, 0.67)

[1]Chi-squared test of heterogeneity p-value < 0.001

Figure 4. Strength for all studies



Of the 32 studies, eight had interventions that were unclassifiable as either primarily strength or primarily endurance. Of the remaining 26, 15 had a single intervention arm that was primarily strength and four had a single intervention arm that was primarily endurance. The five remaining studies had multiple arms: three had both strength and endurance arms; one had two strength arms that were combined for the strength analysis; and one had an endurance arm and a combined endurance and strength arm that was dropped from the stratified analysis. Considering the primarily strength interventions, the pooled effect size was 0.66 (95% CI: 0.38, 0.94); $p < 0.001$ (see Table 3 and Figure 5), with a chi-squared heterogeneity $p < 0.001$, indicating significant heterogeneity between studies. This effect size is equivalent to an increase in strength of almost 10 kilograms in knee extension. The pooled effect size for the interventions that were primarily endurance did not yield any statistically significant benefit for strength (see Table 4 and Figure 6).

Table 3. Strength for strength interventions only

Trial	Total n	Effect Size	95% CI
Ades 1996	24	1.13	(0.26, 1.99)
Buchner 1997	51	0.56	(-0.01, 1.12)
Charette 1991	19	1.50	(0.42, 2.58)
Damush 1999	62	0.34	(-0.16, 0.84)
Gilliam 1994	59	0.73	(0.21, 1.26)
Hagberg 1989	31	0.48	(-0.25, 1.21)
Judge 1993	31	0.98	(0.22, 1.73)
Krebs 1989	120	0.09	(-0.27, 0.45)
McMurdo 1994	55	0.39	(-0.15, 0.93)
Meuleman 2000	58	0.71	(0.18, 1.24)
Morris 1999	248	0.01	(-0.24, 0.26)
Mulrow 1994	180	0.14	(-0.16, 0.43)
Nichols 1995	57	0.25	(-0.30, 0.80)
Pyka 1994	14	2.56	(1.14, 3.98)
Reinsch 1992	95	-0.08	(-0.59, 0.42)
Rhodes 2000	38	1.29	(0.59, 1.99)
Rooks 1997	81	2.43	(1.85, 3.00)
Sherrington 1997	40	0.63	(-0.01, 1.26)
Wolfson 1996	50	0.34	(-0.24, 0.92)
Pooled Random Effects Estimate		0.66[1]	(0.38, 0.94)

[1]Chi-squared test of heterogeneity p-value < 0.001

Figure 5. Strength for strength interventions only

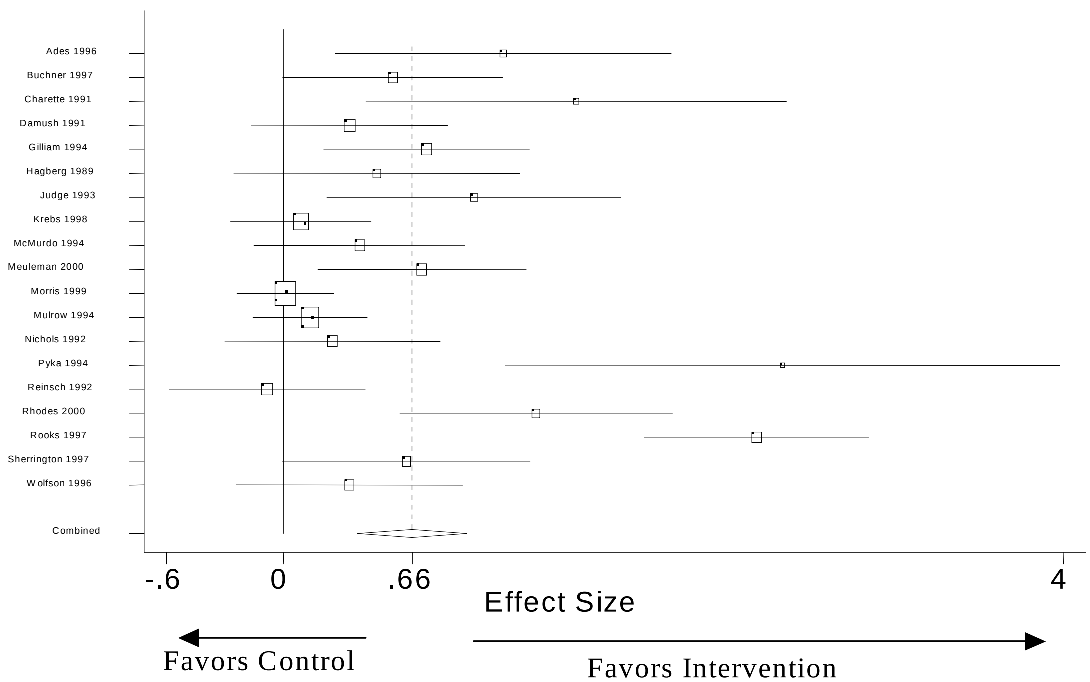
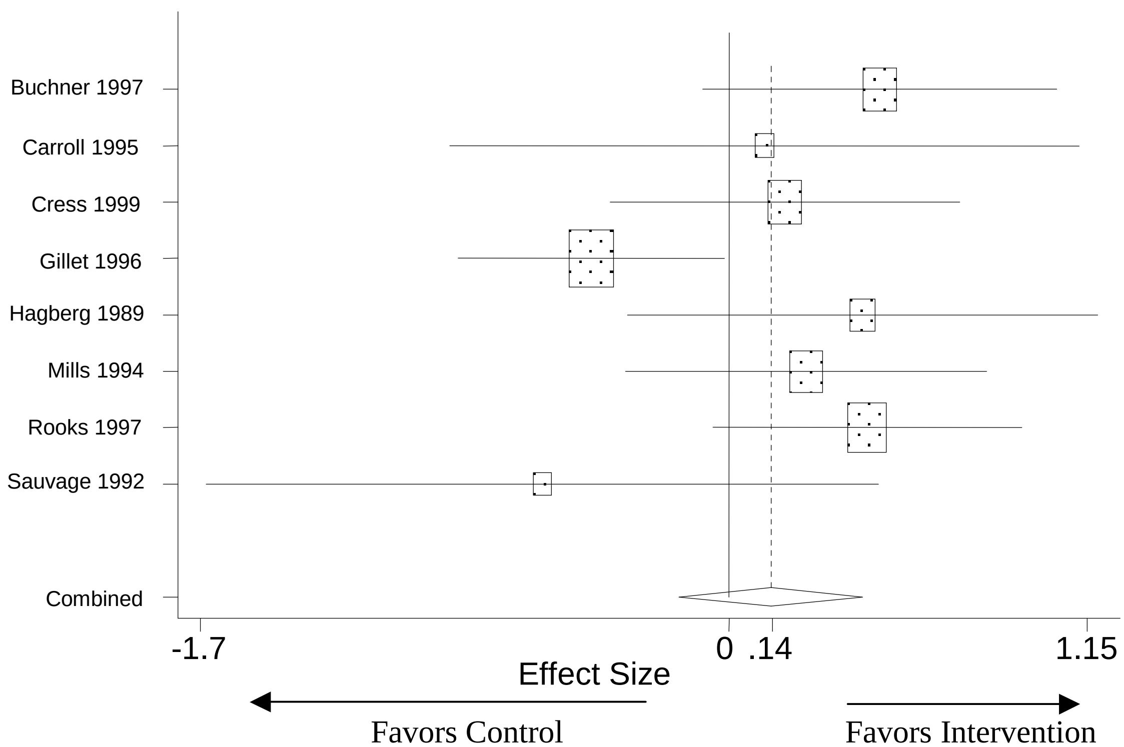


Table 4. Strength for endurance interventions only

Trial	Total n	Effect Size	95% CI
Buchner 1997	50	0.48	(-0.09, 1.05)
Carroll 1995	20	0.11	(-0.90, 1.13)
Cress 1999	49	0.18	(-0.38, 0.74)
Gillet 1996	100	-0.44	(-0.87, -0.01)
Hagberg 1989	28	0.43	(-0.33, 1.19)
Mills 1994	47	0.25	(-0.33, 0.83)
Rooks 1997	69	0.44	(-0.05, 0.94)
Sauvage 1992	14	-0.60	(-1.68, 0.48)
Pooled Random Effects Estimate		0.14[1]	(-0.16, 0.43)

[1]Chi-squared test of heterogeneity p-value < 0.09

Figure 6. Strength for endurance interventions only



Stratifying studies by the duration of the intervention, there were statistically significant pooled effect sizes for all three time strata, with effect sizes of 0.65 and 0.22 at 0-3 months and 3-6 months, respectively, increasing to an effect size of 0.95 at a follow-up of 6-12 months. From these data, we conclude that interventions aimed at improving strength in sedentary older adults result in statistically significant benefits as early as 1-3 months after beginning the intervention and persisting at least through 12 months. (Table 5 and Figure 7).

Table 5. Strength by duration of intervention

Trial 0-3 months	Total n	Effect Size	95% CI
Ades 1996	24	1.13	(0.26, 1.99)
Charette 1991	19	1.50	(0.42, 2.58)
Damush 1999	62	0.34	(-0.16, 0.84)
Judge 1993	31	0.98	(0.22, 1.73)
Meuleman 2000	58	0.71	(0.18, 1.24)
Nichols 1995	57	0.25	(-0.30, 0.80
Sherrington 1997	40	0.63	(-0.01, 1.26)
Pooled Random Effects Estimate		0.65[1]	(0.37, 0.93)

[1]Chi-squared test of heterogeneity p-value = 0.26

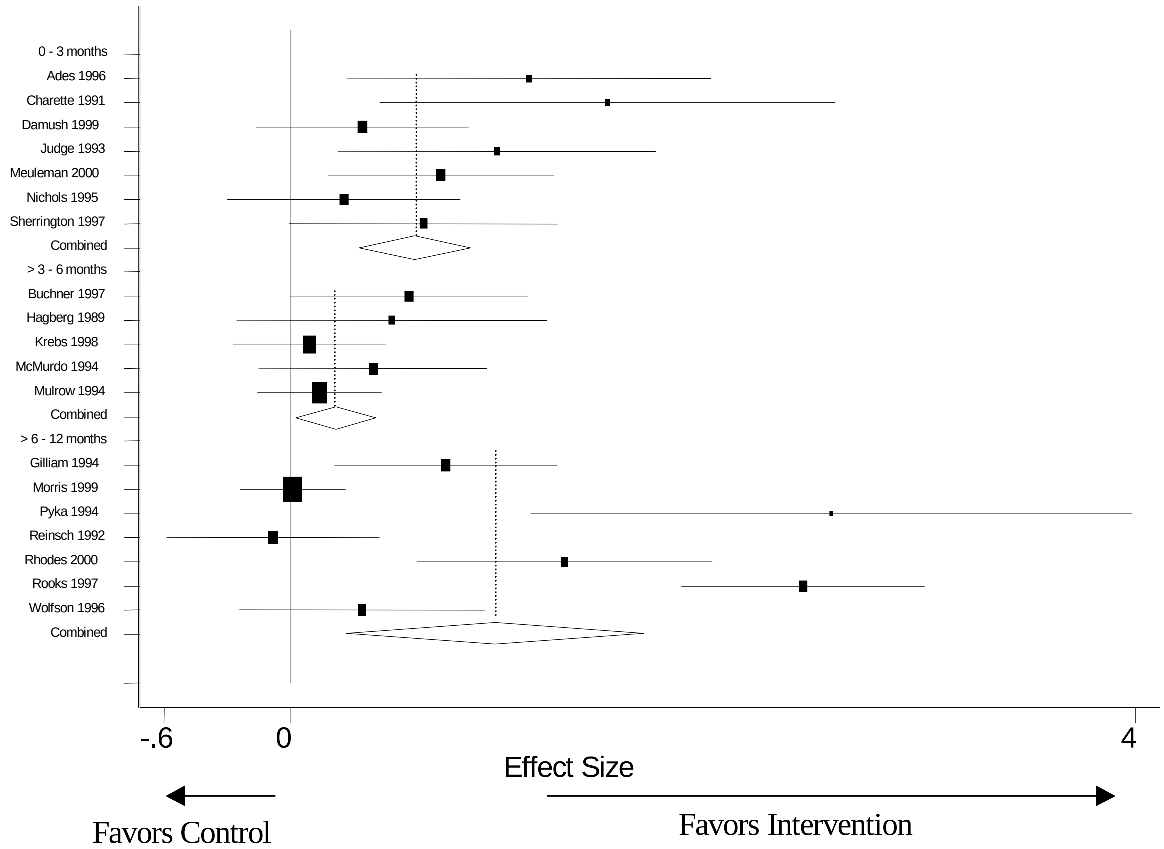
Trial 3 - 6 months	Total n	Effect Size	95% CI
Buchner 1997	51	0.56	(-0.01, 1.12)
Hagberg 1989	31	0.48	(-0.25, 1.21)
Krebs 1998	120	0.09	(-0.27, 0.45)
McMurdo 1994	55	0.39	(-0.15, 0.93)
Mulrow 1994	180	0.14	(-0.16, 0.43)
Pooled Random Effects Estimate		0.22[1]	(0.04, 0.41)

[1]Chi-squared test of heterogeneity p-value = 0.55

Trial 6 - 12 months	Total n	Effect Size	95% CI
Gilliam 1994	59	0.73	(0.21, 1.26)
Morris 1999	248	0.01	(-0.24, 0.26)
Pyka 1994	14	2.56	(1.14, 3.98)
Reinsch 1992	95	-0.08	(-0.59, 0.42)
Rhodes 2000	38	1.29	(0.59, 1.99
Rooks1997	81	2.43	(1.85, 3.00)
Wolfson 1996	50	0.34	(1.85, 3.00)
Pooled Random Effects Estimate		0.95[1]	(0.23, 1.67)

[1]Chi-squared test of heterogeneity p-value < 0.001

Figure 7. Strength by duration of intervention



Endurance or Cardiovascular Fitness:

We identified 18 studies that could be included in a meta-analysis of endurance or cardiovascular fitness, as measured by VO_2 (max). Seventeen of these studies contained an intervention that was primarily aimed at improving endurance, and three studies contained an intervention aimed primarily at improving strength. The studies ranged in follow-up time from 10 weeks to 12 months and ranged in sample size from as few as 14 to as many as 300 participants. With only two exceptions, these RCTs studied subjects at least 70 years of age. Mean VO_2 (max) at baseline was 20 ml/kg/m^2. This VO_2 (max) is equivalent to about 5-6 mets, which indicates the maximal exertion these participants could engage in was walking upstairs, or pitching softball, or doing general gardening.[24]

Across all 18 studies, the pooled effect size in VO_2 (max) was an increase of 0.38, (95% CI; 0.22, 0.54; $p < 0.001$), with a chi-squared heterogeneity $p = 0.08$, meaning there was no evidence of significant heterogeneity between studies. These data are displayed in Table 6 and Figure 8. Considering the subset of 17 interventions primarily aimed at improving endurance, the pooled effect size was 0.41 (95% CI: 0.23, 0.59; $p < 0.001$), with a chi-squared heterogeneity $p = 0.03$; these data are shown in Table 7 and Figure 9. An effect size of 0.41 is equivalent to an increase in VO_2 (max) of about 10 $ml/kg/m^2$, meaning the average VO_2 (max) of participants after endurance training was now about 30 $ml/kg/m^2$, or about 8.5 mets. Clinically, this means the participants could now engage without difficulty in those activities such as walking upstairs, pitching softball, or general gardening that previously had been the limit of their exertion, and their new limit of exertion (8.5 mets) is equivalent to engaging in activities such as climbing hills (with a 21-42 pound load), running a 12 minute mile, or playing singles tennis.[24] The pooled estimate of the effect size for the three interventions primarily aimed at improving strength did not report any statistically significant difference in cardiovascular fitness. There were insufficient data to support an analysis stratified by the duration of the intervention. We interpret these data as indicating that interventions aimed at improving endurance in older sedentary adults produce statistically significant and clinically important benefits in terms of cardiovascular fitness.

Table 6. Endurance or cardiovascular fitness for all studies

Trial	Total n	Effect Size	95% CI
Ades 1996	14	0.32	(-0.48, 1.13)
Blumentha 1991l	101	0.43	(0.01, 0.84)
Boileau 1999	125	0.32	(-0.03, 0.68)
Buchner 1997	157	-0.10	(-0.50, 0.30)
Butterworth 1993	30	0.69	(-0.05, 1.43)
Carroll 1995	44	0.87	(0.12, 1.63)
Cress 1999	49	0.44	(-0.13, 1.01)
Engels 1998	16	0.24	(-0.48, 0.96)
Gillett 1996	100	1.21	(0.76, 1.67)
Hagberg 1989	47	0.51	(-0.15, 1.18)
King 1993	300	0.36	(0.10, 0.63)
Posner 1992	247	0.34	(0.08, 0.61)
Probart 1991	16	-0.20	(-1.22, 0.81)
Sauvage 1992	14	-0.14	(-1.20, 0.92)
Steinhaus 1990	28	0.02	(-0.72, 0.76)
Vito 1997	16	0.85	(-0.25, 1.95)
Vito 1999	20	0.24	(-0.64, 1.13)
Woods 1993	29	0.06	(-0.67, 0.79)
Pooled Random Effects Estimate		0.38[1]	(0.22, 0.54)

[1]Chi-squared test of heterogeneity p-value = 0.08

Figure 8. Endurance or cardiovascular fitness for all studies

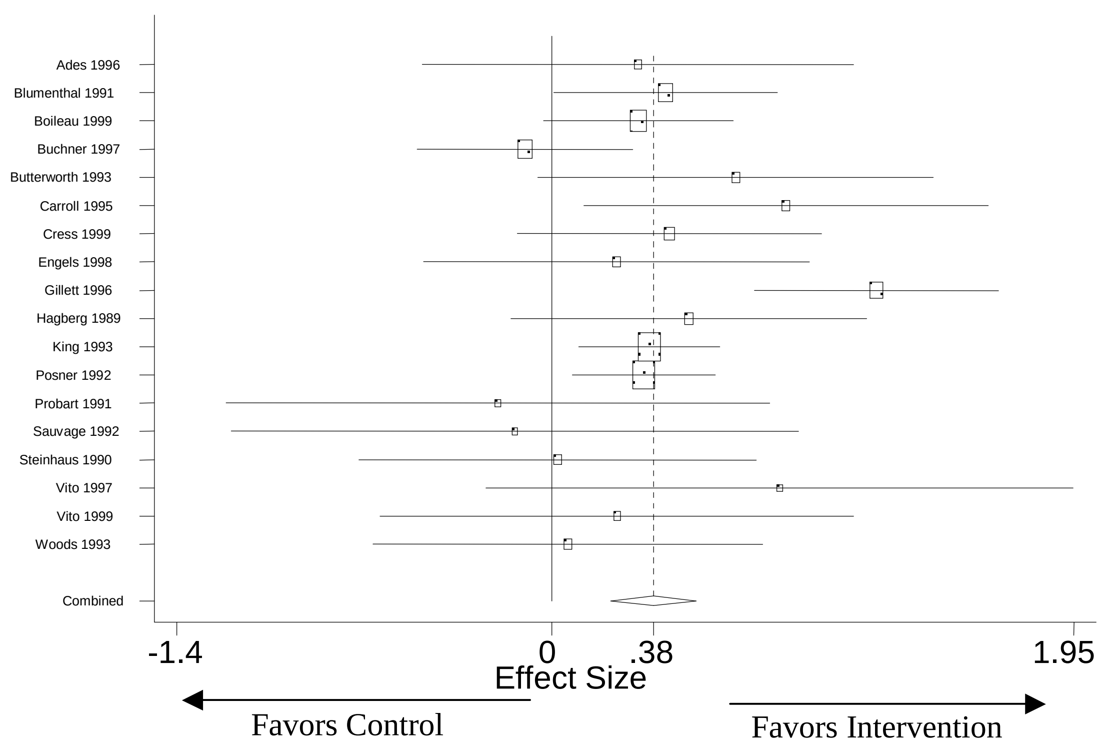
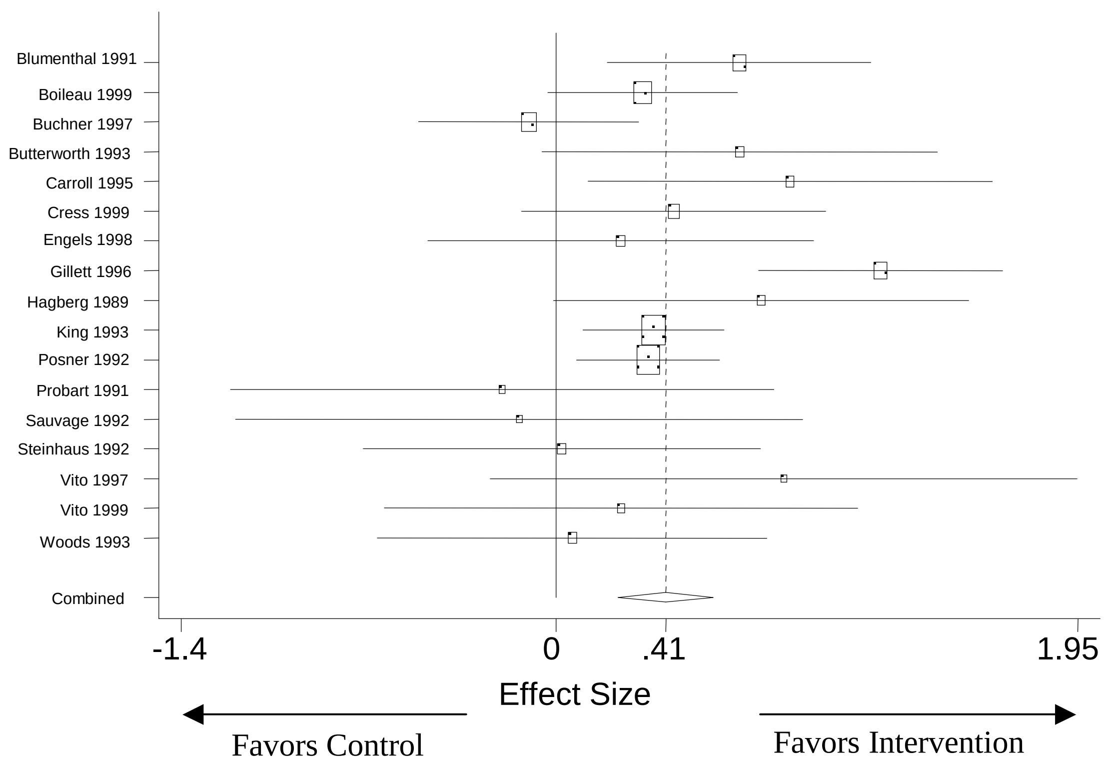


Table 7. Endurance for endurance interventions only

Trial	Total n	Effect Size	95% CI
Blumenthal 1991	67	0.68	(0.19, 1.18)
Boileau 1999	125	0.32	(-0.03, 0.68)
Buchner 1997	135	-0.10	(-0.51, 0.31)
Butterworth 1993	30	0.69	(-0.05, 1.43)
Carroll 1995	44	0.87	(0.12, 1.63)
Cress 1999	49	0.44	(-0.13, 1.01)
Engels 1998	34	0.24	(-0.48, 0.96)
Gillett 1996	100	1.21	(0.76, 1.67)
Hagberg 1989	28	0.77	(-0.01, 1.54)
King 1993	300	0.36	(0.10, 0.63)
Posner 1992	247	0.34	(0.08, 0.61)
Probart 1991	16	-0.20	(-1.22, 0.81)
Sauvage 1992	14	-0.14	(-1.20, 0.92)
Steinhaus 1990	28	0.02	(-0.72, 0.76)
Vito 1997	16	0.85	(-0.25, 1.95)
Vito 1999	20	0.24	(-0.64, 1.13)
Woods 1993	29	0.06	(-0.67, 0.79)
Pooled Random Effects Estimate		0.41[1]	(0.23, 0.59)

[1]Chi-squared test of heterogeneity p-value = 0.03

Figure 9. Endurance for endurance interventions only



Function:

We identified eleven trials that could be included in a meta-analysis, of which six studies reported function as measured by the SF36, four measured function as measured by the Sickness Impact Profile (SIP), and five measured function using the Activities of Daily Living (ADL) scale. We did not judge these scales to be sufficiently similar to pool together, and therefore the results for each of these measures are presented separately. For the six studies that used the SF36, the follow-up time ranged from eight weeks to six months and had sample sizes from 49 to 157 subjects. We pooled the physical function scores from these studies. The pooled effect size of all six studies was 0.15 (95% CI: -0.03, 0.34; $p = 0.11$), with a chi-squared heterogeneity $p = 0.98$; these data are presented in Table 8 and Figure 10. For the SIP, one study reported only adjusted results and therefore we had to exclude that study from the analysis. The pooled effect size of the remaining three studies was 0.08 (95% CI: -0.22, 0.38; $p = 0.61$), with a chi-squared heterogeneity $p = 0.22$; these data are presented in Table 9 and Figure 11. For the outcome Activities of Daily Living (ADL), the pooled effect size of five studies was 0.40 (95% CI: -0.07, 0.87; $p = 0.09$), with a chi-squared heterogeneity $p < 0.001$, indicating significant heterogeneity between studies. These data are displayed in Table 10 and Figure 12. We interpret these data as indicating that interventions to improve physical activity in older adults have not reported statistically significant improvements in function, however, the trend is in the expected direction of better function.

Table 8. Function measured by the SF36

Trial	Total n	Effect Size	95% CI
Buchner 1997	175	0.08	(-0.32, 0.48)
Cress 1999	49	0.31	(-0.26, 0.87)
Damush 1999	62	0.05	(-0.45, 0.55)
Kutner 1997	91	0.10	(-0.31, 0.52)
Rubenstein 2000	55	0.23	(-0.30, 0.76)
Wallace 1998	90	0.22	(-0.19, 0.64)
Pooled Random Effects Estimate		0.15[1]	(-0.03, 0.34)

[1]Chi-squared test of heterogeneity p-value = 0.98

Figure 10. Function measured by the SF36

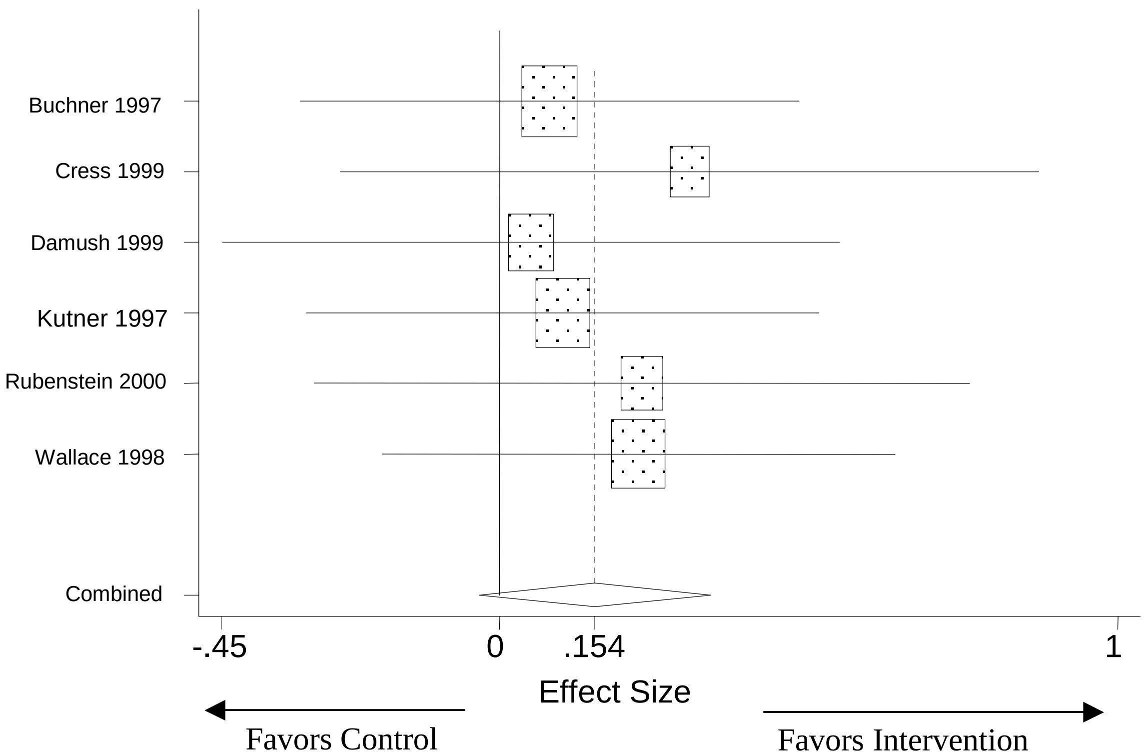


Table 9. Function measured by the SIP

Trial	Total n	Effect Size	95% CI
Buchner 1997	157	-0.06	(-0.47, 0.34)
Cress 1999	35	-0.23	(-0.90, 0.43)
Mulrow 1994	180	0.28	(-0.01, 0.58)
Pooled Random Effects Estimate		0.08[1]	(-0.22, 0.38)

[1]Chi-squared test of heterogeneity p-value = 0.22

Figure 11. Function measured by the SIP

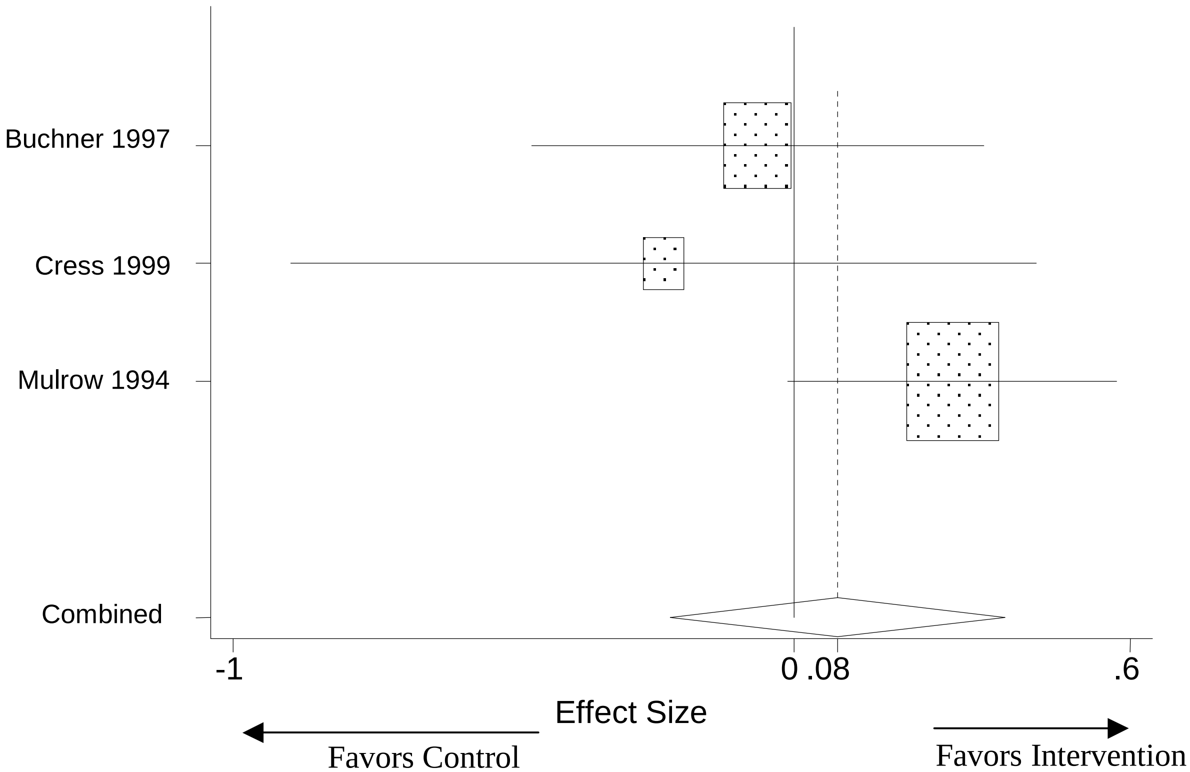
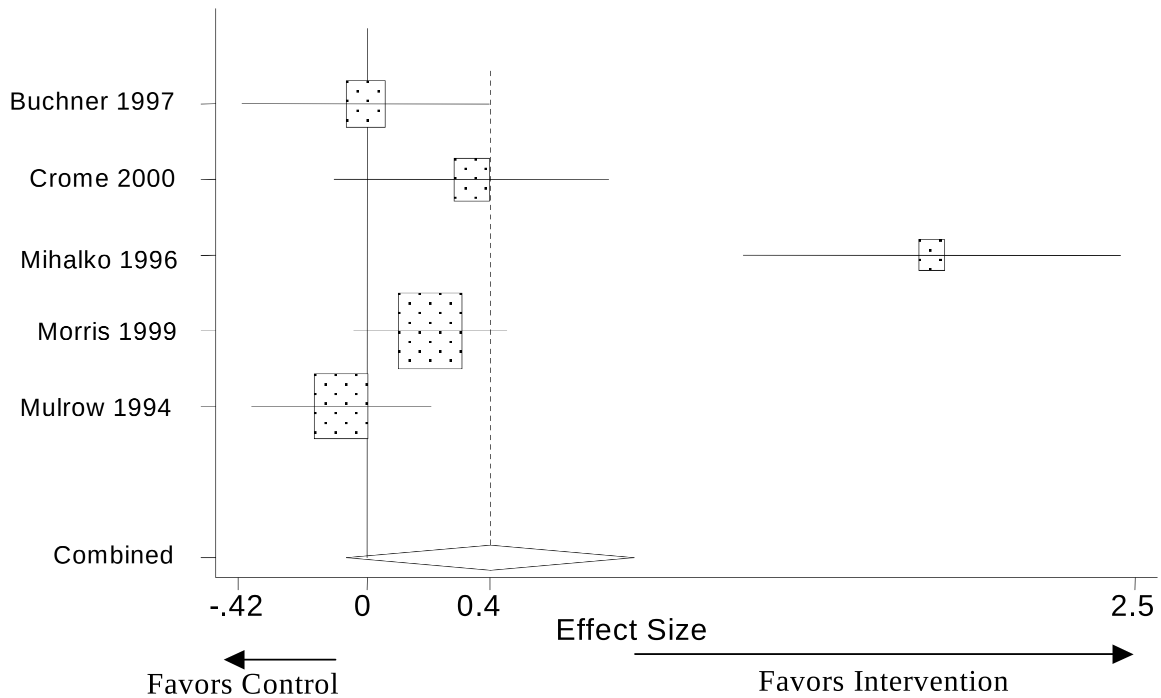


Table 10. Function measured by ADL

Trial	Total n	Effect Size	95% CI
Buchner 1997	157	-0.01	(-0.41, 0.40)
Crome 2000	78	0.34	(-0.11, 0.79)
Mihalko 1996	58	1.84	(1.22, 2.45)
Morris 1999	248	0.20	(-0.04, 0.45)
Mulrow 1994	180	-0.08	(-0.38, 0.21)
Pooled Random Effects Estimate		0.40[1]	(-0.07, 0.87)

[1]Chi-squared test of heterogeneity p-value < 0.001

Figure 12. Function measured by ADL



Depression:

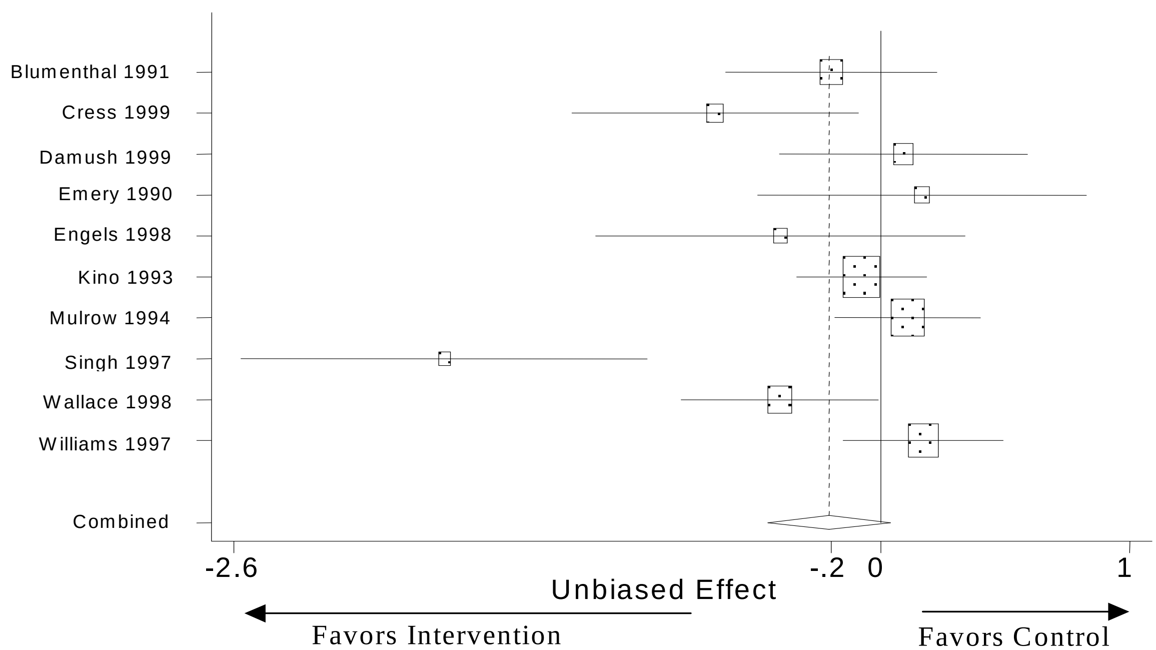
We identified 10 trials that could be included in a meta-analysis of depression; these studies ranged in follow-up time from eight to 52 weeks. The sample sizes ranged from 31 to 300. In this analysis, a lower depression score is considered a better outcome. The pooled effect size of the ten studies was a value of -0.21 (95% CI: -0.46, 0.04; p = 0.10), with a chi-squared heterogeneity p < 0.001, indicating significant heterogeneity between studies. These data are displayed in Table 11 and Figure 13. This effect size is equivalent to about two-thirds of a point in improvement in the Beck Depression Index. We interpret these data as indicating that the interventions assessed do not support a significant effect on measures of depression in sedentary older adults, although a trend of small effect is in the expected direction.

Table 11. Depression for all studies

Trial	Total n	Effect Size	95% CI
Blumenthal 1991	97	-0.20	(-0.62, 0.23)
Cress 1999	49	-0.67	(-1.24, -0.09)
Damush 1999	62	0.09	(-0.41, 0.59)
Emery 1990	38	0.17	(-0.49, 0.83)
Engels 1998	31	-0.40	(-1.15, 0.34)
Kino 1993	300	-0.08	(-0.34, 0.18)
Mulrow 1994	180	0.11	(-0.18, 0.40)
Singh 1997	32	-1.75	(-2.57, -0.94)
Wallace 1998	100	-0.41	(-0.80, -0.01)
Williams 1997	149	0.17	(-0.15, 0.49)
Pooled Random Effects Estimate		-0.21[1]	(-0.46, 0.04)

[1]Chi-squared test of heterogeneity p-value < 0.001

Figure 13. Depression for all studies



Publication Bias:

We assessed for each of our outcomes the possibility of publication bias using funnel plots and statistical tests as outlined in the methods. Only for studies assessing strength did we find statistical evidence of possible publication bias (Table 12). Therefore, our pooled results for strength improvements with exercise must be viewed with some caution.

Table 12. Publication bias tests

Outcome	Adjusted rank correlation test p-value	Regression asymmetry test p-value
Strength	0.05	0.03
Cardiovascular	0.71	0.97
Function: SF36	0.26	0.31
Function: SIP	0.30	0.29
Function: ADL	0.22	0.19
Depression	0.15	0.06

Key Questions #2, #5, #6, #10

- How are seniors motivated to engage in physical activity?
- What are the best strategies for promoting physical activity – by public health, medical model, social services or a combination of these approaches?
- What is the role of the physician?
- What is the role of family and social support?

These four key questions are interrelated and will be dealt with together. We will first deal with the evidence regarding how to promote increased physical activity.

The data on the efficacy of counseling by physicians or other clinicians to improve physical activity in adults were recently reviewed.[25] This summary was prepared for the US Preventive Services Task Force (USPSTF) by the University of Oregon Evidence-based Practice Center. The scope of their review included controlled trials, case-control studies and observational studies that examined counseling interventions aimed at increasing physical activity in general primary care populations. The authors report finding seven randomized controlled trials and one non-randomized controlled study that met their inclusion criteria. Most of the trials involved an initial baseline assessment (often conducted by a nurse or research assistant), which was then reviewed by the clinician and used to exclude patients for whom physical activity was contraindicated and/or to tailor the intervention to each patient's needs. The counseling consisted of advice to sedentary or minimally active patients to achieve regular moderate intensity physical activity. The review reported that among the six controlled trials that compared counseling to a usual care control group, the effects on physical activity after six to 24 months were mixed. Two trials that compared interventions with other interventions reached somewhat different conclusions on the effect of counseling interventions on men compared to women, but both studies reported that more intense interventions were more effective. The overall conclusion of this review was that the evidence is inconclusive regarding whether counseling adults in primary care settings to increase physical activity is effective.

Three of the studies included in the USPSTF review included substantial numbers of older adults. In the study most relevant to the Medicare population, community dwelling Medicare beneficiaries in Baltimore participated in the Medicare Preventive Service Demonstration Project.[26] About 2,000 patients were enrolled in both the intervention and the usual care control group. The intervention consisted of offering preventive examinations that included investigation of a large number of behaviors, such as smoking, physical activity, diet, alcohol use, sleep problems, etc. The visit was designed to include cancer screening, as well as immunizations, and the physician was reimbursed $145 for this collection of services. A follow-up counseling visit within six months was offered if deemed necessary by the physician and reimbursement was set at $40. In the analysis, patients were divided into poor or good health status based on the Quality of Well-Being score. The study reported that about one-third of enrolled patients who reported good health had a sedentary lifestyle, while nearly three quarters of patients who reported poor health had a sedentary lifestyle. The study reported the intervention had no effect on the patient self-report of performing physical activities, such as walking briskly, gardening, or heavy housework.

Two other studies reported data on persons over age 65. One study was performed in Australia and enrolled only patients age 65 or older. General practices were randomized to either the control group or an educational program for physicians. This program had five steps, including a discussion on exercise and social activity, a 15 minute visit to each general practitioner by the principal investigator who outlined the key points in promoting physical activity, distributed summary reading material, and training staff in the use of a card prompt. The card prompt consisted of a yellow card attached to the records of all patients over 65 years of age, prompting discussions of physical and social activity, vaccinations, and drug lists. Lastly, physicians attended a didactic three-hour seminar on health issues in older adults with presentations regarding exercise from a physiologist, along with other specialty lecturers, and were given a resource directory of available health services for elderly patients. Approximately 120 patients enrolled in each of the intervention and control groups. The study reported that among several measures of physical activity, the amount of weekly walking was statistically significantly higher in the intervention group by 44 minutes, although the total minutes of activity was no different between groups.[27]

Another study assessed the effect of brief physician-delivered physical activity counseling on self-reported physical activity levels. Community based primary care medical practices were randomized to control or the intervention, which consisted of physician training with printed materials, lectures, and role-play; and an office implementation system of identification and prompts. Patients received an exercise prescription, a patient manual, and five monthly mailings. The intervention was based on the Transtheoretical Model of Change. Three hundred fifty-five patients were enrolled in 24 primary care practices. The average age of enrolled patients was 66 years of age and 65% were women. The study reported changes in the intervention group in readiness to change, but no differences at eight months in self-reported physical activity between intervention and control.[28]

Four randomized trials are discussed here in more detail as additional examples of studies of physician counseling intervention. The first study, involving a primary care setting in England, randomized 5,023 non-elderly adults (aged 40-64 years) to receive one of four interventions or a control group. The interventions consisted of brief or intensive motivational interviewing, with or without a financial incentive consisting of free access to exercise facilities. The follow-up was one year. The study reported short-term increases in physical activity scores in the intensive intervention group, but that no intervention resulted in sustained long-term adherence to exercise. It concluded that brief interventions promoting physical activity are of questionable effectiveness.[29] The second study is the report of an activity counseling trial, which randomized 395 female and 479 male sedentary primary care patients, aged 35-75, to either advice on how to increase physical activity; assistance, which included advice plus interactive mail and behavioral counseling at physician visits; or a counseling intervention, which included all of the prior interventions, plus regular telephone counseling and behavioral classes. The outcome measures included a measure of cardiorespiratory fitness, the maximal oxygen uptake (VO_2 max) and self-reported total physical activity. The study reported that none of the interventions were effective in improving cardiorespiratory fitness in men at two years, but that both the assistance group and the counseling group had a statistically significant increase in VO_2 (max) compared to the advice group.[30]

The third example of a trial of counseling was performed in England and involved approximately 500 patients randomized to either: a) a usual care control group; or b) an intervention that included a brief negotiation based on motivational interviewing that included feedback about current physical activity, assessment of motivation and confidence for increasing physical activity, weighing up of the pros and cons of increased physical activity, information exchange, exploring concerns about taking up regular physical activity and helping with decision-making; or c) an intervention receiving direct advice based on the health belief model, in which case patients were advised to work towards 30 minutes of brisk walking on at least five days per week, or other similar activity.[31] The main outcome was self-reported physical activity at 12 months. The study reported that all three groups increased their physical activity during this period of time, but that there was no difference between groups. The two intervention groups combined showed a 4% increase in energy expenditure, compared to the control group, a difference, which was not statistically significant. This 4% increase is equivalent to approximately six minutes extra brisk walking per week. When interventions were compared, there was a non-statistically significant trend towards more energy expenditure in the brief negotiation group, compared with the direct advice group. The study concluded that 20-30 minutes of brief negotiation may be more effective than similar attempts to persuade or coerce patients to increase physical activity, but that in general, the most effective way of increasing physical activity in primary care is not yet determined.

The fourth study was conducted in New Zealand and assessed sedentary adults aged 40-79 years in 42 rural and urban general practices encompassing over 800 patients. Practices were randomized to either usual care or to give oral and written advice on physical activity during normal office visits, with exercise specialists providing continued support by telephone and mail. The study followed patients for 12 months and measured changes in physical activity, quality of life, and measures of cardiovascular risk. The study reported greater increases in total energy expenditure and leisure exercise in the intervention group compared to the control. For example, patients spent 34 minutes of exercise more per week in intervention than control, and the proportion of patients engaging in at least two and one-half hours per week of leisure exercise increased by almost 10% more in the intervention than in the control group. The study also reported improvements in SF36 measures and trends towards improvement in blood pressure.[4]

Despite the mixed results of these studies, counseling by primary care physicians to promote physical activity in adults is widely recommended. Practical methods for counseling were summarized in a recent article by Estabrooks and colleagues.[32] The authors of this article based their recommendations on research on behavioral interventions and recommend five key steps. These are:

1. Assess the patient's current level of physical activity and function.
2. Advise the patient by relating the patient's recent laboratory results and symptoms to physical inactivity. Identify the personalized potential benefits of physical activity and provide guidance on the appropriate amount and type of physical activity.
3. Agree with the patient if he or she is planning to develop a physical activity goal at the present time. Ask what barriers he or she anticipates for accomplishing this goal and ask what are the specific goals for the type, intensity, duration, and frequency of physical activity.
4. Assist the patient in developing specific strategies to overcome his or her identified barriers and a specific graduated action plan.
5. Arrange for follow-up assessment support and problem solving.

The authors note that several of these tasks can be completed by clinical staff, rather than by physicians.

In contrast to the mixed and modest results reported for clinician-based counseling, a review done for the Guide to Community Preventive Services was more supportive of various behavior, social, and environmental approaches to improving physical activity.[33] Both randomized and observational studies were included in the review, which focused on all age ranges. Among the interventions assessed that were relevant to older adults, the study reported that several interventions had sufficient evidence that they are effective, including:

- "Point of decision prompts," which are signs placed by elevators and escalators to motivate people to use nearby stairs;
- Community-wide campaigns, which are highly visible broad-based multiple intervention approaches to increasing physical activity that may include a combination of social support (such as self-help groups), risk factor screening, counseling, education about physical activity in a variety of settings, and environmental or policy changes, such as the creation of walking trails;
- Social support interventions in community settings, which typically involve setting up a "buddy" system, making a contract with others to achieve specified levels of physical activity, or setting up walking or other groups to provide companionship and support while being physical active;
- Individually adapted health behavior change programs, which are those tailored to the individual's readiness for change based on established health behavior change models, such as the social cognitive theory, the health belief model, or the transtheoretical model of change, interventions that could be delivered either in group settings or by mail, telephone or directed media;
- The creation of or enhanced access to places for physical activity, combined with informational outreach activities, which included providing access to weight and aerobic fitness equipment and creating walking trails or providing access to nearby fitness centers.

These recommendations can also be considered the evidence regarding "what motivates seniors to engage in physical activity."

Key Question #3

- What are the barriers and how can they be reduced?

The previously mentioned Guide to Community Preventive Services reported noted substantial barriers to implementing all of these interventions, for example, stairways in buildings may be difficult to find or poorly lit making point of decision prompts less effective, that community-wide campaigns require careful planning and sufficient resources to implement, and individually adapted health behavior change programs also require careful planning and coordination, well-trained staff members and resources sufficient to carry out the program. Furthermore, several of these recommended interventions involved policy and environmental approaches, not within the usual domain of health care.

Key Question #4

- What is known about adherence to programs?

Few studies have examined adherence to exercise regimens among older adults. Many of the trials we reviewed did not report adherence rates; very few examined predictors of adherence. The randomized controlled trials, when reported, adherence rates varied widely in type of exercise. Rates ranged from 35.9 to 100 percent.

A recent article by McAuley and colleagues [34] used structural equation modeling to examine predictors of exercise adherence among older adults participating in a six month randomized controlled trial with an 18 month follow-up. The Physical Activity Scale for the Elderly (PACE) measured physical activity over a one–week time period. Social support, exercise affect (how good or bad exercise makes one feel), and exercise frequency had significant paths to self-efficacy at end of a 6 month program; self-efficacy was in turn was related to physical activity levels at 18 months.

In 1996, Dishman and Buckworth [35] published a quantitative synthesis of 127 studies examining interventions for increasing physical activity among adults. To be included, each study had to report a measure of physical activity as an outcome or a measure of fitness that is a surrogate of physical activity. The analysis suggests that large effects were associated with those interventions based on behavior modification principles delivered to healthy people in a community setting. Effects were particularly strong when the interventions were delivered to group (as opposed to individuals) and involved leisure physical activity of low intensity. They found an absence of effects for interventions using health risk appraisals or health education.

Key Question #5

- What are the best strategies for promoting physical activity – by public health, medical model, social services, or a combination of these approaches?

It seems that a combination approach that includes encouragement from public health education, exercise prescriptions from physicians, and widely publicized available programs in senior centers and other social service locations seem to have the best chance of success. From a Medicare standpoint, we reported in our Falls Evidence Report that a specific exercise benefit providing time-limited exercise training by physical therapists or exercise professionals, for patients at risk for recurrent falls, was likely very cost-effective. It is possible that an exercise benefit tied to “sedentariness,” if that condition could be adequately defined, may also be cost-effective. However, evidence for this would need to come from new studies, as existing data are lacking.

Key Question #7

- What are the key messages for seniors?

Clearly, the main messages include:

1. Exercise improves many aspects of health and function for seniors, including strength, cardiovascular conditioning and endurance, falls prevention, and possibly global functioning and mood.
2. Exercise can benefit persons of any age and virtually any level of function, but the types of exercise are best tailored to the specific levels of function and need.
3. The choice to begin an exercise program is perhaps the most difficult step, but that once it is begun, the benefits become readily apparent.

Key Question #8

- Is there an infrastructure that promotes senior exercise? If not, what are the recommendations for building the infrastructure?

The current infrastructure for senior exercise has multiple components, but they are not well coordinated (either between or within types). Most common are the senior center programs, funded by a combination of Older American's Act federal funds, state funds, and local funds and facilities. These exist in most cities of America and many smaller towns and communities. Other programs include other public and private community centers such as adult day health care programs, YMCAs, community hospital outpatient outreach departments, municipal parks and recreation centers. Many health clubs offer senior exercise programs, but usually for an often substantial fee. Many Medicare HMO programs offer an exercise benefit, often through health clubs or franchised "Silver Sneakers" programs, in an attempt to recruit more health-conscious enrollees as well as to keep enrollees as healthy as possible. As well, formal rehabilitation programs, often funded by Medicare for disease-related short-term rehabilitation, provide supervised exercise instruction for short periods of time. Certain states (e.g., California, Connecticut) are attempting to remedy their poor coordination of services through establishment of state-wide coordination plans (e.g., California Blueprint for Falls Prevention), which inventory available programs, assess statewide needs, and establish plans to fill the needs. If successful, other states could be encouraged to emulate this model for falls and for physical activity in general.

Key Question #9

- What is the range of public policy responses towards this intervention? Are there programs/benefits that could be expanded to include additional interventions?

All the above existing programs should be encouraged to expand through greater outreach to a larger population. While few data exist on what proportion of the older population are using these programs, it is thought to be relatively small. Thus, there is much room for growth. The local community programs seem to be on an accelerating trajectory in terms of senior exercise. But these involve mostly healthy, independent seniors. More medically oriented programs for frailer populations should be encouraged as well, perhaps with a expanded Medicare benefit for longer-term rehab oriented exercise programs, possibly tied to specific diagnoses (e.g., hypertension, depression, coronary artery disease). The HMO health club benefit (e.g. Silver Sneakers) might well be offered as a general Medicare benefit to non-HMO Medicare enrollees.

Key Question #11

- What is the interaction between falls prevention and physical activity?

In addition to the current evidence report, we were asked by CMS to produce an evidence report on preventing falls among older adults. The completed report can be found at http://cms.hhs.gov/healthyaging/FallsPI.asp. Our report reviewed interventions such as comprehensive geriatric assessment, environmental modifications, institutional policy change, and exercise programs. Our meta-analyses reported that exercise interventions yielded a statistically significant decrease in a person's risk of falling at least once by 12% and the number of falls by 19%. While several types of exercise programs were included in the trials proven to prevent falls, there were insufficient data to identify the most effective exercises. Falls prevention programs using exercise typically include one or more of the following: cardiovascular endurance, muscular strength, flexibility, and balance. Differences in effectiveness between exercise types were not consistent and not statistically significant. Therefore, while there are compelling data to recommend exercise in general for preventing falls, there are no conclusive data to recommend particular falls prevention exercises.

Key Question #12

- Are different strategies needed for different cohorts?

Clearly exercise needs are different for different individuals, depending on medical conditions and baseline level of exercise and conditioning. Strategies for healthy community living individuals, who can probably be beneficially served by non-medical exercise professionals, will be very different from those for more frail or disabled individuals, who will likely need more medical supervision and tailoring. Additionally, some persons respond to social motivations more than individual motivations, so recruitment and adherence strategies should be tailored to individual psyches and readiness to change as much as possible.

Key Question #13

- Cost effectiveness vs. cost savings – does the intervention appear to reduce health care costs by reducing disease, physician office visits, hospitalization, nursing home admissions, etc.

Only two randomized clinical trial studies were identified in the review of the economic impact of physical activity programs for older adults.(Table 13)

Table 13. Cost-Effectiveness Studies

Article number	Author/ Year	Subjects (S), Follow-up period (F/U), Research design (D) and settings (ST)	Interventions	Costs of intervention	Health consequences (changes in mobility, mortality, and quality of life)	Resource consequences (changes in health care costs and utilization)	C/E Ratings
2513	Stevens et al. 1998	S: 714 inactive people age 45 to 74 (mean = 59.2, 42% men, 36.5% age 65 and older) taken from two west London general practices F/U: 8 months D: RCT ST: Primary care (in leisure center located within the ward)	I: 363 subjects invited to a consultation with an exercise development officer, and offered a personalized 10 week program to increase their level of regular physical activity, combining leisure center and home based activities C: 351 subjects sent information on local leisure centers	Costs of intervention included three stages: 1) identification of people as inactive = £2,517 (£1.95 per person for N = 1288); 2) invited for consultation = £1,580 (£12.54 per person for N = 126); 3) completed program = = £24,043 (£264.21 per person for N = 91). So the cost per complete program attendee was £279. The year of cost was not indicated.	No direct health consequence was measured. Only 35% of the 365 intervention subjects attended the first consultation, of whom only 91 subjects returned for the 2nd consultation at the end of the 10-week exercise program. 200 subjects in intervention and 215 in control group returned follow-up questionnaire. By self-report, 79 subjects moved into a higher level of physical activity with only 17 moving down. The biggest changes moved one level higher from sedentary to low intermediate or from low to high intermediate (14% each). Few subjects moved into the active group.	No resource consequence was measured. The cost-effectiveness analysis calculated the cost to increase levels of physical activity in inactive people. The cost to move a person into a higher level of physical activity was £327. It took a cost of £623 to move a person out of the sedentary group. However, the cost of moving someone to the now commonly recommended level of physical activity was estimated at almost £2500. The sensitivity analysis showed the main factor that would affect the cost-effectiveness of the intervention was the take up rate (i.e., the effectiveness of a recruitment strategy).	Insufficient information
0617	Buchner et al. 1997	S: 105 age 68-85 years old adults (mean = 75) with at least mild deficits in strength and balance were selected from a random sample of enrollees in a HMO F/U: 18 months D: RCT ST: Community classes	I: Supervised strength and endurance training C: Usual activity	Not available	There were no effects of exercise on gait, balance, or physical health status. Exercise had a protective effect on risk of falling (relative hazard = 0.53, C.I. = .30 -.91). 42% of exercise subjects reported a fall compared to 60% of control subjects.	Between 7 and 18 months after randomization, control subjects had more outpatient clinic visits although there were no significant differences between groups in ancillary outpatient costs. Hospital use was similar in both groups. However, hospitalized controls were significantly more likely to spend more than 3 days in the hospital and sustain hospital costs over $5000 (p <.05)	Insufficient information

One of the two studies attempted a cost-effectiveness analysis.[38]. This randomized controlled trial was a primary care-based intervention aimed at increasing levels of physical activity in inactive people aged 45 to 74. Thirty-five percent of the 365 intervention subjects attended the exercise intervention; only 91 subjects completed the 10-week exercise program. By self-report of the 200 intervention subjects who completed the follow-up survey, 39.5% moved into a higher level of physical activity and 8.5% moved down. The biggest changes were moving one level higher either from sedentary to low intermediate or from low to high intermediate (14% each). Few subjects moved into the active group. The authors reported the cost to move a person into a higher level of physical activity was £327 ($640 in 2003 U.S. dollars).* It cost £623 ($1,220 in 2003 U.S. dollars) to move a person out of the sedentary group. The cost of moving someone to the then commonly recommended level of physical activity was estimated at almost £2,500 in this study (almost $5,000 in 2003 U.S. dollars). The sensitivity analysis showed the main factor that would affect the cost-effectiveness of the intervention was the take up rate (i.e., the effectiveness of a recruitment strategy). Neither direct health consequence (i.e., changes in mobility, mortality, and quality of life) nor resource consequence (i.e., changes in health care costs and utilization) was measured. No subgroup analysis by age group was reported.

The other RCT reported that exercise might have beneficial effects on health care use in older adults at increased risk for functional decline.[36] This study included 105 seniors 68 to 85 years old and followed them for 18 months. The study was part of FICSIT, the Frailty and Injuries Cooperative Studies of Intervention Techniques initiative. The

* Assume the cost reported in the study was 1997 dollars. The average currency exchange rate from British pounds to U.S. dollars for the year 1997 was 1.64. A 3% inflation rate was used.

intervention consisted of exercise and/or endurance training in supervised classes for six months, three days per week, one hour each. There were no effects of exercise on gait, balance, or physical health status found in the study, but a protective effect on risk of falling was observed. From HMO computerized records, there were no significant differences between groups in ancillary outpatient costs and hospital use. However, the significant effects of exercise on health care use occurred because the control group had more outpatient clinic visits ($p<.06$) and were more likely to incur hospital costs over $5,000 ($p<.05$). The authors postulated this finding might have been due to the study eligibility criteria that resulted in the selection of a sample on the verge of substantial decline. They further postulated that exercise might have prevented this decline and had a beneficial effect resulting in less outpatient visits and faster recovery during a hospital stay. Since health care use, especially hospitalization is sparse, additional research with larger samples and longer follow-up is needed to shed further light on this finding. No program cost was reported for this study.

In summary, there is very limited evidence in randomized clinical trials regarding the economic impact of physical activity programs for older adults. One study estimated it might cost more than $5,000 to move a person from sedentary to a recommended level of physical activity. No direct health or utilization benefit was assessed in this study. Another trial reported short-term exercise might have beneficial effects on health care use in some subgroups of older adults, although no significant health improvement was found. Further research should investigate through randomized clinical trials the cost-effectiveness of exercise programs as a health promotion strategy for seniors.

Limitations

Our systematic review and meta-analysis of exercise has the following potential limitations:

- We may not have identified all the relevant studies. However, our search procedures for randomized controlled trials were extensive and included canvassing experts regarding studies we may have missed. In addition, we observed no evidence of publication bias via visual inspection or formal testing in any of the condition and outcome settings except for strength. For those non-strength cases for which we did not observe evidence of publication bias, we acknowledge that publication bias may still exist despite our best efforts to conduct a comprehensive search and the lack of statistical evidence of the existence of bias. Publication bias may occur for a variety of reasons, including investigators' loss of interest in the study if "negative" results are found or if results are obtained that are contrary to the interest of the sponsor or investigator.

- As previously discussed, we did find evidence of publication bias for the strength outcome. Therefore, the beneficial results of exercise we discuss in our meta-analysis need to be considered in light of the possible existence of unpublished studies reporting no or negative benefit.

- An important limitation common to systematic reviews is the quality of the original studies. Recent attempts to define elements of study design and execution that are related to bias have shown that in many cases, such efforts are not reproducible and do not distinguish studies based on their results. Therefore, the current state of the science is to not to reject studies or use quality criteria to adjust the pooled outcome. Thus, we made no attempt to give greater importance to some studies based on "quality." As there is lack of empirical evidence regarding other study characteristics and their relationship to bias, we did not attempt to use other criteria.

- For some conditions and outcomes, we did observe some evidence of heterogeneity. Stratification of studies into more subgroups hypothesized to be more homogeneous did not always eliminate the heterogeneity. Even for those settings in which we did not observe heterogeneity, we acknowledge that the chi-squared test of heterogeneity is underpowered. We did use a random effects approach to attempt to incorporate any heterogeneity but our results should still be interpreted in light of the observed heterogeneity.

- We identified no study with a duration of more than one year, limiting our ability to assess the effects of exercise on any of the longer term outcomes that have been reported in cohort studies, such as mortality, cancer prevention, etc.

- The results of the clinical trials are directly applicable only to the persons studied in those trials. In most cases, enrollment was highly selective to avoid certain comorbidities. Whether efficacy would be equivalent in a more representative population is unknown. Also unknown is the relative size of the population that would be potentially recruitable for exercise interventions.

- Many promising and potentially effective interventions may exist that have no RCT data. Moreover, other outcomes might be affected, but these have not been measured in existing RCTs.

Conclusions

The strongest evidence supporting a beneficial effect of exercise in older adults exists in fall reduction. Our evidence report on fall prevention indicates a physician-based intervention targeted at high risk individuals can be highly cost effective and possibly even cost savings.

There are sufficient data to conclude that exercise can modestly to moderately improve strength and cardiovascular performance among previously sedentary older people. The benefits in endurance are equivalent in a change in maximal exertion from pitching softball (before an endurance exercise program) to playing singles tennis (after the endurance exercise program).

There are non-significant trends in the appropriate direction supporting modest benefits of exercise on function and depression.

There have been no long term randomized controlled trials of exercise in older persons, therefore, there is no evidence supporting or refuting any long term health effects of exercise. The significant beneficial effects of exercise have lasted at least as long as the periods of study.

Extrapolating the results from these relatively short-term trials to a longer term could lead to conclusions qualitatively similar to the conclusion of longer term cohort studies with respect to strength, function, and mood. Thus, there is room to be optimistic about possible longer-term benefits.

The existing evidence is inconclusive regarding the efficacy of physician-based intervention to increase physical activity. The evidence is more encouraging regarding community-based interventions.

Recommendations

Even though the benefits of and best methods for performing and promoting senior exercise are still being activity researched, we know enough from the evidence presented here to make some rather firm recommendations to Medicare:

- Community-based exercise programs aimed toward increasing physical activity among relatively sedentary older adults are clearly effective in improving strength and endurance and reducing falls and fall-associated risk factors. Such programs likely have many other benefits still to be fully documented. Therefore, Medicare should creatively address ways to better promote and coordinate those programs, perhaps in ways analogous to programs begun by state-wide initiatives. As a government program, Medicare is in a unique position to work with other federal programs (e.g., older Americans Act programs, Medicaid) to enhance the growth, development and recruitment ability of community senior exercise programs.
- Creative incentives should be considered to enhance the growth of private sector senior exercise programs, perhaps partially funded by projected cost savings from reductions in fall-associated health care service utilization.

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