

**EVIDENCE REPORT
AND EVIDENCE-BASED
RECOMMENDATIONS**

**Falls Prevention Interventions
in the Medicare Population**



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EXECUTIVE SUMMARY

Introduction

Falls are a major health problem among older adults in the United States. One of every three people over the age of 65 years living in the community falls each year, and this proportion increases to one in two by the age of 80 years.¹⁻³

Fall-related injuries in older adults often reduce mobility and independence, and are often serious enough to result in a hospitalization and an increased risk of premature death.⁴ Studies among older persons in the community have found that about 10 percent of the fallers have a serious fall-related injury, including fractures, joint dislocations, or severe head injuries.⁵⁻⁷ Falling has also been found to be associated with subsequent admission to a nursing home.⁸

The costs of health care associated with fall-related injuries and fractures, including hip fractures, are staggering. The total direct cost of all fall injuries in older adults in 1994 was \$20.2 billion and is estimated to reach \$32.4 billion by 2020.⁹ Medicare costs for hip fractures were estimated in 1991 to be \$2.9 billion.¹⁰ With an aging population and a growing number of hip fractures, these cost estimates are projected to rise to as high as \$240 billion by the year 2040.¹¹

Clearly, the prevention of falls is an important issue if it can prevent significant declines in function and independence, and the associated increase in costs of complications. The major risk factors for falling are diverse, and many of them--such as balance impairment, muscle weakness, polypharmacy, and environmental hazards-- are potentially modifiable.³ However, the interventions designed to address these risk factors share the same diversity. Likewise, the evidence for the effectiveness of a single intervention in preventing falls has been inadequate.¹² Since the risk of falling appears to increase with the number of risk factors,³ multifactorial interventions have been suggested as the most effective strategy to reduce falling.

Heretofore, numerous interventions have been studied in the prevention of falls. 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, the results of which are detailed in this report. For this report, CMS asked us to provide evidence in response to the following questions:

1. Are falls prevention programs effective? What are the key components that should be included in a falls prevention intervention? Are multifactorial

- approaches more effective than single intervention approaches?
2. Are public information or education campaigns alone effective in reducing or preventing falls?
 3. Which care settings/approaches have been more effective than others for the delivery of falls prevention interventions? Which providers should deliver this service?
 4. What are the key issues in sustaining falls prevention programs?
 5. Cost effectiveness or cost savings—Do falls prevention interventions appear to reduce health care costs by reducing disease, physician office visits, hospitalizations, nursing home admissions, etc.?
 6. Should falls prevention programs be targeted toward high-risk individuals? Are there a few basic questions to identify these individuals? Can this be done through self-identification?
 7. Are there specific falls prevention exercises recommended for seniors?
 8. Are falls prevention programs acceptable to seniors?

Methods

For our systematic review, we classified intervention components that can be used to prevent falls among persons age 65 or older into the following broad categories:

Exercise:

General Physical Activity. Includes non-physiotherapy activity -- for example walking, cycling, aerobic movements, and other endurance exercises.

Specific Physical Activity. Includes training geared specifically towards balance, strength, or gait.

Multifactorial falls risk assessment and management program. This can include a focused post-fall assessment or a systematic risk-factor screening among at-risk individuals tied to interventions and follow-up for the risks uncovered. A multifactorial falls risk assessment and management program consists of three components: 1) a questionnaire to identify risk factors for falls, which can be self-administered or administered by a professional; 2) a thorough medical evaluation (including examination of vision, gait, balance, strength, postural vital signs, medication review, cognitive and functional status); and 3) follow-up interventions, that may include a tailored exercise program, environmental modifications, and assistive devices.

Education. Educational efforts can be directed toward an individual, group, or entire community. Pamphlets and posters can raise awareness among older adults or staff members at senior centers and nursing homes. More intense interventions include one-to-one counseling about risk factors.

Assistive Devices. These include canes and walkers.

Medication / Medication Review. This category includes two approaches. First, physicians can review patient records to evaluate whether side effects of any medication

may contribute to falls. Second, hormone replacement therapy, calcium, and vitamin D can be used to increase muscle or bone strength in an effort to prevent falls.

Environmental Modification. Environmental modification often includes home visits to older adults living in the community. Professionals examine the environment for hazards such as poor lighting, sliding carpets, and slippery floors. Recommended modifications include installing grab bars, placing bath mats in the shower, and keeping a working flashlight at home.

Staff / Organization Related. These interventions most often take place in hospitals and nursing homes. A falls-prevention specialist may visit a facility and make recommendations, including patient-reminder bracelets, bed alarms, and restraints.

In addition to conducting an extensive library search, we used literature from RAND's Assessing the Care of Vulnerable Elders (ACOVE) project, the Cochrane Collaboration, the American Physical Therapy Association (APTA), CMS, and the American Geriatrics Society (AGS) Falls Guidelines Taskforce. When articles arrived, we reviewed each reference list in order to find additional relevant literature.

We reviewed the articles retrieved from the literature searches against exclusion criteria to determine whether to include articles in the evidence synthesis. To be accepted for inclusion, a study had to be either a randomized controlled trial (RCT) or a controlled clinical trial (CCT).

We abstracted data from the articles on a specialized Quality Review Form (QRF). The form contained 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 Dr. Laurence Rubenstein, an expert on falls prevention and Principal Investigator of the Healthy Aging Project. Two physicians, working independently, extracted data in duplicate and resolved disagreements by consensus.

We entered all data on outcomes and interventions into the statistical programs SAS¹³ and Stata.¹⁴ Our summary of the evidence is both qualitative and quantitative. For questions on effectiveness, we conducted two meta-analyses using statistical pooling and meta-regression. The first analysis was on the outcome “falling at least once” during a specified follow-up period and was measured using a risk ratio. The second analysis was of the outcome “monthly rate of falling,” which was calculated from the mean number of falls per person and the follow-up time, and which was measured with an incidence rate ratio. Our approach is described in detail in the Methods Section of the main report.

Results

In total, the above mentioned sources yielded 851 articles, of which we were able to obtain 826 for the screening process.

Of the 826 articles screened, 73 did not discuss falls prevention. Six hundred twenty-eight were rejected because they were not RCTs or CCTs. Another 16 articles were duplicates of articles already on file. Thirteen others did not include outcomes; i.e. they were simply descriptions of a falls prevention program. One did not report on a study population of the appropriate age. Eliminating these articles left 95 articles for quality review.

On detailed review of these 95 articles, we rejected 38 that did not have falls outcomes or reported falls as a secondary outcome of an intervention whose primary goal was something else (such as hormone replacement therapy). Thus 57 articles were considered for meta-regression analysis. Three of the 57 studies were excluded either because they presented the data in aggregate or did not provide data on outcomes by intervention or control group. Additionally, seven of the 65 studies were rejected as duplicate publications from the same study population (only one report of a particular intervention and study population could be included in the meta-analyses). Another 6 studies were rejected as being of the wrong intervention type for our conceptual model. Studies were included in the meta-analyses if the study reported data on either “subjects who fell at least once during the study period” and the study included follow-up data at a time point between six and 18 months after the baseline; or “mean number falls per subject.” These last criteria excluded two studies.

QUESTION 1. ARE FALLS PREVENTION PROGRAMS EFFECTIVE? WHAT ARE THE KEY COMPONENTS THAT SHOULD BE INCLUDED IN A FALLS PREVENTION INTERVENTION? ARE MULTIFACTORIAL APPROACHES MORE EFFECTIVE THAN SINGLE INTERVENTION APPROACHES?

Our meta-analyses support the effectiveness of falls prevention programs at reducing both the number of older adults who fell and the monthly rate of falling per person. The pooled risk ratio from 20 randomized clinical trials was 0.89, 95% CI [0.81, 0.98], indicating the interventions in these studies are significantly associated with a reduced risk of falling. We also pooled data in 26 randomized clinical trials and determined the incidence rate ratio was 0.77, 95% CI [0.68, 0.87], indicating these interventions are significantly associated with a reduced number of falls per person.

We did not find any clinical trials that directly compared the effectiveness of single component falls intervention programs (for example, a trial comparing environmental modification with exercise.) To assess the relative effectiveness of intervention components, we entered all studies in meta-regression models to assess the effect of individual intervention components while controlling for other intervention components and study level differences. While there were no statistically significant differences among components, there was a clear trend that a multifactorial falls risk assessment and management program was highly effective and appeared to be the most effective intervention. The most commonly assessed risks in such programs were medication review, vision, environmental hazards, and orthostatic blood pressure. Exercise was the next most effective intervention component. There was no evidence that environmental modification or education were effective as independent components, but the paucity of studies precludes firm conclusions. There were no data regarding the independent effects

of other components in our conceptual model (assistive devices, medication review, and staff/organizational changes). As nearly all interventions were to some extent multifactorial, it was not possible to directly test the relative effectiveness of multifactorial versus single component approaches.

QUESTION 2. ARE PUBLIC INFORMATION OR EDUCATION CAMPAIGNS ALONE EFFECTIVE IN REDUCING OR PREVENTING FALLS?

We found no specific studies about the effectiveness of public information or mass education campaigns. In the meta-regression analyses, patient education given as part of multifactorial falls prevention programs did not show a significant independent effect.

QUESTION 3. WHICH CARE SETTINGS/APPROACHES HAVE BEEN MORE EFFECTIVE FOR THE DELIVERY OF FALLS PREVENTION INTERVENTIONS? WHICH PROVIDERS SHOULD DELIVER THIS SERVICE?

Successful interventions have been conducted in physician offices, patient homes, hospitals, nursing homes, community centers and specialized research centers. No evidence currently exists to advocate for increased effectiveness based on care setting. Successful falls-prevention interventions have been provided by exercise leaders, nurses, physical therapists, social workers, and teams of multiple providers. Insufficient evidence currently exists to conclude that one provider type is preferable over another.

QUESTION 4. WHAT ARE THE KEY ISSUES IN SUSTAINING FALLS PREVENTION PROGRAMS?

There are two key issues in sustaining falls prevention programs – insufficient funding and lack of available programs. The interventions reviewed in this report were performed through the use of special funding from research grants or demonstration projects, and none of them were continued as regular programs. Funding seems to be needed to sustain falls prevention programs and would be required to bring about the widespread use of such effective interventions as supervised exercise programs and multifactorial fall risk assessments and management.

QUESTION 5. COST EFFECTIVENESS OR COST SAVINGS: DO FALLS PREVENTION INTERVENTIONS APPEAR TO REDUCE HEALTH CARE COSTS BY REDUCING DISEASE, PHYSICIAN OFFICE VISITS, HOSPITALIZATIONS, NURSING HOME ADMISSIONS, ETC.?

Whether a falls prevention intervention is cost effective or cost saving is a function of many parameters including the targeted population, the environment where the targeted population resides, the effectiveness of the intervention due to design and implementation, the effect of time, the account of benefits and costs, the perspective of costing, and the selection of comparator. We found 15 studies of cost-effectiveness with substantial heterogeneity in these parameters. Thus, we were unable to compare the relative cost-effectiveness by type of intervention or draw definitive conclusions about the economic impact of falls prevention interventions. Common threats to the validity of cost-effectiveness analyses in the studies included 1) the highly selective trial population (which results in “cost-efficacy” instead of “cost-effectiveness” findings and unknown

generalizability); 2) lack of a clear perspective in accounting costs and benefits; and 3) inadequate sample size (which causes the health care cost and utilization outcomes to be substantially influenced by a few outliers).

Overall, the evidence is not conclusive but suggests that an effective intervention provided to people with a high risk of falling has the potential to be cost-effective or even cost saving compared with current practice. Further research is needed before informing policy-makers about which intervention is effective for what population, and such research should use sound methodology to provide more solid evidence of the cost-effectiveness.

We made estimates of the potential cost-effectiveness of a new Medicare benefit, a falls prevention rehabilitation program, that combines multifactorial assessment of falls risk with individually tailored recommendations and a supervised exercise program. We assumed that Medicare would pay \$95 for the initial multifactorial assessment, and that 60% of these people would subsequently be eligible for an eight session, six week supervised exercise program reimbursed at \$280. All patients would also need one follow-up visit dedicated to assuring that recommendations were being implemented, reimbursed at \$40. We used existing data regarding the number of people aged 65 and over, the annual number of falls with injury in this population, the mean cost of a fall with injury, and our pooled estimate of the effectiveness of a multifactorial falls risk assessment and management program. This analysis was not sophisticated, yet still instructive. Under these assumptions, a falls prevention rehabilitation program would have a net cost to Medicare of \$272 million annually, and would avert 542,000 falls with injury, or about \$500 per fall averted. This supports the hypothesis that falls prevention programs may be cost-effective by reducing health care costs due to injuries.

QUESTION 6. SHOULD FALLS PREVENTION PROGRAMS BE TARGETED TOWARD HIGH RISK INDIVIDUALS? ARE THERE A FEW BASIC QUESTIONS TO IDENTIFY THESE INDIVIDUALS? CAN THIS BE DONE THROUGH SELF-IDENTIFICATION?

Existing data support that identifiable risk factors exist for falls. These risk factors can be identified using basic questions and a physical examination. However, we assessed the effectiveness of what had proven to be the two most effective interventions, exercise and a multifactorial falls risk assessment and management program, in high-risk and non-high-risk populations. Estimates of efficacy were not statistically or clinically different from each other, which prevents us from concluding whether falls prevention programs are more effective in high risk compared to non-high risk populations.

That being said, interventions targeted to high and low risk populations have been different in most studies. For example, post-fall assessments and low-intensity exercise programs have been mostly targeted to frail and high-risk populations, while high intensity exercise programs have been targeted to broader populations (often excluding high-risk participants because of poor endurance). Therefore, comparing trials that focused on either high or low risk populations is not possible without some confounding by intervention variation.

Though not proven, it makes clinical and scientific sense that comprehensive post-fall assessments and fall risk assessments should be targeted to persons at higher risk. Because of their increased fall risk, they have the most to gain and would tend to have the largest effect size. In terms of identifying individuals at high risk for falls, there are a number of instruments, of varying length and complexity, with greater and lesser degrees of sensitivity and overall accuracy. From a practical standpoint, a simple identifier or set of questions is better, as long as it is reasonably accurate. With this in mind, the American Geriatrics Society evidence-based clinical guideline for prevention of falls recommended the following persons to have a comprehensive fall evaluation (risk assessment): 1) older persons presenting for medical attention with one or more falls, 2) older persons who report recurrent falls (2 or more in a 6 month period), or 3) older persons with abnormalities of gait and/or balance.

QUESTION 7. ARE THERE SPECIFIC FALLS PREVENTION EXERCISES RECOMMENDED FOR SENIORS?

Exercise is effective in falls prevention programs. Our meta-analyses showed that exercise interventions reduced the risk of falls by 12% (pooled risk ratio: 0.88, 95% CI [0.78, 1.00]), and the number of falls by 19% (pooled incidence rate ratio: 0.81, 95% CI [0.72, 0.92]). Falls prevention programs using exercise typically included one or more of the following: cardiovascular endurance, muscular strength, flexibility, and balance. While both the FICSIT meta-analysis and our meta-analysis showed some trends in differing effectiveness among exercises, these differences were not consistent and not statistically significant. Therefore, while there are compelling data to recommend exercise in general, there are no conclusive data to recommend particular falls prevention exercises.

QUESTION 8. ARE FALLS PREVENTION PROGRAMS ACCEPTABLE TO SENIORS?

We did not find any direct evidence that answered this question, either in the form of surveys, focus groups, or other methods that directly assess the general acceptability of falls prevention interventions among seniors. Some indirect evidence can be obtained from the clinical trials of falls prevention interventions. About half of the studies reported the "refusal rate" of those contacted and eligible for the intervention. These figures represent a mix of studies that attempted to enroll subjects from large populations or small specialty clinics, and hence variation in the "refusal rates" may represent differences in the stages of "readiness to change" of various populations. Furthermore, this refusal rate includes people who refuse for reasons other than the acceptability of the intervention; for example, people may refuse to participate in any clinical trial because they equate this with "experimentation." With these caveats in mind, we calculated an average "refusal rate" of 30.5 percent. Furthermore, among the studies that reported both the number of persons beginning the study and those completing the study, the average "dropout" rate was 16 percent. Taken together, these data suggest that the proportion of seniors for whom falls prevention programs are acceptable, while not precisely known, is likely substantial.

Limitations

The primary limitation of this systematic review, common to all such reviews, is the quantity and quality of the original studies. Heterogeneity is another major issue. Even more so than in reviews of single therapies (e.g., coronary revascularization for coronary artery disease, pharmaceutical therapy for rheumatoid arthritis), the studies presented here are heterogeneous in terms of the interventions tested and populations included. Furthermore, many of the study-level variables are highly idiosyncratic and inter-correlated (e.g., all studies of restraints take place in institutions). Many interventions have multiple components, making the assessment of the effect of the individual components challenging. Furthermore, the populations studied were heterogeneous in that some enrolled population-based samples of patients, while others enrolled attendees at a special clinic or even respondents to advertisements. Also, our assessment of the relative effectiveness of individual components was made using indirect methods, as we did not find any direct comparisons of individual components. Such indirect comparisons are not as powerful as direct comparisons. However, the convergent results of our two meta-analyses lend validity to our conclusions.

We gave equal importance to all studies that met our minimum criteria (RCTs that measured the percent of a group with at least one fall or the number of falls per person). We made no attempt to give greater importance to some studies based on "quality." The only validated assessment of study quality includes criteria not possible in falls prevention trials (double-blinding). As there is a lack of empirical evidence regarding other study characteristics and bias, we did not attempt to use other criteria.

Our results regarding exercise need to be interpreted in light of the results of the pre-planned meta-analysis of the FICSIT trials. One of the original eight FICSIT studies was excluded from this pre-planned meta-analysis as it did not have a relevant treatment arm and we also excluded it from our analysis. The FICSIT meta-analysis¹⁵ included seven RCTs that assessed a variety of exercise interventions, including endurance, flexibility, platform balance, Tai Chi, and resistance. This meta-analysis used individual patient-level data. We could include only two of the individual FICSIT trials in one of our meta-analyses ("subjects who fell at least once").^{16, 17} Six of the FICSIT studies did contribute data to our second meta-analysis, one was excluded due to insufficient statistics. Our results are in general agreement with the central FICSIT meta-analysis result: exercise programs help prevent falls (FICSIT pooled effect: 0.9, 95% CI [0.81 – 0.99]; our pooled effect for percent with at least one fall: 0.89, 95% CI [0.81 – 0.98] and for monthly rate of falling: 0.77, 95% CI [0.68, 0.87]). FICSIT also reported pooled effects for balance that were greater than (but not statistically different from) the overall effect. Our analysis assessing monthly rate of falling also found this result, however our analysis assessing number of subjects who fell at least once did not.

Regarding study populations, few studies of falls prevention stratified results by gender or ethnicity. Most studies either did not report the ethnic composition of the sample or used predominantly Caucasian samples. Thus, without further evidence, it should not be assumed such interventions will be similarly effective among all ethnic groups.

Conclusions

1. Falls prevention programs as a group have been shown to reduce the risk of experiencing a fall by 11% and monthly rate of falling by 23%.
2. Because few studies of single falls prevention interventions exist, statistical models were used to examine the independent effects of the four interventions with sufficient evidence to synthesize – multifactorial falls risk assessment and management; exercise; environmental modification; and education. Evidence supports a multifactorial falls risk assessment and management program as the most effective intervention. Exercise is the next most effective independent intervention. Thus, the evidence suggests that to be successful, falls prevention interventions should either use a multifactorial falls risk assessment and management program or exercise. However, the best approach to preventing falls is likely to use both a multifactorial falls risk assessment and management program along with exercise.
3. Falls risk assessments must be coupled with individually-tailored follow-up interventions to be effective.
4. Risk factor identification, which is one component of a multifactorial falls risk assessment and management program, may be self administered or administered by a professional. Both population-based public health approaches and medical model approaches are effective.
5. Our meta-analyses showed that exercise interventions reduce the risk of falls by 12% and the number of falls by 19%. While numerous exercise programs have been recommended to help prevent falls, there are insufficient data to identify the most effective exercises.
6. Successful falls prevention interventions have been delivered by a variety of providers, including exercise instructors, nurses, physical therapists, social workers, and teams of multiple providers. There is currently insufficient evidence to conclude that one provider type is preferable over another.
7. While not conclusive, the evidence suggests that falls prevention programs provided to seniors have the potential to be highly cost-effective compared with current practice. We estimate that a falls prevention rehabilitation program as a new Medicare benefit would be highly cost effective (even cost-saving in persons older than age 75) by preventing Medicare costs from injuries due to falls.
8. In the absence of new resources, it seems unlikely that much progress will be made in getting seniors to receive the benefits of falls prevention activities.

Recommendations

1. There is strong evidence that falls prevention programs are effective at preventing falls, and therefore ways are needed to better integrate these programs into the current care received by seniors.
2. There is strong evidence to support adding a falls prevention rehabilitation program as a new Medicare benefit. Such a program would be eligible to beneficiaries who have fallen, and would encompass a multifactorial risk assessment with a supervised exercise program.

INTRODUCTION

Falls are a major health problem among older adults in the United States. One of every three people over the age of 65 years living in the community falls each year, and this proportion increases to one in two by the age of 80 years.¹⁻³

Fall-related injuries in older adults often reduce mobility and independence and are often serious enough to result in a hospitalization and an increased risk of premature death.⁴ Studies among older persons in the community have found that about 10 percent of the fallers have a serious fall-related injury, including fractures, joint dislocations, or severe head injuries.⁵⁻⁷ Falling has also been found to be associated with subsequent admission to a nursing home.⁸

The costs of health care related to fall-related injuries and fractures, including hip fractures, are staggering. The total direct cost of all fall injuries in older adults in 1994 was \$20.2 billion and is estimated to reach \$32.4 billion by 2020.⁹ Medicare costs for hip fractures were estimated in 1991 to be \$2.9 billion.¹⁰ With an aging population and a growing number of hip fractures, these cost estimates are projected to rise to as high as \$240 billion by the year 2040.¹¹

The causes of falls are diverse and complex. Older adults often have several predisposing risk factors, many as a result of chronic diseases and age-related physiologic changes. The contribution of each risk factor depends on the medical and environmental factors themselves. Some of the common medical conditions that may contribute to falling and also tend to be more prevalent in older adults include impaired vision, dizziness, parkinsonism, transient ischemic attacks, hypotension, arrhythmia, incontinence, osteoarthritis, muscle weakness, osteoporosis, hypothyroidism, anemia, dehydration, depression, dementia, and polypharmacy. Some of the common environmental factors that may contribute to falling include hazardous floors, slippery bathtubs, low toilet seats, lack of grab bars, insecure carpets, and poor lighting. All older persons are at risk, regardless of activity level. While the majority of falls do not result in a serious injury, falls tend to recur, and the subsequent fear of falling often leads to restrictions in activity and functional decline.¹⁸

Several key risk factors for falling (such as balance impairment, muscle weakness, polypharmacy, and environmental hazards) are potentially modifiable.³ However, the interventions designed to address these risk factors share the same diversity. Likewise, the evidence for the effectiveness of any single intervention on the prevention of falls has been inadequate.¹² Since the risk of falling appears to increase with the number of risk factors,³ multifactorial interventions have been suggested as the most effective strategy to reduce falling. A few multifactorial interventions have shown some reduction in the risk of falling among elderly in the community,¹⁶ but more evidence on the reduction in the rate of falls is needed. While numerous interventions have been studied in the prevention of falls, results have been mixed and there is still uncertainty as to which interventions are clinically effective or cost-effective, or what kind or combination of interventions should be included in a program to prevent falls.

The prevention of falls is an important issue if it can prevent significant declines in function and independence and the associated increased costs of complications. To better understand 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 aimed at preventing falls; the results of this review are detailed in this report.

METHODS

We synthesized evidence from the scientific literature on effectiveness of falls prevention 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).¹⁹
- 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.

The following are broad categories of interventions that can be used to prevent falls among persons age 65 or older:

- exercise:
 - general physical activity
 - specific physical activity
- education
- assistive devices
- medication / medication review
- environmental modification
- organizational / staff related changes
- multifactorial falls risk assessment and management program, which can incorporate several of the components listed above.

These interventions are described below:

Exercise:

General Physical Activity. Includes non-physiotherapy activity - for example, walking, cycling, aerobic movements and other endurance activities.

Specific Physical Activity. Includes training geared specifically towards balance, strength, or flexibility.

Education. Educational efforts can be directed toward an individual, group, or entire community. Pamphlets and posters can raise awareness among older adults or staff members at senior centers and nursing homes. More intense interventions include one-on-one counseling about risk factors.

Assistive Devices. These include canes, walkers, and hip pads.

Medication / Medication Review. This category includes two approaches. First, physicians should review patient records to evaluate whether side effects of any medication may contribute to falls. Second, treatment with hormone replacements, calcium, and vitamin D can be used to increase strength in an effort to prevent falls.

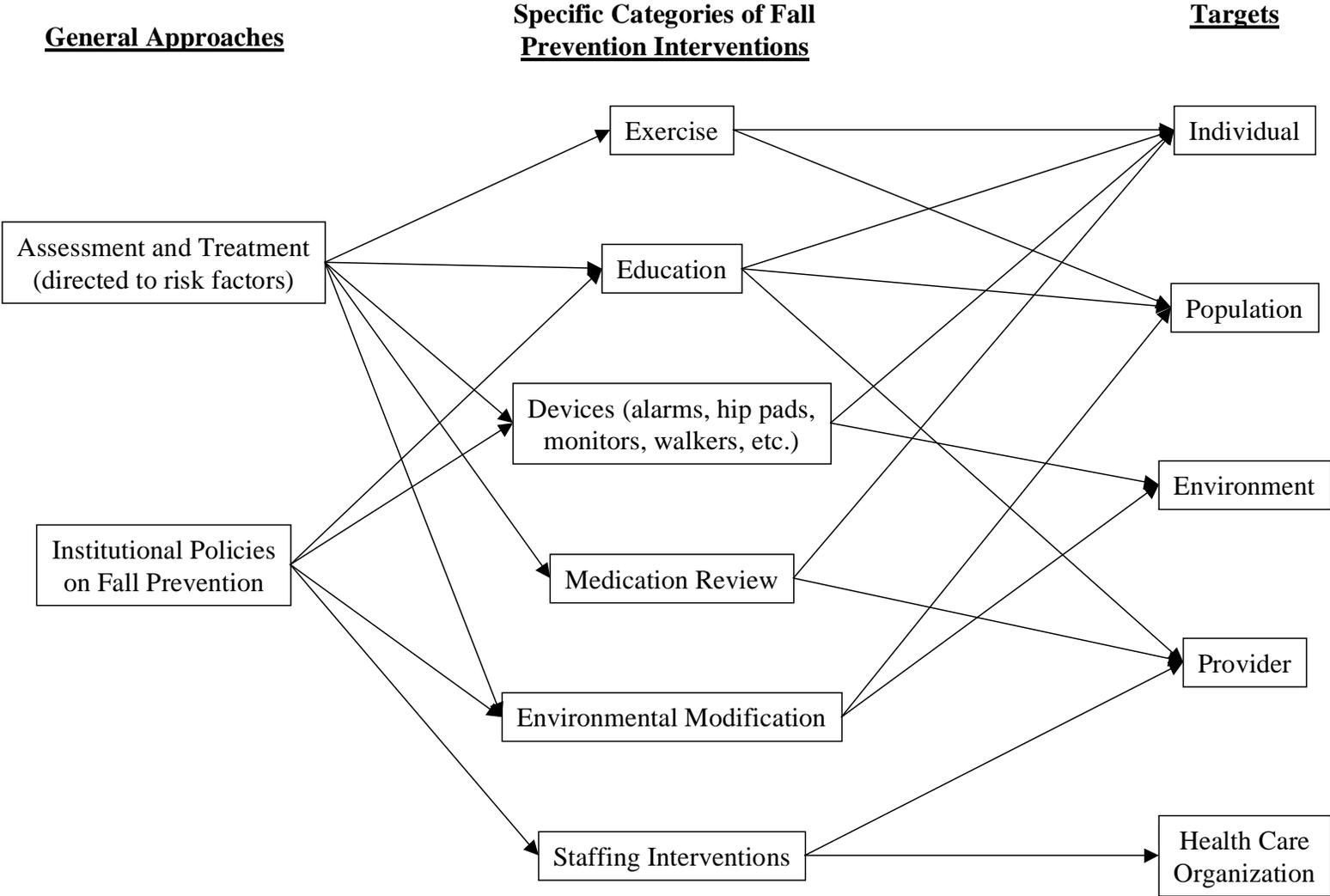
Environmental Modification. Environmental modification often begins with home visits to older adults living in the community. Professionals examine the environment for hazards such as poor lighting, sliding carpets, and slippery floors. Recommended modifications include installing grab bars, placing bath mats in the shower, and keeping a working flashlight at home.

Staff / Organization Related. These interventions most often take place in hospitals and nursing homes. A falls prevention specialist may visit a facility and make recommendations, including patient reminder bracelets, bed alarms, and restraints.

The relationships of these broad categories of falls prevention interventions to potential targets (individual, provider, etc.), which form our conceptual model, are shown in Figure 1.

A multifactorial falls risk assessment and management program consists of three components: 1) a questionnaire to identify risk factors for falls, which can be self-administered or administered by a professional; 2) a thorough medical evaluation (including examination of vision, gait, balance, strength, postural vital signs, medication review, cognitive and functional status); and 3) follow-up interventions, including a tailored exercise program, and possibly environmental modifications and assistive devices.

Figure 1. Conceptual Model



Identification of Literature Sources

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

ASSESSING THE CARE OF VULNERABLE ELDERLY PROJECT

RAND's Assessing the Care of Vulnerable Elders (ACOVE) project was charged with developing tools to measure the quality of care in several areas. As part of this project, RAND conducted a literature review regarding potential quality indicators for falls and mobility disorders among older adults.²⁰ All articles referenced therein were screened for possible inclusion in this 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 health 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 one meta-analysis on falls prevention;¹² we obtained all studies referenced therein. In addition, we conducted a library search for all falls studies published after this meta-analysis, using the Cochrane search terms listed below.

Table 1. Literature Search Terms

<p>In MEDLINE, the first two sections of the optimal MEDLINE search strategy (Dickersin et al 1994) were applied along with the following specific search terms :</p> <ol style="list-style-type: none">1. Fall*2. Elderly3. Aged4. Older5. Senior*6. exp ACCIDENTAL FALLS/7. (2 or 3 or 4 or 5) and (1 or 6)
<p>In CINAHL, the search strategy was:</p> <ol style="list-style-type: none">1. exp clinical trials/2. (clin: adj 10 trial:) ti, sh, ab, it.3. ((singl: or doubl: or trebl: or tripl:):adj10 (blind: or mask:)).ti,sh,ab, it4. placebo: (ti)5. placebo: (ab)6. random: (ti)7. random: (ab)8. exp "study design (non-cinahl)"/9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 810. comparative studies/11. exp evaluation research/12. exp prospective studies/13. (control: or prospective: or volunteer:).ti,sh,ab,it.14. 10 or 11 or 12 or 1315. 14 not 916. aged/17. (elderly or older or senior). ti, sh, ab, it.18. exp accidental falls/19. (fall: not fall).ti,sh,ab,it.20. 16 or 1721. 18 or 1922. 20 and 2123. 9 and 2224. 15 and 22

AMERICAN PHYSICAL THERAPY ASSOCIATION

The American Physical Therapy Association (APTA) is a national professional organization representing more than 66,000 physical therapists, physical therapy assistants, and students. Its goal is to foster advancements in physical therapy practice, research, and education. The APTA expressed interest in our falls prevention project and sent a list of articles (with abstracts) that they thought might be of interest.

HEALTH CARE QUALITY IMPROVEMENT PROJECTS (HCQIP)

Each U.S. state and territory is associated with a Medicare Quality Improvement Organization (QIO), also known as a Peer Review Organization, that conducts various research projects. CMS maintains a database with a narrative description of each research

project, called a Narrative Project Document (NPD). An NPD includes the aims, background, quality indicators, collaborators, sampling methods, interventions, measurement, and results of a project. Our search of the NPD database for studies on falls prevention identified two studies.

AMERICAN GERIATRICS SOCIETY

The American Geriatrics Society (AGS) is a professional organization of over 6,000 health care providers dedicated to improving the health and well-being of all older adults. The AGS was in the process of producing a clinical practice guideline on falls prevention while we were completing this report.²¹ Our Principal Investigator served as Co-Chair of their expert panel. Our literature search provided AGS with initial articles reviewed for their guideline; they agreed to send us new articles they identified.

PREVIOUS REVIEWS AND BACKGROUND ARTICLES

We identified 73 other previously completed reviews relevant to this project (see Table 2). Each review discusses, among other things, at least one intervention aimed at falls prevention. We retrieved all relevant documents referenced in these publications.

Table 2. Review and Background Articles

Biomechanics: human locomotion and gait training. Rehabil Rd Prog Rep 1995 32:36-50.

Preventing falls and further injury in older people. Nursing Standard 1996 10:(47)32-33.

Preventing falls in elderly. Physiother Frontline 1997 3:(23)18.

Aguilar JJ, Santos FJ, Usabiaga T, Renau E, San Segundo R, Galvez S. Physical exercise and prevention of osteoporosis. Review [Spanish]. Rehabilitacion 1999 33:(3)195-9.

American Medical Directors Association. Falls and Fall Risk. Clinical Practice Guideline 1998. AMA; 1998.

Askham J, Glucksman E, Owens O, Swift C, Tinker A, Yu G. A Review of Research on Fall Among Elderly People. London: Age Concern Institute of Gerontology; 1990.

Askham J, Glucksman E, Owens O, Swift C, Tinker A, Yu G. A review of research on falls among elderly people. London: Age Concern Institute of Gerontology; 1990.

Baraff LJ, Della Penna R, Williams N, Sanders A. Practice guideline for the ED management of falls in community-dwelling elderly persons. Kaiser Permanente Medical Group. Ann Emerg Med 1997 30:(4)480-92.

Brown AP. Reducing falls in elderly people: A review of exercise interventions. Physiother Theory Pract 1999 15:(2)59-68.

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- Buchner D, Cress ME, Wagner EH, de Lateur BJ . The role of exercise in fall prevention: Developing targeting criteria for exercise programs. In: Vellas B, Toupet M, Rubenstein L, Albaredo JL, Christen Y. (Eds.) Falls, balance, and gait disorders in the elderly. Amsterdam: Elsevier; 1992. p. 55-68.
- Campbell AJ. Role of rehabilitation in fall recovery and prevention. *Rev Clinical Gerontol* 1992 2:(1)53-65.
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- Campbell JA. Drug treatment as a cause of falls in old age. A review of offending agents. *Drugs Aging* 1991 1:289-302.
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- Edwards N. A structured and individualised safety programme reduced falls in high risk nursing home patients. *Evid Based Nurs* 1998 1 :(2)52.
- Evans D, Hodgkinson B, Lambert L, Wood J. Fall prevention: A systematic review. *Clinical Effectiveness in Nursing* 1999 3:106-111.
- Evans D, Hodgkinson B, Lambert L, Wood J. Falls risk factors in the hospital setting: a systematic review. *Int J Nurs Pract* 2001 7:(1)38-45.
- Feder G, Cryer C, Carter Y. Guidelines for the prevention of falls in people over 65. *BMJ* 2000 321:(7267)1007.
- Fitzsimmons A, Freundlich B, Bonner F. Osteoporosis and rehabilitation. *Crit Rev Phys Rehabil Med* 1997 9:(3/4)331-53.
- Fletcher A. Multidimensional assessment of elderly people in the community. *Br Med Bull* 1998 54:(4)945-60.
- Gardner MM, Buchner DM, Robertson C, Campbell AJ. Practical implementation of an exercise-based falls prevention programme. *Age and Ageing* 2001 30:77-83.

Table 2. Review and Background Articles

- Gardner MM, Robertson MC, Campbell AJ. Exercise in preventing falls and fall related injuries in older people: a review of randomised controlled trials. *Br J Sports Med* 2000 34:(1)7-17.
- Gillespie LD, Gillespie WJ, Cumming R, Lamb SE, Rowe BH. Interventions for preventing falls in the elderly. In: *The Cochrane Library*, Issue 3. 2002.
- Gillies D. Elderly trauma: they are different. *Aust Crit Care* 1999 12:(1)24-30.
- Hayes N. A risk assessment score predicted which elderly patients would fall during a hospital stay. *Evid Based Nurs* 1998 1:(3)90.
- Hill-Westmoreland EE, Soeken K, Spellbring AM. A meta-analysis of fall prevention programs for the elderly: how effective are they? *Nurs Res* 2002 51:(1)1-8.
- Hillsdon M, Thorogood M, Anstiss T, Morris J. Randomised controlled trials of physical activity promotion in free living populations. *J Epidemiol Community Health* 1995 49:448-453.
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- King MB, Tinetti ME. Falls in community-dwelling older persons. *J Am Geriatr Soc* 1995 43:1146-1154.
- King MB, Tinetti ME. A multifactorial approach to reducing injurious falls. *Clin Geriatr Med* 1996 12:(4)745-59.
- Lacroix AZ. Thiazide diuretic agents and prevention of hip fracture. *Compr Ther* 1991 17:(8)30-9.
- Lange M. The challenge of fall prevention in home care: A review of the literature. *Home Healthcare Nurse* 1996 14:(3)198-206.
- Lauritzen JB. Hip fractures. Epidemiology, risk factors, falls, energy absorption, hip protectors, and prevention. *Dan Med Bull* 1997 44:(2)155-68.
- Leipzig RM, Cumming RG, Tinetti ME. Drugs and falls in older people: a systematic review and meta-analysis: I. Psychotropic drugs. *J Am Geriatr Soc* 1999 47:(1)30-39.
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- Lewis RD, Modlesky CM. Nutrition, physical activity, and bone health in women. *Int J Sport Nutr* 1998 8:(3)250-284.
- Mahoney JE. Immobility and falls. *Clin Geriatr Med* 1998 14:(4)699-726.
- Maki BE, McIlroy WE. Control of compensatory stepping reactions: age-related impairment and the potential for remedial intervention. *Physiother Theory Pract* 1999 15:(2)69-92.

Table 2. Review and Background Articles

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- Monane M, Avorn J. Medications and Falls. Causation, correlation and convention. *Clin Geriatr Med* 1996 12:847-858.
- Myers AH, Young Y, Langlois JA. Prevention of falls in the elderly. *Bone* 1996 18:(1 Suppl)87S-101S.
- Nakamura DM, Holm MB, Wilson A. Measures of balance and fear of falling in the elderly: a review. *Phys Occup Ther Geriatr* 1998 15:(4)17-32.
- Newbury J, Marley J. Preventive home visits to elderly people in the community. Visits are most useful for people aged ≥ 75 . *BMJ* 2000 321:(7259)512; discussion 513.
- Nicholl JP, Coleman P, Brazier JE. Health and healthcare costs and benefits of exercise. *Pharmacoeconomics* 1994 5:109-122.
- Nichols AW. Moderate exercise improves stability in elders. *Phys Sportsmed* 1999 27:(11)16-28.
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- Oakley AE, France Dawson M, Holland J, Arnold S, Cryer C, Doyle Y, et al. Preventing falls and subsequent injury in older people. *Qual Health Care* 1996 5:243-9.
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- Overstall PW. Prevention of falls in the elderly. *J Am Geriatr Soc* 1980 28:(11)481-4.
- Perle SM, Mutell DB, Romanelli R. Age-related changes in skeletal muscle strength and modifications through exercise: A literature review. *J Sports Chiro Rehab* 1997 11:(3)97-103.
- Perry BC. Falls among the elderly: a review of the methods and conclusions of epidemiologic studies. *J Am Geriatr Soc* 1982 30:(6)367-71.
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- Rhymes J, Jaeger R. Falls: Prevention and management in the institutional setting. *Clinics Geriatr Med* 1988 4:613-622.
- Robertson MC, Campbell AJ, Gardner MM, Devlin N. Preventing injuries in older people by preventing falls: a meta- analysis of individual-level data. *J Am Geriatr Soc* 2002 50:(5)905-11.
- Rubenstein L, Robbins A, Josephson K, Tureblood P, Wallis RA, Loy S. Effects of an exercise intervention on fall-prone elderly men. *J Am Geriatr Soc* 1994 149:(suppl)SA5.

Table 2. Review and Background Articles

- Rubenstein LA, Robbins AS, Schulman BL, et al . Falls and instability in the elderly. *J Am Geriatr Soc* 1988 36:266-278.
- Rubenstein LZ, Josephson KR, Osterweil D. Falls and fall prevention in the nursing home. *Clin Geriatric Med* 1996 12:(4)881-902.
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- Simpson JM, Marsh N, Harrington R. Guidelines for managing falls among elderly people. *Br J Occup Ther* 1998 61:(4)165-8.
- Skelton DA, Dinan SM. Exercise for falls management: rationale for an exercise programme aimed at reducing postural instability. *Physiother Theory Pract* 1999 15:(2)105-20.
- Smith EL, Tommerup L. Exercise - A prevention and treatment for osteoporosis and injurious falls in the older adult. *J Aging Phys Activity* 1995 3:(2)178-92.
- Snow CM. Exercise effects on falls in frail elderly: Focus on strength. *J Appl Biomech* 1999 15:(1)84-91.
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- Stalenhoef PA, Crebolder H, Knottnerus A, Van Der Horst F. Incidence, risk factors and consequences of falls among elderly subjects living in the community: A criteria-based analysis. *Eur J Public Health* 1997 7:328-334.
- Steinmetz HM, Hobson SJ. Prevention of falls among the community-dwelling elderly: An overview. *Phys Occup Ther Geriatr* 1994 12 :(4)13-29.
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- Udani JK, Ofman JJ. Tai Chi for the prevention of falls in the elderly. *Integr Med* 1998 1:(4)167-169.
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- Weinstein BE, Devons CA. The dizzy patient: stepwise workup of a common complaint. *Geriatrics* 1995 50:(6)42-6, 49.
- Whitney SL, Poole JL, Cass SP. A review of balance instruments for older adults. *Am J Occup Ther* 1998 52:(8)666-71.
- Wolter LL, Studenski SA. A clinical synthesis of falls intervention trials. *Top Geriatr Rehabil* 1996 11:(3)9-19.

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 yes/no questions (Figure 2). 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.

While we were searching primarily for data relevant to the Medicare population, we included studies that contained data on populations under age 65 to avoid loss of potentially useful data. To be accepted for inclusion, we required that 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 forms of health care, 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 forms of health care 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 forms of health care 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 2. Falls Prevention Article 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/VO₂Max, 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

Notes:

Extraction of Study-Level Variables and Results

Using a specialized Quality Review Form (QRF) displayed as Figure 3, 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 Dr. Laurence Rubenstein, an expert on falls prevention and Principal Investigator of the Healthy Aging Project. 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.²² To pass beyond the QRF stage, the studies had to measure falls at least three months after the start of the intervention.

An exploratory meta-regression analysis showed that categorizing components of interventions at the level of detail of the QRF yielded uninformative results due to a high degree of inter-correlation among components (in specific, our overall pooled analysis yielded a statistically significant effect of all components considered together, but no individual component was itself statistically significantly associated with a reduction in falls). Therefore, the interventions were recoded into one of four categories: exercise, environmental modifications, education, or a multifactorial falls risk assessment and management program, (we found too few controlled trials of other interventions to meaningfully pool). This recoding was performed independently by a content expert (Laurence Rubenstein) and a methods expert (Paul Shekelle) with consensus resolution and reflected their assessment of the principal intervention component that was investigated in the study. In order to minimize bias, all articles had their methods section retyped onto plain white paper using the same font without other identifying information (such as author, title, journal or results). This was the only part of the article that was reexamined and recoded. A follow-up assessment showed this attempt at blinding was satisfactory. Dr. Shekelle was not able to associate any of the blinded methods sections with their respective articles, and Dr. Rubenstein was able to identify only two successfully, his own study and one other. These reviewers also judged the intensity of each intervention on a 1-5 scale, using their own expertise in health-related behavior change. For example, exercise interventions that involved one-time recommendations to exercise were judged to be of low intensity, while those involving actual supervised exercise sessions were judged as being higher intensity. Assessments of intensity were made independently, and any differences were resolved by consensus.

Exercise interventions were further classified into four categories: balance, endurance, flexibility, and strength. This classification was done by all four physicians and based on the description of the exercise information in the article. “Brisk walking” was classified as endurance exercise.

Figure 3. Falls Prevention Article Quality Review Form

Article ID: _____	Reviewer: _____
First Author: _____ <small style="text-align: center;">(Last Name Only)</small>	
Study Number: _____ of _____ Date of Publication: _____ <small style="text-align: center;">(Enter '1 of 1' if only one)</small>	
Description (if more than one study): _____	

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

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

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

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

4. Is the study described as randomized? (circle one)
 - Yes..... 1
 - No 2

5. If the study was randomized, what was the unit of randomization? (circle one)
 - Patient..... 1
 - Provider 3
 - Organization (practice, hospital, HMO)..... 4
 - Community 5
 - Other (specify: _____) 6
 - Not reported..... 8

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

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

8. Is the study described as: (circle one)
 - Double blind..... 1
 - Single blind, patient 2
 - Single blind, outcome assessment 3
 - Open..... 4
 - Blinding not described 8

9. If reported, was the method of double blinding appropriate? (circle one)
 - Yes 1
 - No..... 2

10. Are refusal rates (the number of refusals) reported? (circle one)
 - Yes 1
 - No..... 2

11. Are the numbers of withdrawals and dropouts reported? (circle one)
 - Yes 1
 - No..... 2

12. Is this a cross-over study design? (circle one)
 - Yes 1
 - No..... 2

Figure 3. Falls Prevention Article Quality Review Form (continued)

13. Are inclusion/exclusion criteria described? (circle one)

Yes..... 1

No 2

14. Are any of the following populations specifically included and described? (check all that apply)

African-Americans

Hispanic.....

Other minority pops.(specify:_____)

Low-income populations

Nursing home

Other (specify:_____)....

None of the above

15. Are any prognostic indicators (including history of functional decline, disability, dementia, or hospice care) given?

(circle one)

Yes..... 1

No 2

16. Types of co-morbidities described in the groups:

(check all that apply)

Healthy elderly/no previous history of falling.....

Specific problem:

Balance

Gait

Vision

Stroke/cerebrovascular disease.....

Previous history of falling

Other (specify:_____)...

Not described.....

Figure 3. Falls Prevention Article Quality Review Form (continued)

27. If the study allows co-interventions, were the specific co-interventions described? (circle one)
 Yes.....1 (ANSWER #28)
 No2 (SKIP to #29)
 Not applicable (co-interventions not allowed) ..8 (SKIP to #29)

28. If co-interventions were described, are they equally distributed in each arm of the study? (circle one)
 Yes.....1
 No2
 Not described.....8

Outcomes

29. Type of outcomes measured:
 (Check all that apply. Circle at least one of the letters “P”, “A”, and “L” for each outcome measured. If rating method is not described, circle ONLY “ND”.)

Balance	<input type="checkbox"/>	P	A	L	ND
Body composition measurements (Height, Weight, BMI)	<input type="checkbox"/>	P	A	L	ND
Cardiovascular measurements (Heart Rate, BP, VO ₂ max)	<input type="checkbox"/>	P	A	L	ND
Costs	<input type="checkbox"/>	P	A	L	ND
Falls	<input type="checkbox"/>				
Falls risk	<input type="checkbox"/>	P	A	L	ND
Functional status (General Health).....	<input type="checkbox"/>	P	A		ND
Functional status (Physical).....	<input type="checkbox"/>	P	A		ND
Gait	<input type="checkbox"/>	P	A	L	ND
Injury rate/Fracture rate.....	<input type="checkbox"/>	P	A	L	ND
Mortality	<input type="checkbox"/>		A	L	ND
Psychological status/ fear of falling/self-efficacy	<input type="checkbox"/>	P	A		ND
Quality of life (SF-36, SF-12, SIP, QWB).....	<input type="checkbox"/>	P			ND
Strength/Endurance	<input type="checkbox"/>	P	A	L	ND
Utilization	<input type="checkbox"/>	P	A	L	ND
Other (specify: _____) ..	<input type="checkbox"/>	P	A	L	ND

30. Was falls prevention the study’s primary outcome? (circle one)
 Yes 1
 No..... 2 (SKIP to #36)

31. How are falls reported? (check all that apply)
 Number of falls
 Percent of subjects who fell
 Falls rate.....
 Other (specify: _____)
 Not described

32. How are falls measured? (check all that apply)
 Self-report
 Diary
 Provider observation
 Chart review.....
 Other (specify: _____)
 Not described

33. How are falls classified in the study? (check all that apply)
 Fall
 Fall with injury.....
 Injury.....
 Accident
 Other (specify: _____)
 Not described

Figure 3. Falls Prevention Article Quality Review Form (continued)

Evaluation

34. If falls was described as an outcome, was there a follow-up time of 3 months or more for all participants? (circle one)

- Yes..... 1
- No 2
- Not described..... 8

35. If there was a follow-up time of 3 months or more, what was the number of months of follow-up? (If varying follow-up times, list the minimum follow-up time for all participants.)

____, ____ - ____ - ____ • ____ months

36. Was the outcome assessment comparable in each intervention arm? (circle one)

- Yes..... 1
- No 2
- Outcome assessment not described 9

37. Which adverse effects were reported?

	Reported & measured	Mentioned only	Not Mentioned
Increased falls.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased musculoskeletal problems ...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased injuries (not fracture).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Increased number of fractures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other complications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (specify: _____).....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
None described.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

38. Are the validity and/or reliability of outcome measures known or described? (circle one)

- Yes..... 1
- No 2

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

- Yes..... 1
- No 2

Statistical Methods

Prior to our analysis, we entered all data on outcomes and interventions into the statistical programs SAS¹³ and Stata.¹⁴ For this report, CMS asked us to provide evidence on the following questions:

1. What are the key components that should be included in a falls prevention intervention? Are multifactorial approaches more effective than single intervention approaches?
2. Are public information or education campaigns alone effective in reducing or preventing falls?
3. Which care settings/approaches have been more effective for the delivery of falls prevention interventions? Which providers should deliver this service?
4. What are the key issues in sustaining falls prevention programs?
5. Cost effectiveness or cost savings—Do falls prevention interventions appear to reduce health care costs by reducing disease, physician office visits, hospitalizations, nursing home admissions, etc.?
6. Should falls prevention programs be targeted toward high-risk individuals? Are there a few basic questions to identify these individuals? Can this be done through self-identification?
7. Are there specific falls prevention exercises recommended for seniors?
8. Are falls prevention programs acceptable to seniors?

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

META-REGRESSION ANALYSIS

We first retrieved all studies that assessed the effects of an intervention or interventions relative to either a group that received usual care or a control group, and that provided falls outcome data.

We considered two patient outcomes in our analysis: falling at least once during a specified follow-up period, and monthly rate of falling. These outcomes were chosen as they are clinically relevant and most commonly reported in the retrieved studies. Other clinically relevant outcomes, such as injuries due to falls or fear of falling were not reported sufficiently often to justify statistical pooling. We will discuss each outcome and its analysis in turn.

FALLING AT LEAST ONCE

This analysis included those studies that provided the number of patients in each arm (treatment and control or usual care) who fell at least once during a specified follow-up period.

The follow-up periods for measuring falling at least once varied greatly across studies, from as few as three months to as many as 24 months. We assessed whether the risk ratio (the risk of someone in the treatment group falling at least once divided by the risk of someone falling at least once in the control or usual care group) varied over time. One might hypothesize that the treatment effect would dissipate over time, for example. However, we descriptively compared risk ratios over time for each study that provided data at more than one endpoint. We could not discern a pattern within studies, e.g., the risk ratios did not decrease over time but rather displayed some heterogeneity across time. We thus sought to narrow the follow-up periods over which we combined data to protect ourselves against heterogeneity.

Clinically, we judged that six to 18 months, i.e., an average of a year, was a comparable enough interval in terms of treatment effect so that we could allow this amount of heterogeneity in follow-up. For studies that provided more than one follow-up data point in the six to 18 month intervals, we chose the data point closest to 12 months.

We estimated the DerSimonian and Laird random effects²³ pooled log risk ratio across all studies in our analysis. We also present the chi-squared test for heterogeneity p-value²⁴ for the individual study log risk ratios. We conducted the analysis on the logarithmic scale to stabilize variances and symmetrize the distribution of errors. We backtransformed the results to the risk ratio scale for interpretation, and present the pooled risk ratio and its 95% confidence interval. If the risk ratio is 0.80 for example, this means that the risk of falling at least once in the treatment group is 80% of the risk of falling at least once in the control group or analogously, the risk of falling in the treatment group is 20% less than the risk in the control group.

We also estimated a series of meta-regressions of these studies. Our primary modeling approach was to fit a random effects meta-regression of the log risk ratio for falling at least once, as a function of various treatment component predictors.²⁵ Twenty studies appear in these meta-regressions, but one study has three treatment arms, resulting in three log risk ratios for this study. Given that we wanted to evaluate the treatment arms singly in order to examine the treatment components employed, we entered multiple treatment arms from the same study as separate log risk ratios in the meta-regressions. Thus, our models contain 22 observations in all.

In our first model, the predictors in the regression were intervention components – for example, education or environmental modifications. A treatment arm might contain more than one intervention component. Our second group of meta-regressions contained two models: high risk and not high risk; and also an interacted model in which we interacted the intervention components with risk status. Our fourth model contained three levels of intensity, and our fifth model focused on exercise components for those studies that

included exercise in their interventions. Our final model addressed the provider setting. We estimated these models in the statistical package Stata¹⁴ using the “metareg” command with the restricted maximum likelihood estimation option.²⁶

MONTHLY RATE OF FALLING

In this analysis, we restricted attention to those studies that provided the total number of falls and the average follow-up period in each arm (treatment and control or usual care). The follow-up times varied greatly across studies, from as little as one month on average of follow-up to as much as 24 months. We included all studies that provided sufficient statistics for analysis regardless of follow-up period. Of the 24 studies that assessed a relevant treatment, only one did not provide sufficient statistics.

For each of the 26 studies with sufficient statistics, we calculated the monthly incidence rate of falling in each arm, which is the total number of falls by patients in that arm divided by the total person-months observed for patients in that arm. For each pair of treatment and control arms within a study, we then calculated the incidence rate ratio, which is the incidence rate in the treatment arm divided by the incidence rate in the control arm, and its standard deviation.²⁷ One of the studies had two treatment arms, so our model contained 27 incidence rate ratios in all.

We estimated the DerSimonian and Laird random effects²³ pooled log incidence rate ratio across all studies in our analysis. We also present the chi-squared test for heterogeneity p-value²⁴ for the individual study log risk ratios. We backtransformed the results to the risk ratio scale for interpretation, and present both the pooled incidence rate ratio and its 95% confidence interval. If the incidence rate ratio is 0.70 for example, this means that the monthly falls rate in the treatment group is 70% the monthly falls rate in the control group or analogously, the monthly falls rate in the treatment group is 30% less than the monthly falls rate in the control group.

We also estimated a series of meta-regressions for the log incidence rate ratios similarly to those fit for the log risk ratios of falling at least once.

PUBLICATION BIAS

We assessed the possibility of publication bias by evaluating a funnel plot of the log risk ratios or log incidence rate ratios respectively graphically for symmetry resulting from the non-publication of small, negative studies. Because graphical evaluation can be subjective, we also conducted an adjusted rank correlation test²⁸ and a regression asymmetry test²⁹ as formal statistical tests for publication bias.

SENSITIVITY ANALYSES

Correcting for randomization at the cluster rather than at the individual patient level, correcting for correlation across treatment arms within a single study (each treatment arm in a study is compared to the same usual care or control group in that study so the risk ratios or incidence rate ratios for treatment arms in the same study are correlated), and

considering different sources of data for the FICSIT¹⁵ studies were the subjects of our sensitivity analyses.

For the falls at least once analysis, six studies were randomized at the cluster level^{16, 30-34} and for the monthly rate of falls analysis, four studies were randomized at the cluster level.³⁴⁻³⁷ We adjusted their sample sizes using the observed number of clusters within each and an intra-cluster correlation of 0.05, which is probably an over-estimate of the intra-cluster correlation and therefore the design effect. We re-estimated all models with the data adjusted for this correlation.

Each of the two outcomes had one study with multiple treatment arms. To determine if correlation across multiple treatment arms in the same study had an effect, we re-estimated all models including each treatment arm from the multiple treatment arm study in turn.

The FICSIT trials consisted of eight studies, one of which did not have a relevant treatment arm so it is excluded from our analysis of either falls outcome, and is also excluded from the FICSIT meta-analysis¹⁵ for the same reason. One of the remaining seven studies truncated the number of falls measured so it is excluded from our analyses. Of the six remaining studies, five had publications that provided outcome data while one did not. Data for all six were also available in the meta-analysis that pooled the FICSIT studies,¹⁵ and we note that these two data sources did not agree. In the primary analysis, we used the FICSIT meta-analysis data for the study that did not have a publication reporting outcomes, and in the data sensitivity analysis, we re-estimated all models using the FICSIT meta-analysis data for all six FICSIT studies.

None of these sensitivity analyses results differed markedly from that of the primary analysis we present in this report.

Cost effectiveness

To assess the cost-effectiveness of the interventions, we first determined whether the studies included cost data. We chose to summarize these studies qualitatively because of heterogeneity.

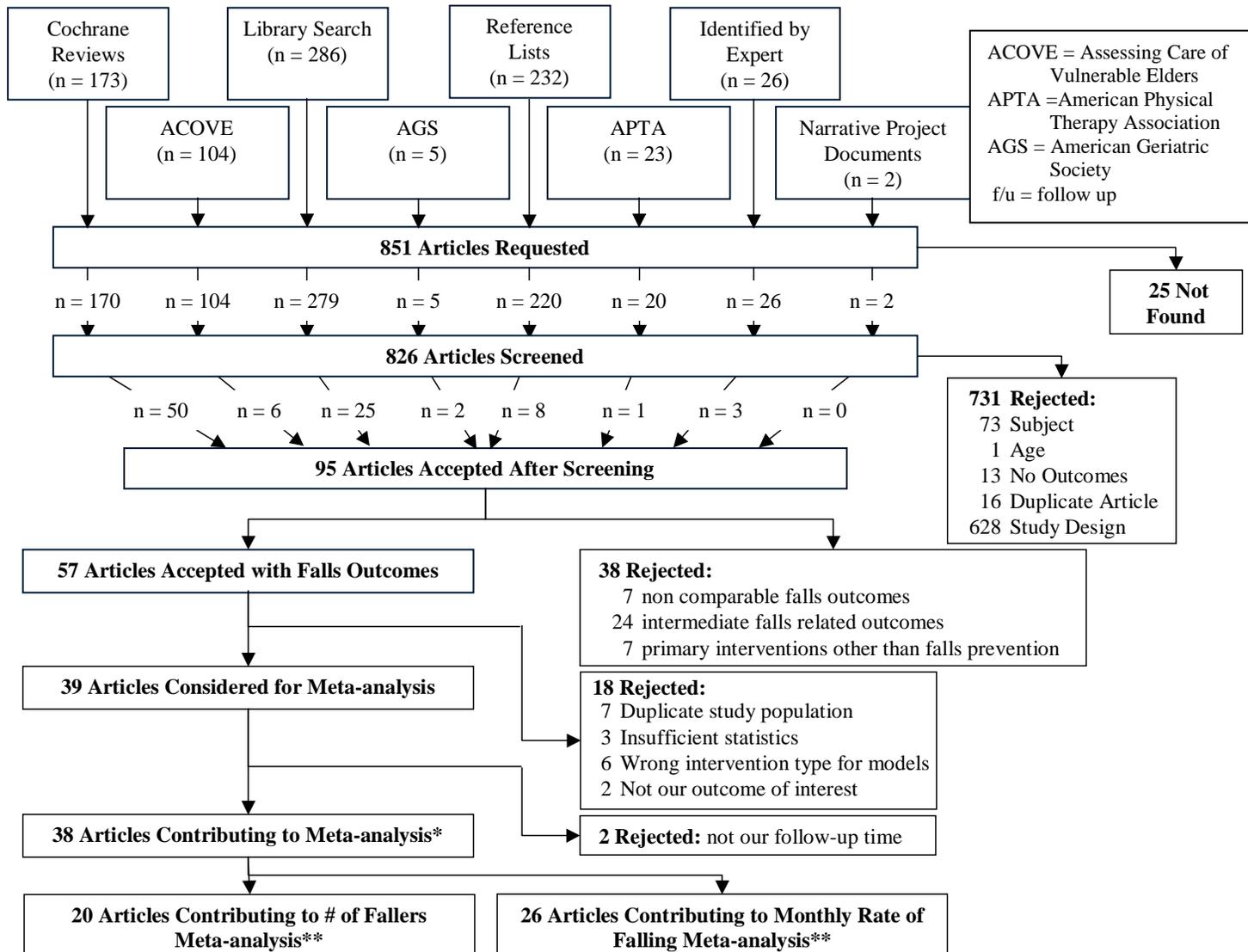
RESULTS

Identification of Evidence

Figure 4 describes the flow of evidence from the original sources to final acceptance for our review. The Cochrane Collaboration provided 173 relevant citations, while the Assessing Care of the Vulnerable Elderly (ACOVE) Project files contained 104 possibly relevant additional articles. Another five articles were sent to us by the American Geriatric Society (AGS), and the American Physical Therapy Association (APTA) sent us 23 article abstracts. We found two CMS Narrative Project Documents regarding falls prevention. A library search yielded 286 articles not previously noted; 232 additional articles were found by examining the reference lists of all articles we obtained. Twenty-six additional articles were obtained from experts. In total, the above sources yielded 851 articles, but we were unable to obtain 25 of these. This left 826 articles for the screening process.

Of the 826 articles screened, 73 did not discuss falls prevention. Six hundred twenty-eight were rejected because they were not randomized controlled trials (RCTs) or controlled clinical trials (CCTs). Another 16 articles were duplicates of articles already on file. Thirteen others did not include outcomes; i.e. they were simply descriptions of a falls prevention study in progress. One article did not study the age of interest. This left 95 articles for quality review.

Figure 4. Article Flow



* These 38 articles include one study originally rejected as Review (see text for complete description).

** These numbers are not mutually exclusive as some articles contributed to more than one analysis.

Selection of Studies for the Meta-Regression Analyses

Following the initial screening, we reviewed the articles retrieved from the literature sources to determine whether to include them in the evidence synthesis. We created a one-page screening review form to record the subject, study design, age of the study participants, and type of outcomes from each article.

Studies were included for further review after meeting three major inclusion criteria. First, a study had to have falls prevention as a principal objective. Second, while we were searching primarily for data relevant to the Medicare population, we also included studies containing data on participants age 60 and older to avoid losing potentially useful articles. Third, a study had to be either a randomized controlled trial (RCT) or controlled clinical trial (CCT). We employed this restriction on study design in order to maximize our ability to evaluate whether differences in outcomes could be attributed to the interventions being studied. We created an eight-page quality review and abstraction form to collect detailed information about the interventions and outcomes used in each study (Figure 3).

Of the 95 controlled trials that underwent quality review, 38 provided only outcomes other than falls or falls reduction was not the principal aim of the study (such as studies of hormone replacement therapy whose primary outcome was bone density assessments but may have also report falls). Since the focus of this project was the systematic review of interventions for the prevention of falls, only the 57 studies that provided falls outcomes were reviewed for potential inclusion in the meta-regression. We abstracted data on how falls were reported in the studies, the follow-up times, and the study populations. In order to maximize the inclusion of studies with common outcomes in the meta-regression, we examined how falls outcomes were reported. We discovered that the most widely reported falls outcome among the accepted studies was “subjects who fell at least once during the study period.” The second most commonly reported outcome was a measure of falls rate, such as the monthly rate of falling per person. Three of the 61 studies were excluded because they did not provide data on outcomes by intervention and control group. Additionally, seven of the 61 studies were rejected when the study populations were determined to be already in the analysis through another publication (only one article from the same study population could be included in the meta-analysis). Six studies were excluded as the intervention type was not represented in our conceptual model. Two studies were excluded because they did not report either of our outcomes of interest. This left 39 studies which were considered for meta-analysis. Table 3 reports the follow-up time points that were measured in the remaining studies.

Table 3. Follow-up Periods for Articles with Falls Outcomes

Study	3 Months	12 Months (6-18 months)	24 Months	Greater than 24 Months
Buchner DM, 1997 ID #617		X (7-18)		

Table 3. Follow-up Periods for Articles with Falls Outcomes

Study	3 Months	12 Months (6-18 months)	24 Months	Greater than 24 Months
Campbell AJ, 1997 ID #483		X		
Campbell AJ, 1999a ID #1504		X	X	
Campbell AJ, 1999b ID #1593		X (11)		
Carpenter GI, 1990 ID #443				X
Cerny K, 1998 ID #717		X (6)		
Close J, 1999 ID #1524		X		
Coleman EA, 1999 ID #1510		X	X	
Crome P, 2000 ID #3633		X (6)		
Cumming RG, 1999 ID #1699		X		
Ebrahim S, 1997 ID #1204		X	X	
El Faizy, 1994 ID #583		X (9)		
Fabacher D, 1994 ID #444		X		
Fiatarone, 1993 ID # 528		X (18)		
Gallagher EM, 1996 ID #578		X (6)		
Hornbrook MC, 1994 ID #445			X (23)	
Jensen J, 2002 ID #3654		X (8.5)		
Jitapunkul S, 1998 ID#3604				X
Lord SR, 1995 ID #446		X		
Mayo NE, 1994 ID #448		X		
McMurdo ME, 1997 ID #449			X	
McMurdo ME, 2000 ID #1984		X (7-12)		
McRae PG, 1994 ID #2027		X		
Means KM, 1996 ID #450		X (6)		
Millar AM, 1999 ID #3617		X (6)		
Mulrow CD, 1994 ID #451	X (4)			

Table 3. Follow-up Periods for Articles with Falls Outcomes

Study	3 Months	12 Months (6-18 months)	24 Months	Greater than 24 Months
Pereira MA, 1998 ID #1533		X		
Reinsch S, 1992 ID #491		X		
Robertson MC, 2001 ID #3260		X		
Rubenstein LZ, 1990 ID #492		X	X	
Rubenstein LZ, 2000 ID #1988	X			
Ryan JW, 1996 ID #681	X			
Salkeld, 2000 ID #3094		X		
Schoenfelder DP, 2000 ID #3624		X (6)		
Steinberg M, 2000 ID #2523		X		
Tinetti ME, 1994 ID #494		X		
Van Haastregt J, 2000 ID #3091		X X (18)		
Vetter NJ, 1992 ID #501				X
Wagner EH, 1994 ID #502		X	X	
Wolf SL, 1996 ID #503		X (8)		
	3	32	7	3

Our first analysis included all studies that reported sufficient data on the number of people who fell at least once. We found 22 studies that reported this with follow-up times ranging from 3 to 24 months. As the effectiveness of the intervention may not be stable over time, we examined the relative effectiveness of falls prevention interventions in those studies that reported multiple time points. Table 4 shows those studies that presented data at multiple time points. Again, this table is restricted to those studies that reported the number or percent of patients who fell at least once. Both the time point at which the data are collected (column labeled “Data collection point”) and the period over which the data are collected (column labeled “Accumulation time period”) are displayed. We note that these two times may be different. For example, at six months after the study began, a study might report data for the number of patients who fell at least once during the previous three months, i.e., between three and six months.

Table 4 shows the risk ratio and associated 95% confidence interval for each study with multiple time points. This risk ratio represents the risk of a person falling at least once as compared to the risk for a person in the control or usual care group. The key message from the table is that within and across studies, the risk ratios do not stay constant, nor do they increase or decrease consistently over time.

Table 4. Studies with Multiple Time Point Measures

* Note: Total reported is sum of respondents in each accident group

Author	Group	N	Data Collection Point	Accumulation Time Period	# People who had at Least One Fall	Risk Ratio (95% C.I.)
Bowling, 1992 ID#513	Hosp. Ward	48	3 months	3 months	11	0.76 (0.39, 1.49)
	Nursing Home	50	3 months	3 months	15	
	Hosp. Ward	38	6 months	3 months	6	0.29 (0.13, 0.64)
	Nursing Home	38	6 months	3 months	21	
	Hosp. Ward	29	9 months	3 months	4	0.31 (0.11, 0.82)
	Nursing Home	31	9 months	3 months	14	
	Hosp. Ward	49*	12 months	3 months	18	0.53 (0.35, 0.80)
	Nursing Home	52*	12 months	3 months	36	
Coleman, 1999 ID#1510	Intervention	79	12 months	12 months	34	1.13 (0.75, 1.69)
	Control	63	12 months	12 months	24	
	Intervention	78	24 months	12 months	34	1.26 (0.79, 1.99)
	Control	49	24 months	12 months	17	
Ebrahim, 1997 ID#1204	Intervention	52	12 months	12 months	22	1.18 (0.72, 1.91)
	Control	50	12 months	12 months	18	
	Intervention	49	24 months	12 months	17	0.93 (0.54, 1.57)
	Control	48	24 months	12 months	18	
Rubenstein, 1990 ID#492	Intervention	79	12 months	12 months	56	0.94 (0.78, 1.14)
	Control	81	12 months	12 months	61	
	Intervention	79	24 months	12 months	64	0.97 (0.84, 1.11)
	Control	81	24 months	12 months	68	

Table 4. Studies with Multiple Time Point Measures

* Note: Total reported is sum of respondents in each accident group

Author	Group	N	Data Collection Point	Accumulation Time Period	# People who had at Least One Fall	Risk Ratio (95% C.I.)
Van Haastregt, 2000 ID#3091	Intervention	129	12 months	12 months	63	1.13 (0.87, 1.48)
	Control	123	12 months	12 months	53	
	Intervention	120	12 months	12 months	68	1.12 (0.88, 1.43)
	Control	115	12 months	12 months	58	
Wagner, 1994 ID#502	Intervention	635	12 months	12 months	175	0.75 (0.64, 0.88)
	Usual Care	607	12 months	12 months	223	
	Intervention	635	24 months	12 months	199	1.07 (0.91, 1.27)
	Usual Care	607	24 months	12 months	177	

Given this lack of empirical information on the stability of intervention effectiveness over time, we used expert judgment to determine that falls occurring between six and 18 months post-intervention were sufficiently clinically similar to support statistical pooling. Therefore, studies were included in the meta-analysis if the study reported data on “subjects who fell at least once during the study period,” and the study included follow-up data at a time point between six and 18 months. Two studies without data during this time period were excluded; therefore, 20 studies were included in this analysis.

MONTHLY RATE OF FALLING

In this second analysis, we restricted attention to those studies that provided the total number of falls and the average follow-up period in each arm (treatment and control or usual care), which would allow calculation of monthly falls rates per subject. The follow-up times varied greatly across studies, from as little as one month on average of follow-up to as much as 38 months. We included all studies that provided sufficient statistics for analysis regardless of follow-up period. Twenty-five studies provided sufficient statistics. We compared our pool of studies with those used in the FICSIT trial. Five of the 7 FICSIT sites were included in our pool of studies. Two had been excluded at the screener stage because they were descriptive papers. We decided to use the data reported in the FICSIT paper for one of the studies.³⁸ We decided to exclude the results from the other FICSIT article³⁹ as it truncated the number of falls. Therefore, 26 studies contributed to the analysis of falls rate.

Controlled Trials Excluded from the Meta-Regression Analyses

Excluded studies fall into eight major categories:

1. RCTs with non-comparable falls outcomes
2. RCTs with intermediate “falls-related” outcomes
3. RCTs with primary interventions other than falls prevention
4. Multiple published reports on the same study
5. RCTs with insufficient statistics
6. RCTs evaluating interventions outside of our conceptual model
7. RCTs reporting an outcome not of interest in this analysis
8. RCTs outside our range of follow-up times

We present a qualitative summary of these studies below.

RCTs WITH NON-COMPARABLE FALLS OUTCOMES

We identified seven studies⁴⁰⁻⁴⁶ that reported at least one falls outcome, but either the type of outcome measured or how the outcome was reported was not comparable to nor poolable with our outcomes of interest. Therefore, these studies were not included in the meta-analysis. One⁴¹ study reported the number of “accidents” which included falls, but also included other causal factors. Another study⁴² measured falls only as an outcome as part of a platform sensory test; not falls outside of the balance testing environment. Most of the other studies either did not provide adequate information about the number of unique persons falling in each group or the numbers provided were not poolable with our outcomes of interest. The types of interventions among these studies varied and included balance and strength training, hormone replacement therapy, nutritional supplementation, and selecting a specific location for care.

RCTs WITH INTERMEDIATE FALLS RELATED OUTCOMES

We identified twenty-four studies⁴⁷⁻⁷⁰ that did not report falls but reported falls-related outcomes. Most of these studies included exercise interventions and primarily measured exercise performance measures, such as performance time, balance, strength, and flexibility; and functional measures, such as fear of falling and self-rated falls risk. One study⁷⁰ focused on the use of hip protectors to improve falls self-efficacy.

RCTs WITH PRIMARY INTERVENTIONS OTHER THAN FALLS PREVENTION

We identified seven studies⁷¹⁻⁷⁷ that have implications for falls prevention, but contained primary interventions other than falls prevention. Three studies^{74, 75, 77} studied calcium and vitamin D on the outcomes of hip fractures, other fractures, and bone mineral density. One study⁷¹ studied the effect of hormone replacement therapy on functional

balance. One study⁷² studied the effect of diazepam on balance and neurocognitive tests. One study⁷³ studied the effect of physical therapy on mobility in patients with dementia.

MULTIPLE PUBLISHED REPORTS ON THE SAME STUDY

We identified seven publications that reported results of study populations already included in the meta-analysis⁷⁸⁻⁸⁴ via another publication^{16, 37, 85-88}.

RCTs WITH INSUFFICIENT STATISTICS

Three studies were excluded from the meta-analyses because they did not report the necessary statistics. Two studies^{89, 90} reported falls for the entire study population, but not by intervention group. A third study only reported falls for the treatment group. None were reported for the control group.⁹¹

RCTs EVALUATING INTERVENTIONS OUTSIDE OUR CONCEPTUAL MODEL

Six studies reported on interventions that were not included in our conceptual model. The interventions were bed alarm systems,⁹² physical restraints,⁸⁵ “hospital-in-the-home,”⁴⁴ home rehabilitation,⁹³ use of a medication (Raubasine-Dihydroergocristine),⁹⁴ and cardiac pacing for carotid sinus syndrome.⁹⁵

RCTs REPORTING AN OUTCOME NOT OF INTEREST IN THIS ANALYSIS

Two studies reported a falls outcome other than monthly falls rate or number of people who fell at least once. These studies only reported on the number of recurrent fallers.^{96, 97}

RCTs OUTSIDE OUR RANGE OF FOLLOW-UP TIMES

Seven studies were rejected from the percent of fallers analysis because the follow-up times reported were outside of six to eighteen months (the time conceptualized by our study to be comparable). Five studies^{35, 98-101} reported both number of subjects with at least one fall and percent of fallers. These five studies contributed to the number of subjects with at least one fall analysis but not to the percent of fallers analysis. Two studies^{102, 103} reported only percent of fallers with a followup time greater than 24 months and therefore were excluded from the analysis. The types of interventions among these studies were exercise programs, education, and home visits.

The majority of exclusions from the meta-analyses were due to the use of falls outcomes that we judged clinically too heterogeneous to support pooling. This finding suggests that future research would benefit from the development of a consensus outcome measure for falls (e.g. percentage of subjects falling during follow-up period or monthly rate of falling). While future research in falls prevention and exercise may include a number of outcomes, ensuring the inclusion of at least one consensus measurement for falls would allow for easier comparisons and enhanced information, by ensuring inclusion of all future trials into pooled analyses.

Table 5 displays randomized falls prevention trials excluded at the final decision point. Thus 38 studies remained for inclusion in the meta-analysis, 20 contributing to the “subjects who fall at least once” analysis and 26 contributing to the monthly rate of falling per person analysis. Some studies contributed data to both analyses. These studies are listed in Table 6.

Table 5. Studies Excluded from Meta-Regression Analyses

Author, Year	Reason for Exclusion
Armstrong AL, 1996 ID#576	Doesn't report people w/ at least one fall or falls rate
Capezuti EA, 1995 ID#1316	Intervention type not in conceptual model – restraints
Capezuti, 1998 ID#621	Duplicate data of study Capezuti, 1995 ID#1316
Gardner, 1998 ID#1297	Duplicate data of study Campbell, 1999a ID#1504
Jitapunkul S, 1998 ID#3604	Wrong follow-up time (3 months)
Kannus P et al., 2000 ID#3089	Insufficient statistics - control outcomes not reported
Kenny RA, 2001 ID#3622	Intervention type not in conceptual model
Peel N et al., 1998 ID#3259	Insufficient statistics - doesn't report outcomes by group
Peel N, 2000 ID#3607	Duplicate data of study Steinberg, 2000 ID#2523
Pereira MA, 1996 ID#3618	Duplicate data of study Pereira, 1998 ID#1533
Pfeifer M, 2000 ID#3605	Intervention type not in conceptual model
Ray WA et al., 1997 ID#1198	Doesn't report people w/ at least one fall or falls rate
Rizzo, 1996 ID#418	Duplicate data of study Tinetti, 1994 ID#494
Robertson MC, 2001b ID#3601	Duplicate data of study Campbell, 1997 ID#483
Tennstedt S et al., 1998 ID#1195	Insufficient statistics - no valid outcomes, reported mean change scores
Tideiksaar R et al., 1993 ID#493	Intervention type not in conceptual model – bed alarm
Tinetti, 1996 ID#497	Duplicate data of study Tinetti, 1994 ID#494
Vellas B, 1991 ID#3619	Intervention type not in conceptual model
Vetter NJ et al., 1992 ID#501	Wrong follow-up time
Widen Holmqvist L, 1998 ID#3610	Intervention type not in conceptual model

Table 6. RCT Studies Included in Meta-Regression Analyses

	Number or falls rate	% with at least one fall
Buchner DM, Cress ME, de Lateur BJ, Esselman PC, Margherita AJ, Price R, et al. The effect of strength and endurance training on gait, balance, fall risk, and health services use in community-living older adults. <i>J Gerontol A Biol Sci Med Sci.</i> 1997;52(4):M218-24. ID#617	X	X
Campbell AJ, Robertson MC, Gardner MM, Norton RN, Tilyard MW, Buchner DM. Randomised controlled trial of a general practice programme of home based exercise to prevent falls in elderly women. <i>BMJ.</i> 1997;315(7115):1065-9. Rec #: 483	X	X
Campbell AJ, Robertson MC, Gardner MM, Norton RN, Buchner DM. Falls prevention over 2 years: a randomized controlled trial in women 80 years and older. <i>Age Ageing.</i> 1999a;28(6):513-518. Rec #: 1504	X	
Campbell AJ, Robertson MC, Gardner MM, Norton RN, Buchner DM . Psychotropic medication withdrawal and a home-based exercise program to prevent falls: a randomized, controlled trial. <i>J Am Geriatr Soc.</i> 1999b;47(7):850-3. Rec #: 1593	X	
Carpenter GI, Demopoulos GR. Screening the elderly in the community: Controlled trial of dependency surveillance using a questionnaire administered by volunteers. <i>BMJ.</i> 1990;300(6734):1253-6. Rec #: 443	X	
Cerny K, Blanks R, Mohamed O, Schwab D, Robinson B, Russo A, et al. The effect of a multidimensional exercise program on strength, range of motion, balance, and gait in the well elderly. <i>Gait & Posture.</i> 1998;7:185-186. ID#717		X
Close J, Ellis M, Hooper R, Glucksman E, Jackson S, Swift C, et al. Prevention of falls in the elderly trial (PROFET): a randomised controlled trial. <i>Lancet.</i> 1999;353(9147):93-97. ID#1524	X	X
Coleman EA, Grothaus LC, Sandhu N, Wagner EH . Chronic care clinics: a randomized controlled trial of a new model of primary care for frail older adults. <i>J Am Geriatr Soc.</i> 1999;47(7):775-783. ID#1510		X
Crome P, Hill S, Mossman J, Stockdale P. A randomised controlled trial of a nurse led falls prevention clinic [abstract]. <i>Journal of the American Geriatrics Society.</i> 2000;48:S78 Rec#: 3633	X	
Cumming RG, Thomas M, Szonyi G, Salkeld G, O'Neill E, Westbury C, et al. Home visits by an occupational therapist for assessment and modification of environmental hazards: a randomized trial of falls prevention . <i>J Am Geriatr Soc.</i> 1999;47(12):1397-402. ID#1699		X

Table 6. RCT Studies Included in Meta-Regression Analyses

	Number or falls rate	% with at least one fall
Ebrahim S, Thompson PW, Baskaran V, Evans K. Randomized placebo-controlled trial of brisk walking in the prevention of postmenopausal osteoporosis. <i>Age Ageing</i> . 1997;26(4):253-60. ID#1204	X	X
El Faizy M, Reinsch S. Home safety intervention for the prevention of falls. <i>Phys Occup Ther Geriatr</i> . 1994;12(3):33-49. Rec #: 583	X	
Fabacher D, Josephson K, Pietruszka F, Linderborn K, Morley JE, Rubenstein LZ. An in-home preventive assessment program for independent older adults: A randomized controlled trial. <i>J Am Geriatr Soc</i> . 1994;42(6):630-8. ID#444		X
Fiatarone MA, O'Neill EF, Doyle N, Clements KM, Roberts SB, Kehayias JJ, et al. The Boston FICSIT study: the effects of resistance training and nutritional supplementation on physical frailty in the oldest old. <i>J Am Geriatr Soc</i> . 1993;41(3):333-7. Rec #: 528	X	
Gallagher EM, Brunt H. Head over heels: Impact of a health promotion program to reduce falls in the elderly. <i>Can J Aging</i> . 1996;15:84-96. Rec #: 578	X	
Hornbrook MC, Stevens VJ, Wingfield DJ, Hollis JF, Greenlick MR, Ory MG. Preventing falls among community-dwelling older persons: Results from a randomized trial. <i>Gerontologist</i> . 1994;34(1):16-23. Rec #: 445	X	
Jensen J, Lundin-Olsson L, Nyberg L, Gustafson Y. Fall and Injury Prevention in older people living in residential care facilities. <i>Ann Intern Med</i> . 2002;136:733-41. Rec#: 3654	X	X
Lord SR, Ward JA, Williams P, Strudwick M. The effect of a 12-month exercise trial on balance, strength, and falls in older women: a randomized controlled trial. <i>J Am Geriatr Soc</i> . 1995;43(11):1198-206. ID#446	X	X
Mayo NE, Gloutney L, Levy AR. A randomized trial of identification bracelets to prevent falls among patients in a rehabilitation hospital. <i>Arch Phys Med Rehabil</i> . 1994;75(12):1302-8. ID#448		X
McMurdo ME, Mole PA, Paterson CR. Controlled trial of weight bearing exercise in older women in relation to bone density and falls. <i>BMJ</i> . 1997;314(7080):569. Rec #: 449	X	
McMurdo ME, Millar AM, Daly F. A randomized controlled trial of fall prevention strategies in old peoples' homes. <i>Gerontology</i> . 2000;46(2):83-87. ID#1984	X	X
McRae PG, Feltner ME, Reinsch SA. A one-year exercise program for older women: Effects on falls, injuries, and physical performance. <i>J Aging Phys Activity</i> . 1994;2:127-142. ID#2027		X

Table 6. RCT Studies Included in Meta-Regression Analyses

	Number or falls rate	% with at least one fall
Means KM, Rodell DE, O'Sullivan PS, Cranford LA. Rehabilitation of elderly fallers: Pilot study of a low to moderate intensity exercise program. <i>Arch Phys Med Rehabil.</i> 1996;77(10):1030-6. Rec #: 450	X	
Millar AM. A trial of falls prevention. <i>Age and Ageing.</i> 1999;28:15 Rec#: 3617		X
Mulrow CD, Gerety MB, Kanten D, Cornell JE, DeNino LA, Chiodo L, et al. A randomized trial of physical rehabilitation for very frail nursing home residents. <i>JAMA.</i> 1994;271(7):519-24. Rec #: 451	X	
Pereira MA, Kriska AM, Day RD, Cauley JA, Laporte RE, Kuller LH. A randomized walking trial in postmenopausal women: effects of physical activity and health 10 years later. <i>Arch Intern Med.</i> 1998;158(15):1695-1701. ID#1533		X
Reinsch S, MacRae P, Lachenbruch PA, Tobis JS . Attempts to prevent falls and injury: A prospective community study. <i>Gerontologist.</i> 1992;32(4):450-6. ID#491		X
Robertson MC, Devlin N, Gardner MM, et al. Effectiveness and economic evaluation of a nurse delivered home exercise programme to prevent falls. 1: Randomized controlled trial. <i>BMJ.</i> 2001a;322:697-701. Rec #: 3260	X	
Rubenstein LZ, Robbins AS, Josephson KR, Schulman BL, Osterweil D. The value of assessing falls in an elderly population. A randomized clinical trial. <i>Ann Intern Med.</i> 1990;113(4):308-16. ID#492		X
Rubenstein LZ, Josephson KR, Trueblood PR, Loy S, Harker JO, Pietruszka FM, et al. Effects of group exercise program on strength, mobility and falls among fall-prone elderly men. <i>J Gerontol .</i> 2000;6:M1-M5. Rec #: 1988	X	
Ryan JW, Spellbring AM. Implementing strategies to decrease risk of falls in older women. <i>J Gerontol Nurs.</i> 1996;22(12):25-31. Rec #: 681	X	
Salkeld G, Cumming RG, O'Neill E, Thomas M, Szonyi G, Westbury C. The cost effectiveness of a home hazard reduction program to reduce falls among older persons. <i>Aust NZ J Public Health.</i> 2000;24(3):265-71. Rec #: 3094	X	
Schoenfelder DP. A fall prevention program for elderly individuals. Exercise in long- term care settings. <i>J Gerontol Nurs.</i> 2000;26:43-51. Rec#: 3624	X	
Steinberg M, Cartwright C, Peel N, Williams G. A sustainable programme to prevent falls and near falls in community dwelling older people: results of a randomised trial. <i>J Epidemiol Community Health.</i> 2000;54(3):227-32. Rec #: 2523	X	
Tinetti ME, Baker DI, McAvay G, Claus EB, Garrett P, Gottschalk M, et al. A multifactorial intervention to reduce the risk of falling among elderly people living in the community. <i>N Engl J Med.</i> 1994;331(13):821-7. ID#494	X	X

Table 6. RCT Studies Included in Meta-Regression Analyses

	Number or falls rate	% with at least one fall
van Haastregt J, Diederiks J, Crebolder H. Effects of a programme of multifactorial home visits on falls and mobility impairments in elderly people at risk: randomised controlled trial. <i>BMJ</i> . 2000;321(7267):994. ID#3091		X
Wagner EH, LaCroix AZ, Grothaus L, Leveille SG, Hecht JA, Artz K, et al. Preventing disability and falls in older adults: A population-based randomized trial. <i>Am J Public Health</i> . 1994;84(11):1800-6. ID#502		X
Wolf SL, Barnhart HX, Kutner NG, McNeely E, Coogler C, Xu T. Reducing frailty and falls in older persons: an investigation of Tai Chi and computerized balance training. Atlanta FICSIT Group. Frailty and Injuries: Cooperative Studies of Intervention Techniques. <i>J Am Geriatr Soc</i> . 1996;44(5):489-97. Rec #: 503	X	

Responses to Questions Specified by CMS

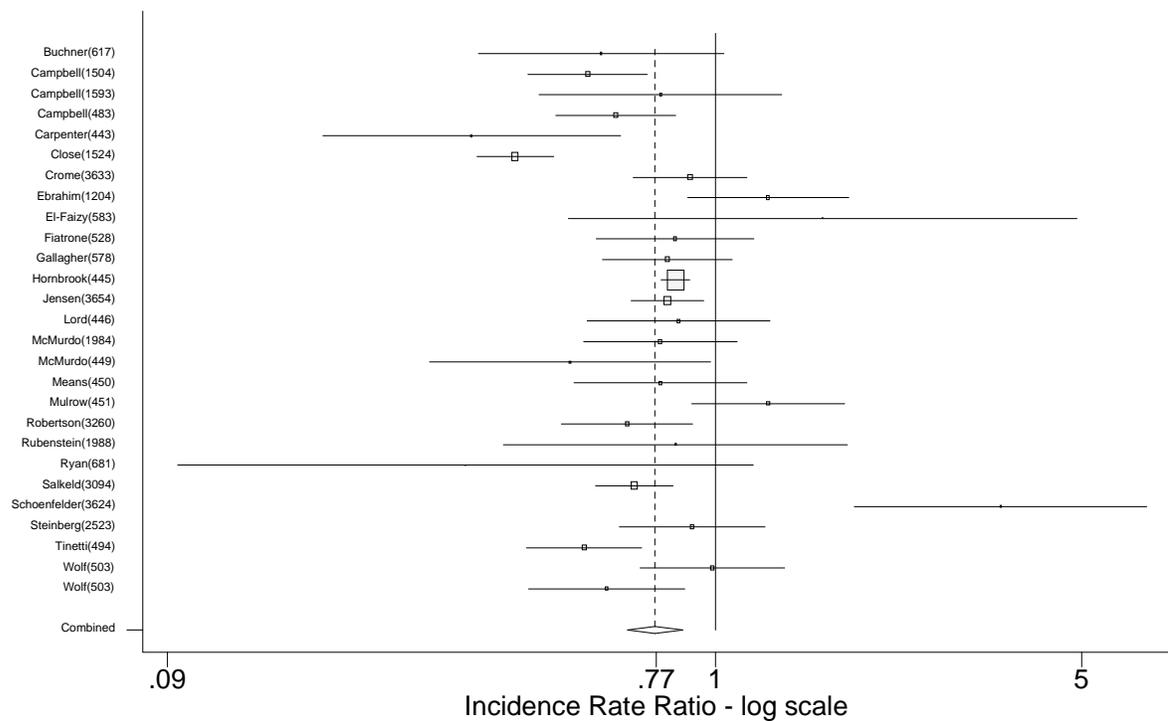
QUESTION 1. ARE FALLS PREVENTION PROGRAMS EFFECTIVE? WHAT ARE THE KEY COMPONENTS THAT SHOULD BE INCLUDED IN A FALLS PREVENTION INTERVENTION? ARE MULTIFACTORIAL APPROACHES MORE EFFECTIVE THAN SINGLE INTERVENTION APPROACHES?

We performed meta-analyses on two clinically relevant outcomes: subjects who fell at least once and monthly rate of falling. The first meta-analysis included data from 22 treatment arms in 20 studies. The pooled risk ratio was calculated to determine whether combined studies would be associated with a reduced risk of falling, within a clinically comparable follow-up period – six to 18 months as described in the methods. The pooled risk ratio is 0.89, 95% CI [0.81, 0.98] indicating that the interventions in these studies are associated with a significantly reduced risk of falling. This is graphically displayed in Figure 5.

Figure 5. Shrinkage Plot of Clinical Trials of Falls Prevention Interventions Assessing the Outcome "Subjects Who Fell at Least Once"

The second meta-analysis, for efficacy in reducing monthly rate of falling, included data from 26 treatment arms in 27 studies which are displayed in the shrinkage plot below. The pooled incidence rate ratio is 0.77, 95% CI [0.68, 0.87] indicating that the interventions in these studies are associated with a significantly reduced number of falls, as displayed in Figure 6.

Figure 6. Shrinkage Plot of Clinical Trials of Falls Prevention Interventions Assessing the Outcome "Monthly rate of falling"



Area of the box is proportional to the variance.
Line represents 95% confidence intervals

Treatment Components

To investigate the effects of the differing intervention components of each of the treatment arms, detailed information about the type(s), intensity, exercise components, and setting of the interventions was obtained. The pooled risk ratio of studies that included a multifactorial falls risk assessment and management program was 0.84, 95% CI [0.73, 0.97] for risk of falling, while the pooled incidence rate ratio was 0.65, 95% CI [0.49, 0.85] for the number of falls. Similarly, when pooling studies that included an exercise intervention, we find that this subgroup of studies is significantly associated with a reduced risk of falling (adjusted risk ratio: 0.88, 95% CI [0.78, 1.00]) and with reduced number of falls (adjusted incidence rate ratio: 0.81, 95% CI [0.72, 0.92]). Four studies had both types of interventions and were included in both sub-analyses of intervention type.

Table 7. Pooled Analyses

Study Type	Subjects who fell at least once			Monthly rate of falling		
	Number of Studies	Number of Arms	Adjusted Risk Ratio (95% CI)	Number of Studies	Number of Arms	Adjusted Incident Rate Ratio (95% CI)
All Studies Combined	20	22	0.89 (0.81, 0.98)	26	27	0.77 (0.68, 0.87)
Multifactorial falls risk assessment and management program	10	10	0.84 (0.73, 0.97)	7	7	0.65 (0.49, 0.85)
Exercise Only	12	13	0.88 (0.78, 1.00)	19	20	0.81 (0.72, 0.92)

We did not find any studies that directly assessed the relative effectiveness of intervention components by comparing them head to head in a clinical trial (for example, trials comparing environmental modifications with exercise interventions). Therefore, our assessment of the relative effectiveness of intervention components used indirect methods, by comparing the magnitude of the effect of each independent component to a control group that received usual care. To assess the relative effectiveness of intervention components, we entered all such studies in meta-regression models that assess the effect of individual intervention components while controlling for other intervention components and study level differences. The results of the analyses are presented in Table 8. A multifactorial falls risk assessment and management program had a statistically significant beneficial effect in both analyses, and is probably the most effective intervention component in reducing both fall outcome measures. Exercise was an intervention component in the largest number of studies in both analyses. The pooled result favored exercise in reducing both the risk of falls and the rate of falls, although the results did not quite reach conventional levels of statistical significance. The balance of evidence supports exercise as the second most effective intervention component. Environmental modifications were the principal component of a small number of studies, and the pooled estimate of effect was beneficial but not statistically significant. Education also was studied in only a small number of studies, and the pooled result was not

statistically significant for either outcome. However, the 95% confidence intervals for the estimate are very wide and these results neither support nor refute the use of education as an effective individual intervention component.

We were not able to directly test whether multifactorial interventions were superior to single factor interventions, due to a paucity of single factor studies identified. However, an indirect argument favoring multifactorial interventions can be made since the most effective intervention, a multifactorial falls risk assessment and management program, is usually multifactorial.

The risk assessments included in multifactorial risk assessment varied among studies. Table 9 lists the included studies and the risks they assessed. The most commonly assessed risks were medication review, vision, environmental hazards, and orthostatic blood pressure

Table 8. Meta-regression Estimates of the Effect of Individual Intervention Components

Treatment Component	Subjects who fell at least once		Monthly rate of falling	
	Number of Studies (Arms)	Adjusted Risk Ratio (95% CI)	Number of Studies (Arms)	Adjusted Incident Rate Ratio (95% CI)
Multifactorial falls risk assessment and management program	10 (10)	0.80 (0.68, 0.95)	7 (7)	0.60 (0.44, 0.82)
Exercise	12 (13)	0.87 (0.73, 1.04)	19(20)	0.84 (0.70, 1.01)
Environmental Modifications	2 (2)	0.95 (0.72, 1.25)	3 (3)	0.77 (0.49, 1.21)
Education	2 (3)	1.25 (0.91, 1.73)	1 (1)	0.33 (0.08, 1.35)

Table 9. Components of a Multifactorial Falls Risk Assessment

Study	Orthostatic BP	Vision	Balance & gait	Med Review	IADL/ ADL	Cognitive Evaluation	Environmental Hazards	Other
104					X			
105	X	X	X	X	X	X	X	Hearing, depression assessment
106	X	X	X	X			X	Neuro & Musculoskeletal exam, lab tests, Holter
16	X		X	X			X	Muscle strength and range of motion
107		X		X			X	Hearing, alcohol abuse assessment, assessment of physical activity
108	X	X	X	X	X	X	X	Health problems list
31				X				Self management skills, health assessment
109	X	X	X	X	X	X	X	Affect, carotid sinus studies (where clinical suspicion is high)
110	X	X		X				Review of lighting
111				X	X	X	X	Physical health, psychosocial functioning
33	X	X		X				Review of lighting
112	No specific components stated							
34		X	X	X	X	X	X	Hearing, review of lighting, review/repair assistive devices

Among exercise interventions, we were not able to detect statistically significant differences in the efficacy between different types of exercises, although only endurance exercise individually achieved a significant effect in our analysis on subjects who fell at least once, while only balance exercise individually achieved a significant effect in our analysis on monthly rate of falling. There emerged no clear pattern and no conclusive evidence from these data to recommend particular exercises for falls prevention. Results are displayed in Table 10.

Table 10. Exercise Components

Exercise Type	Subjects who fell at least once		Monthly rate of falling	
	Number of Studies (Arms)	Adjusted Risk Ratio (95% CI)	Number of Studies (Arms)	Adjusted Incident Rate Ratio (95% CI)
Balance	7 (8)	1.22 (0.64, 2.33)	14 (15)	0.76 (0.57, 1.01)
Endurance	7 (7)	0.89 (0.69, 1.15)	5 (5)	1.63 (1.06, 2.50)
Flexibility	4 (4)	0.90 (0.51, 1.59)	5 (5)	1.00 (0.63, 1.58)
Strength	8 (9)	0.82 (0.43, 1.56)	14 (14)	1.02 (0.73, 1.45)

We assessed the effect of the intensity of intervention on efficacy. In our analysis on subjects who fell at least once, low intensity interventions were not effective, while medium or high intensity interventions were effective. Our analysis on monthly rate of falling showed no difference in effectiveness by intensity.

PUBLICATION BIAS

We assessed the possibility of publication bias for the risk ratio of falling at least once and for the falls incident rate for all studies included in the meta-analyses. Neither the adjusted rank correlation test ($p=0.26$, $p=0.92$), nor the regression asymmetry test ($p=0.06$, $p=0.79$) indicated publication bias. A visual inspection of the funnel plots (Figure 7 and Figure 8) confirmed this conclusion.

Figure 7. Funnel plot of studies assessing risk of falling at least once

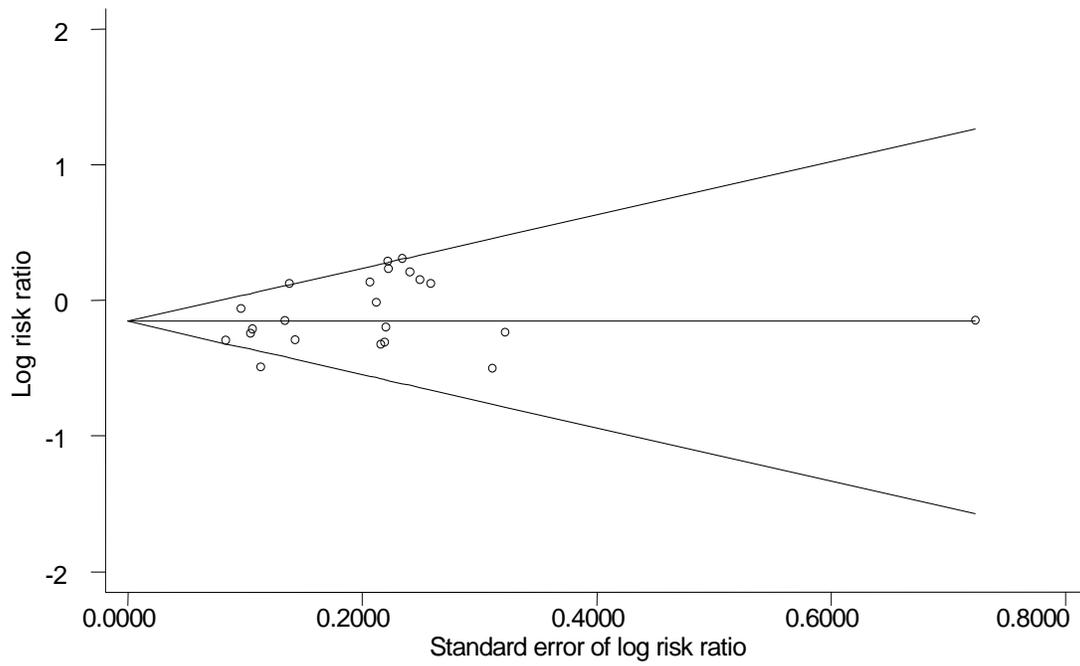
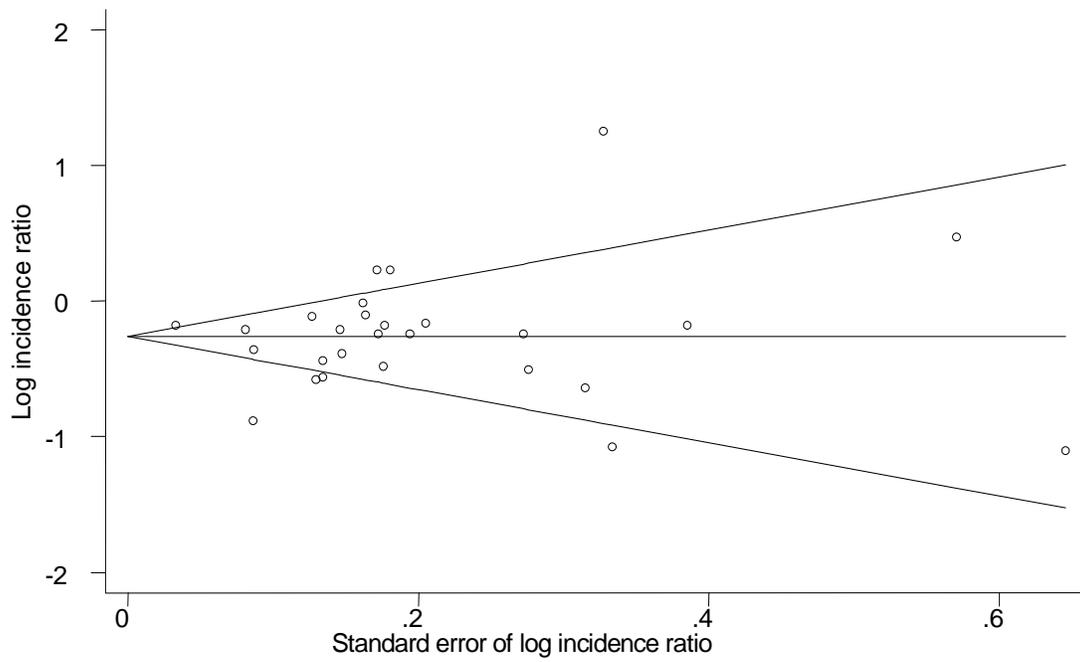


Figure 8. Funnel plot of studies assessing rate of falls



Preventing Injuries Resulting from Falls

In addition to interventions that seek to prevent falls, there are also interventions that seek to prevent injuries from falls rather than prevent falls themselves. Several recent articles have reported promising results.

The strongest evidence for preventing injuries comes from the large-scale randomized study on the use of external hip protectors by Kannus et al.⁹¹ A total of 653 elderly subjects with multiple falls risk factors were randomized to the hip-protector group, and 1,148 were assigned to the control group. The study showed the rate of hip fracture to be lower in the intervention group than in the control group (21.3 vs. 46.0 per 1,000 person years, respectively; relative hazard in the hip protector group: 0.4, 95% CI [0.2, 0.8] P=0.008). In the intervention group, the rate of hip fracture per fall was 84% lower among hip protector users than non-users (relative hazard: 0.2, 95% CI [0.05,0.5] P=0.002).

Lauritzen and colleagues¹¹³ had previously conducted a randomized trial of hip protectors among Copenhagen nursing homes. The relative risk of hip fractures among residents in the intervention group was 0.44, 95% CI [0.21,0.94]. While eight of the residents in the intervention group had a hip fracture, none of these were wearing the device at the time of the fracture.

A randomized study by Cameron and colleagues studied the effect of the use of hip protectors and contact with a nurse who promoted adherence on a subject's fear of falling and falls self-efficacy.⁷⁰ Subjects were elderly women with risk factors for falls who were randomized to an intervention group (N=61) and to a control group (N=71). At the 4-month follow-up, fear of falling was expressed by 43% of the subjects using the hip protector compared to 57% in the control group ($\chi^2=2.58$, $P=0.11$). Also, the subjects using the hip protector had greater improvement in falls self-efficacy as measured by the *Falls Efficacy Scale* ($t=2.44$, $P=0.16$), and the *Modified Falls Efficacy Scale* ($t=2.08$, $P=0.039$).

We also identified one study on a device for the prevention of injuries and cost. Zacker and colleagues,¹¹⁴ conducted an economic evaluation of an energy-absorbing flooring for the prevention of hip fractures compared to regular flooring. The study showed a payback period of 10.5 years when evaluating direct costs only, and a period of just over 11 months when evaluating both direct and indirect costs. The estimated cost-effectiveness ratios were less than \$1 per hip fracture prevented and life-year saved.

QUESTION 2. ARE PUBLIC INFORMATION OR EDUCATION CAMPAIGNS ALONE EFFECTIVE IN REDUCING OR PREVENTING FALLS?

We found no specific studies about the effectiveness of public information or mass education campaigns. In the meta-regression analyses, patient education given as part of multifactorial falls prevention programs did not show a significant independent effect.

QUESTION 3. WHICH CARE SETTINGS/ APPROACHES HAVE BEEN MORE EFFECTIVE FOR THE DELIVERY OF FALLS PREVENTION INTERVENTIONS? WHICH PROVIDERS SHOULD DELIVER THIS SERVICE?

Successful examples of falls prevention programs have been identified using a variety of approaches in a variety of settings. For example, Close¹⁰⁹ and Rubenstein¹⁰⁶ in the medical care system and Wagner¹⁰⁷ and Buchner¹⁷ in the population-based public health model obtained beneficial results.

Providers

Falls prevention interventions have been delivered by many different types of providers. Interestingly, physicians have rarely been the sole provider type. Successful falls prevention interventions have been provided by fitness instructors, nurses, physical therapists, social workers, and teams of multiple providers. The evidence is currently not sufficient to conclude that any one provider type is preferable over another. Our exploratory analysis revealed a poor distribution of provider types, which left us unable to perform a pooled analysis on this topic.

Care Settings

Falls prevention interventions have been carried out in a variety of settings. Successful interventions have been conducted in physician offices, patient homes, hospitals, nursing homes, community centers, and specialized research centers. No evidence currently exists to advocate for increased effectiveness based on care setting. Our meta-regression of setting (Table 11) did not show statistically significant differences in efficacy between setting types.

Table 11. Setting Types

Setting Type	Subjects Who Fell at Least Once		Monthly rate of falling	
	Number of Studies (Arms)	Adjusted Risk Ratio (95% CI)	Number of Studies (Arms)	Adjusted Incident Rate Ratio (95% CI)
Medical	7 (7)	0.90 (0.76, 1.05)	9 (9)	0.85 (0.66, 1.09)
Non-Medical	7 (9)	0.95 (0.80, 1.12)	7 (7)	0.69 (0.54, 0.87)
Not Described	6 (6)	0.80 (0.65, 0.99)	9 (10)	0.81 (0.64, 1.03)

QUESTION 4. WHAT ARE THE KEY ISSUES IN SUSTAINING FALLS PREVENTION PROGRAMS?

Two key issues are involved in sustaining falls prevention programs: obtaining and maintaining sufficient funding and availability of programs. The interventions reviewed in this report were performed through the use of special funding from research grants or

demonstration projects, and none of them continued as regular programs. Funding clearly seems to be needed to sustain falls prevention programs and would be required to bring about the widespread use of effective interventions.

QUESTION 5. COST EFFECTIVENESS OR COST SAVINGS: DO FALLS PREVENTION INTERVENTIONS APPEAR TO REDUCE HEALTH CARE COSTS BY REDUCING DISEASE, PHYSICIAN OFFICE VISITS, HOSPITALIZATIONS, NURSING HOME ADMISSIONS, ETC.?

The high incidence of falls among people 65 and older and the substantial associated costs constitute a major problem (see Introduction). The growing elderly population exacerbates the problem in the United States and most other countries. For instance, annual Medicare costs for hip fractures are projected to increase from \$2.9 billion in 1991¹⁰ to \$240 billion by the year 2040.¹¹ Thus, one of the questions of interest is whether the provision of falls prevention interventions reduces health care costs, and if so, how (e.g. by reducing injuries, physician office visits, hospitalizations, nursing home admissions)? In this section, we review the evidence presented by 15 studies (16 publications) regarding the cost-effectiveness or cost-savings of falls prevention interventions. We first summarize the overall findings, irrespective of type of intervention. Then we discuss the findings by type of intervention. One must keep in mind that cost effectiveness is discussed only in a small portion of published studies; thus, we did not limit this section to controlled trials.

Overall cost-effectiveness of falls prevention interventions

Among the 15 studies of cost-effectiveness reviewed, six studies utilized multifactorial interventions,^{16, 35, 78, 105, 106, 108, 109} and nine studies implemented a single intervention. These include four studies using specific physical activity or exercise programs;^{17, 99, 115, 116} three focused on environmental modification (including two simulation-based modeling studies);^{114, 117, 118} one study using practice redesign by chronic care clinics;³¹ and one study using patient reminders.¹¹⁹ Three of the 15 studies were intended to improve overall health and functional status for the elderly, where falls prevention was just one domain of the measured outcomes.^{31, 99, 105} The rest of the studies are focused exclusively on falls prevention and fall-related injury reduction for the elderly. Most studies recruited community-living seniors, except for two that focused on nursing home residents,^{99, 106} one that used simulated nursing home residents,¹¹⁴ and one study of rehabilitation hospital patients.¹¹⁹ A summary of the 15 studies is presented in Table 12. Although all the studies provided information on health care costs or utilization, only eight of the studies, including the two simulation studies, reported information on the costs of the intervention.^{78, 99, 106, 114-118}

Table 12. Cost Effectiveness Articles

Type of intervention	Author, Year	Subjects	Settings Research design Follow-up period Control	Costs of intervention Effectiveness Health care costs or utilizations	C/E Ratings
Risk factor identification (physical, functional, and medication examination) Tailored multifactorial prevention program (combination of medication adjustment, behavioral recommendations, and exercises, as determined by participants' baseline assessment.)	Tinetti , 1994 and Rizzo , 1996	301 men and women >= 70 years old (mean = 78) who had at least one of eight targeted risk factors for falling (153 = TI; 148 = CT)	Patient's home RCT 1 year Home visits from social work students	\$905 (range \$588 to \$1346, 1993 dollars) per targeted intervention participant. Assumed no cost to the control group. Mean intervention costs per fall prevented = \$2150	Cost effective. Maybe cost saving.
				Significant reduction in the risk of falling. The proportion of persons with the targeted risk factors for falling was reduced.	
				Mean health care costs were \$2000 less in the intervention than control group, but median costs were \$1100 higher in the intervention than control group. The intervention strategy showed its strongest effect among individuals at high risk of falling	
Risk factor identification (physical examination and environmental assessment) Tailored preventive & therapeutic recommendations	Rubenstein , 1990	Within 7 days of a fall, 160 ambulatory nursing home patients (mean = 87 years old) were randomly assigned to receive either a postfall assessment (n = 79) or usual care (n = 81)	A nursing home RCT 2 years Usual care	Less than \$300 (1989 dollars) per pt for the costs of a 1-hour standardized assessment of institutionalized fallers done by a nurse practitioner followed by recommended interventions	Cost effective and cost saving.
				Through the use of the assessment, many remediable problems were detected. Int. pts had 9% fewer falls (NS) and 17% fewer deaths (NS).	
				At the end of the 2-year period, the int. group had 26% fewer hospitalizations (p <.05) and a 52% reduction in hospital days (p < .01). Such reduced hospitalizations are estimated to save more than \$800 annually per institutionalized faller.	
A structured detailed medical, functional, and environmental assessment with individual counseling about safety and home modifications and referral to relevant services if indicated	Close, 1999	397 community-living patients 65 years and older (mean = 78) who presented to an accident and emergency department with a fall (213 in control and 184 in intervention group)	Hospital and patient's home RCT 1 year Usual care	Not available	Insufficient information
				At 12-month follow-up, the intervention group reported 183 falls, whereas the control group reported 510 falls. The risk of falling was significantly reduced in the intervention group (odds ratio 0.39). The decline in functional status with time was greater in the control group.	
				The odds of at least one hospital admission were lower in the intervention group (0.61 [0.35-1.05]).	
A comprehensive intrinsic and extrinsic risk assessment, individualized feedback about identified risks, and a motivational video and booklet	Gallagher, 1996	100 community-living persons 60 years and older (mean = 75 years) (50 in intervention group and 50 in control group) who had	Patient's home RCT 6 months Usual care	Not available	Insufficient information (implied not cost effective)
				No statistically significant differences between the intervention and control groups on the outcome measures including fall incidence, falls self-efficacy, fear of falling, social functioning, and quality of life.	

Table 12. Cost Effectiveness Articles (continued)

Type of intervention	Author, Year	Subjects	Settings Research design Follow-up period Control	Costs of intervention Effectiveness Health care costs or utilizations	C/E Ratings
		experienced a fall in the preceding three months		No statistically significant differences between the intervention and control groups in health service utilization, which was determined by a 15-item scale itemizing local health services that are available for the elderly.	
Home safety hazards assessment and modification recommendations and assistance. Non-tailored health behavior interventions consisted of group meetings led by a health behaviorist and a physical therapist to address fall risks and included exercise component	Hornbrook, 1994	3182 independently living persons aged 65 years and older (mean = 73) who were members of a group-model HMO (intervention = 1611; control = 1571)	Patient's home RCT 2 years Home assessment. Informed about potential home - safety hazards and given a safety booklet	<p>Not available</p> <p>Only marginal success in reducing falls. The intervention decreased the odds of falling by 0.85, but reduced the average number of falls among those who fell by only 7%. The effect was strongest among men age 75 and older.</p> <p>The intervention program had no significant effects on the probability of medical care falls or the number of medical care falls among fallers. Neither did the effects on fracture falls. The intervention did not have significant effects on the probability of being hospitalized as a result of a fall or on the number of hospitalized falls.</p>	Insufficient information (implied not cost saving)
In-home geriatric assessments to screen for medical, functional, psychosocial and home hazards problems, followed by a letter describing findings and recommendations and follow-up visits by trained volunteers at 4-month intervals for 1 year. The goal is to provide preventive health care and improved health and functional status.	Fabacher, 1994	254 community-living veterans, 70 years and older, not currently receiving health care at the Sepulveda VA Medical Center (131 intervention; 123 controls)	Patient's home RCT 1 year Usual care	<p>Not reported in dollar values. Available information includes 183 hours of physician's assistant or nurse time and 600 hours of volunteers' time in home visits. 20 hours of volunteer training program.</p> <p>Home modification to reduce risk for falls was recommended to 28 subjects (out of 385 recommendations). Self-reported fall rates were not significantly different between the groups; however, there was a trend toward fewer intervention subjects falling during the follow-up year (14% vs. 23%, p = 0.10). Intervention subjects had better functional status scores than controls.</p> <p>Non-prescription drug use increased significantly among controls, but not among intervention subjects. The percent of subjects hospitalized in the follow-up year was similar in the two groups. No subject in either group was admitted to a nursing home.</p>	Insufficient information
Individually prescribed home-based exercise program	Robertson , 2001a	240 women and men aged 75 years and older (mean = 81). Exercise group = 121 and control	Patient's home RCT 1 year Usual care	The program costs \$NZ432 (at 1998 dollars) per person to deliver, or \$NZ1803 per fall prevented. \$NZ155 per fall prevented when hospital costs averted were considered.	Cost effective. Cost saving for those age 80 years and older.

Table 12. Cost Effectiveness Articles (continued)

Type of intervention	Author, Year	Subjects	Settings Research design Follow-up period Control	Costs of intervention Effectiveness Health care costs or utilizations	C/E Ratings
		group = 119		46% reduction in the number of falls for the exercise group. The number of falls was significantly reduced in those aged 80 years and older, but no difference was found in participants ages 75 to 79 years. Five hospital admissions were due to injuries caused by falls in the control group and none in the exercise group. The program resulted in cost savings of \$NZ576 per fall event prevented and \$NZ1563 per injuries fall event prevented for those age 80 years and older.	
Individually prescribed home-based exercise program	Robertson, 2001b	450 women and men aged 80 years and older (mean = 84). Exercise group = 330 and control group = 120.	Patient's home CCT 1 year Usual care	The program costs \$NZ418 (at 1998 dollars) per person to deliver, or \$NZ1519 (£441) per fall prevented. 30% reduction in the number of falls. Fewer participants had falls resulting in injuries, but there was no difference in the number who had serious injuries. No difference in hospital costs resulting from falls. The difference in the actual costs of hospital admissions between participants from the exercise and control group as a results of a fall was not significant.	Cost effective but not cost saving.
Individually tailored one-on-one physical therapy sessions three times a week for 4 months.	Mulrow, 1994	194 (97 in each group) nursing home residents older than 60 years (mean=81), dependent in at least two activities of daily living, residing in the nursing home for at least 3 months	Nursing homes RCT 4 months Friendly visits three times a week for 4 months.	Charge for the 4-month physical therapy program was \$1220 (1993 dollars) per subject. For friendly visits program was \$189 per subject. Compared with the FV group, the PT group experienced NO significant improvements in overall Physical Disability Index, Sickness Impact Profile, or activities of daily living scores. PT used fewer assistive devices. 79 falls in PT vs. 60 falls in FV. Health care charges did not differ significantly between PT and FV groups.	Not cost effective.
Supervised strength and endurance training	Buchner , 1997	105 adults, age 68-85 years old, (mean = 75) with at least mild deficits in strength and balance were selected from a random sample	Community classes RCT 18 months Usual activity	Not available 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. No effects of exercise on gait, balance, or physical health status.	Insufficient information

Table 12. Cost Effectiveness Articles (continued)

Type of intervention	Author, Year	Subjects	Settings Research design Follow-up period Control	Costs of intervention Effectiveness Health care costs or utilizations	C/E Ratings
		of enrollees in a HMO		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)	
Home assessment and modifications	Salkeld , 1999	530 subjects age 65 years and older (mean=77) recruited mostly during a hospital stay. Intervention group = 264, and control group = 266.	Patient's home RCT 1 year Usual care	Occupational therapist intervention costs = \$116 (1997 Australian dollars) and home modification costs = \$7. Mean intervention costs per fall prevented = \$129 226 falls in the intervention group and 324 falls in the control group. The reduction in falls was significant in the subgroup of people who had a falls history, but insignificant among subjects without falls history. The intervention led to increased overall health care costs (mean = \$1805). The average cost per fall prevented was \$4986. A sensitivity analysis was conducted by removing 15 outlier subjects. The average cost per fall prevented was \$1921 for all intervention subjects and was cost saving for subjects who had falls history.	Cost effective. Maybe cost saving for subjects who have falls history in the previous year.
Home assessment and modifications	Smith & Widiatmoko, 1998	75 years or over, living independently in the community	N/A Simulation-based decision-analytic model 1 year and 10 years No intervention	The average cost of the intervention per person was estimated to be \$190 (1996 Australian dollars). It was assumed the fall rate = 0.4 and injury rate after a fall = 0.1 with no intervention. It was assumed that the intervention would reduce the fall rate over any one-year period by 25%. It was estimated on average \$71.68 would be spent on fall-related treatment per elderly person with no intervention, and decreasing to \$53.76 following intervention. Over a one-year period, incremental costs of introducing the intervention = \$172 per person. Cost per fall prevented = \$1721, and cost per injury prevented = \$17208. Over a 10-year period, the intervention resulted in a cost saving of \$92 per person.	Indicative of cost saving under assumed effectiveness
Practice redesign –	Coleman , 1999	169 patients ages 65	Nine primary care	Not available	Insufficient

Table 12. Cost Effectiveness Articles (continued)

Type of intervention	Author, Year	Subjects	Settings Research design Follow-up period Control	Costs of intervention Effectiveness Health care costs or utilizations	C/E Ratings
Chronic care clinics (disease management planning, medication review, patient self-management/support group)		and older (mean = 77) with the highest risk for being hospitalized or experiencing functional decline (Intervention group = 5 physicians, and 96 patients, and control group = 4 physicians and 73 patients)	physician offices in a large staff-model HMO RCT 2 years Usual care	<p>After 24 months, no significant improvements in frequency of incontinence, proportion with falls, depression scores, physical function scores, or prescriptions of high-risk medications were demonstrated. A higher proportion of intervention patients rated the overall quality of their medical care as excellent than did control patients (40% vs. 25%, $p = 0.1$)</p> <p>Costs of medical care including frequency of hospitalization, hospital days, emergency and ambulatory visits, and total costs of care were not significantly different between intervention and control groups.</p>	information
Energy-absorbing flooring in nursing home	Zacker & Shea, 1998	8 nursing home residents who will experience at least five falls per year and are at greatest risk of fracturing a hip.	Atypical 200-bed nursing home Simulation-based decision-analytic model 40 years Traditional floors	<p>The total 40-year costs of the flooring intervention are estimated to be \$75,391(1995 dollars)</p> <p>The probability of hip fracture from fall was assumed to be 2% without safety floor and 1% with safety floor, yielding an estimated 6.86 hip fractures prevented and 15.44 life-years saved over 40 years.</p> <p>The total 40-year direct medical costs avoided were estimated to be \$123,545. When adding indirect morbidity and mortality avoided, the total benefits of the flooring intervention were estimated to be \$1, 247,876. Cost effectiveness ratios of less than \$0 per hip fracture prevented and life-year saved were estimated.</p>	Indicative of cost saving under assumed effectiveness
Identification bracelets as a reminder to prevent falls	Mayo, 1994	134 high-risk patients (mean age = 72) who are undergoing in-patient physical rehabilitation (65 with bracelet and 69 with no bracelet)	A rehabilitation hospital RCT From admission to discharge Patients were told to remember to be careful	<p>Not available</p> <p>The persons with the identification bracelet had a higher probability of falling (a hazard ratio of 1.3). There were no differences between the two groups on location of fall or its severity, functional status, time-to-first-fall, and frequency of falling</p> <p>There was no significant difference between the two groups on length of stay (75.5 days for intervention group and 67.2 days for control group).</p>	Insufficient information (implied not cost effective)

Of the 13 clinical trials, six studies reported a significant reduction in the risk of falling (at $\alpha = .05$ level),^{16, 17, 106, 109, 115, 116} three studies found a marginal reduction,^{35, 105, 117} and four studies did not find such an effect.^{31, 99, 108, 119} Among the six studies that reported significant effects in reducing the risk of falling, one reported significantly fewer hospitalizations and a reduction in hospital days in the intervention group compared to the control patients¹⁰⁶ (the subjects in this study had fallen in the week prior to having been recruited for the study). Three other studies also found cost saving potentials for high-risk elderly although not for all study subjects.^{78, 115, 117}

Utilization of health care services was measured in two studies

One study reported that the odds of at least one hospital admission were lower in the intervention group than the control group.¹⁰⁹ Another study found fewer outpatient clinic visits among intervention subjects than control subjects, and the intervention group was significantly less likely to spend more than three days in the hospital and to sustain hospital costs over \$5000 than controls.¹⁷ However, these two studies did not report the costs of interventions, so we cannot compare their cost-effectiveness with other studies, nor can we judge their cost savings compared to usual care.

One study that reported a significant reduction in the risk of falling also found that fewer intervention participants had falls resulting in injuries, compared to control patients.¹¹⁶ However, since there was no difference in the two groups in terms of serious injuries, and the distribution of hospital cost data was highly skewed, this study did not find savings in hospital costs resulting from reduced falls. The remainder of the six RCT studies that found either marginal or no effects on falls prevention correspondingly found no significant reduction in health care costs or utilization.^{31, 35, 99, 105, 108, 119}

The results of the two simulation-based studies^{114, 118} suggested that cost savings would result from most interventions that were assumed to be effective. Even in the worst-case estimates, Zacker and Shea¹¹⁴ reported that the cost per life-year saved by preventing hip fractures compared very favorably with other injury-prevention interventions.

Cost-effectiveness review by type of falls prevention intervention

Although we identified studies of five types of interventions that included costs or health care utilization information, available evidence on two of them did not warrant a detailed discussion. Mayo and colleagues¹¹⁹ concluded that using identification bracelets as a reminder was of no benefit in preventing falls among high-risk hospitalized patients. Coleman and colleagues³¹ also did not find beneficial effects of practice redesign by implementing chronic-care clinics on falls prevention. Thus, although program costs were not reported in these two studies, these two types of interventions do not appear to be cost effective or cost saving. As for the other types of intervention – multifactorial, exercise alone, and environmental modification alone – they are discussed in greater detail below. However, the available evidence does not support a conclusion regarding which type of falls prevention intervention is most cost effective, because of the heterogeneity among studies and inadequate quality of the cost-effectiveness analyses.

Multifactorial Interventions. All six multifactorial interventions involved risk-factor identification and tailored multifactorial prevention program or recommendations, except for one that utilized non-tailored group meetings.³⁵ However, only three of the six studies showed reductions in healthcare costs or utilization.^{78, 106, 109} Close and colleagues¹⁰⁹ did not provide cost data, so we could not assess the economic impact of that study.

Two studies reported both costs of interventions and health care costs or utilization outcomes. Rizzo and colleagues⁷⁸ conducted a detailed economic evaluation of a home-based multifactorial intervention. The authors compared the mean health care costs of the intervention group with those of the control group, in particular among high-risk individuals. However, a few control subjects incurred very costly hospitalizations; thus, the median cost may be more a representative measure of central tendency in such cases. If one compares median health care costs between the two groups, total health care costs were higher in the intervention group as well as in high-risk subgroups than in controls.

Rubenstein and coworkers¹⁰⁶ did not intend to conduct a formal cost-benefit analysis, but their rough estimation was that the costs of intervention averaged less than \$300 (in 1989 dollars), while the savings averaged more than \$800 annually per nursing-home faller. We cannot determine from these numbers whether the intervention is cost saving, because this report did not use a consistent perspective in costing (program vs. societal). The costing method which resulted in the omission of costs that were beyond the program implementation (from the societal perspective) and/or overestimation of the health care cost savings (from the program implementation perspective).

Specific Exercise. Four studies assessed the use of specific exercises to prevent falls. One study used an individually prescribed home-based exercise program that involved trained nurses for home visits and exercise prescription.^{115, 116} The second study implemented individually tailored one-on-one physical therapy sessions provided by physical therapists to nursing-home residents.⁹⁹ The third study involved supervised strength and endurance training in community classes to enrollees of an HMO.¹⁷

Robertson and colleagues¹¹⁵ studied 240 women and men aged 75 years and older and reported fewer hospitalizations because of fall-related injuries in the exercise group than in the control group. In addition, the authors reported that the individually prescribed exercise intervention was cost saving for those aged 80 years and older. However, when this intervention was replicated in a multicenter controlled trial, the reduction of the number of falls resulted in no difference in hospital costs.¹¹⁶ The authors discussed several possible reasons for the discrepancy in the results. One possible reason is that the low incidence of serious injurious falls in the study samples and the highly skewed hospital cost distribution make the findings of reduced health care costs unreliable.

Although the goal of the second study was to improve the function of very frail, long-term nursing home residents, the physical therapy program provided only modest mobility benefits.⁹⁹ Health care charges did not differ significantly, although the cost of delivering the physical therapy program was over \$1000 more per subject than was the cost of the control intervention (friendly visits).

The study of strength and endurance training¹⁷ reported fewer outpatient clinic visits in their intervention group than in the control group, but the reduction did not result in significant differences between groups in ancillary outpatient costs. Nevertheless, although hospital use was similar in both groups, the study did report that the hospitalized control subjects were likely to have a significantly longer length of stay and were significantly more likely to incur hospital costs over \$5000 than the intervention subjects. However, cost-effectiveness cannot be assessed for this study, because the cost of intervention was not reported.

Environmental Modification. Information regarding cost-effectiveness of environmental modification is available from one RCT and two simulation-based modeling studies.

The home hazard reduction program reported that the intervention led to increased health care costs, although there was a reduction in the number of falls.¹¹⁷ The program was more effective and had a better cost-effectiveness ratio among persons who had fallen in the previous year. In their sensitivity analysis, the authors removed 15 outliers from the analysis who either incurred total costs that were more than three standard deviations above the group mean or reported more than 50 falls in the study year. With the removal of the outliers, the authors found that the (mean or median) cost per fall prevented actually represented a cost saving among subjects who had fallen in the previous year. However, as the authors also noted, nearly all hospital admissions during the study period were unrelated to falls (similar to the findings of Rizzo and colleagues⁷⁸). Thus, the observed/apparent increase in health care costs was assumed to be a chance result.” Such a conclusion also challenges the validity of the cost-saving results found for the high-risk subjects in the sensitivity analysis.

The long-term benefits (or effects) of an environmental modification intervention are more predictable than those of multifactorial interventions or exercise programs. Hence, both the simulation-based studies investigated the cost-effectiveness of environmental modification interventions over the long term (10 years in Smith and Widiatmoko¹¹⁸ and 40 years in Zacker and Shea¹¹⁴), using available published literature. As we mentioned above, the two decision analytic models indicated the potential for considerable benefit to be gained from either a home assessment and modification program or the Penn State University Safety Floor, a type of energy-absorbing flooring. Smith and Widiatmoko¹¹⁸ showed that over a 10-year period, the study's home assessment and modification program resulted in a cost saving of \$92 per person (1996 Australian dollars). The study by Zacker and Shea¹¹⁴ “revealed a payback period of 10½ years if using only direct costs and just over 11 months when direct and indirect costs were included.” Actual clinical trials are needed to demonstrate the efficacy and cost-effectiveness of these falls-prevention strategies.

Conclusion from Published Literature

Whether a falls prevention intervention is cost effective or cost saving is a function of many parameters, including the targeted population, the environment where the targeted population resides, design and implementation, time, the accounting of benefits and costs, the perspective of costing, and the selection of a comparison group. The limited studies of

cost-effectiveness include substantial heterogeneity in the above parameters. This heterogeneity hinders us from comparing the relative cost-effectiveness by type of intervention and from drawing definitive conclusions about the economic impact of falls prevention interventions. In the preceding discussion, we also assessed the quality of the available studies in conducting their cost-effectiveness analysis. Common threats to the validity of cost-effectiveness analyses in the above studies include 1) the highly selective trial population (that results in “cost-efficacy” instead of “cost-effectiveness” findings, and unknown generalizability); 2) lack of a clear perspective in accounting for costs and benefits; and 3) inadequate sample size (which causes the health care cost and utilization outcomes to be influenced substantially by a few outliers).

Overall, the evidence is not conclusive but suggests that an effective intervention provided to people with a high risk of falling has the potential to be cost saving compared with current practice. An effective falls prevention intervention is also likely to result in more efficient resource allocation than many other types of prevention interventions (e.g., hypertension control interventions to prevent myocardial infarctions) for elderly people. Further research is needed to inform policy-makers about which intervention is effective for what population and should use sound methodology to provide more solid evidence for cost-effectiveness of falls prevention interventions.

Preliminary Cost-Effectiveness Analysis

We conducted a preliminary analysis on the economic impact to Medicare of providing a falls prevention rehabilitation benefit to Medicare beneficiaries age 65 and older who have just fallen. The findings presented in Tables 13-18 are based on published estimates of fall rates, medical costs, and population projections. They are also based on conservative estimates of risk reduction, penetration rate, and the share of medical costs borne by Medicare. This analysis uses our meta-analytic estimates of the effectiveness of falls prevention interventions.

Population Projection. We used data from the 2000 Census to estimate the number of eligible Medicare beneficiaries in 2002. Assuming 1% annual growth, there will be 18.66 million Medicare beneficiaries age 65 to 74, and 16.94 million beneficiaries age 75 and older in 2002.

Number of Falls with Injury. The most comprehensive study of slip and fall injuries among older adults is by Rice et al., 1989,¹²⁰ which was updated by Englander et al in 1996. Englander⁹ estimated the annual number of falls with injury was 6,215 per 100,000 population for persons age 65 to 74, and 10,932 per 100,000 for those age 75 and older. Multiplying these rates by the age-specific Medicare population in 2002 yields estimates of 1.16 million falls with injury among 65 to 74 year olds, and 1.85 million for Medicare beneficiaries age 75 and older in 2002.

Cost per Fall with Injury. Englander⁹ estimated the direct medical cost of a fall resulting in injury was \$6,215 in 1994 dollars. This estimate includes expenditures for hospital and nursing home care, physician and other professional services, rehabilitation, community-based services, drugs and medical equipment, insurance administration, and home

modification. Inflating this figure at a 5% annual rate yields a direct cost of \$9,182 per fall with injury in 2002 dollars. If we assume (conservatively) that Medicare pays 60% of direct medical costs of beneficiaries, then the total cost to Medicare associated with these falls is \$16.6 billion in 2002.

Risk Reduction. We used our meta-analysis to estimate the expected reduction in falls due to the proposed intervention. The pooled estimate of the independent effect of a multifactorial falls assessment and management program was a 40% reduction in falls of all types (with and without injury). We assume the same rate of reduction in falls from the falls prevention rehabilitation benefit, and that the effect is proportionate across fall types and will reduce the number of falls with injury by 40%.

Cost Estimates. We assume a falls prevention rehabilitation benefit will be available to 90% of seniors who suffer a fall, assuming the other 10% of seniors are too ill or frail for a rehabilitation program, or their fall results in death. Since it was estimated that 50% of all falls are recurrent falls^{3, 121, 122}, the expected number of falls with injuries should reduce by 542,000 (209,000 from age 65 to 74 years old; 333,000 from people 75 and older). The reduction of falls are from the assumed 30% of people age 65 to 74, and the 38% of people age 75 years and older who fall at least once in a given year.

We assume a falls prevention rehabilitation benefit will include a detailed evaluation by a specialist(s) for the 90% of previous fallers, of whom, 60% will go through a rehabilitation program. The others will only be given recommendations for behavioral, environmental, or medical modifications (e.g., change of medicine). Additionally, all of these people (i.e., 90% of previous fallers) will need at least 1 follow-up visit to ensure that fall prevention recommendations are being implemented.

In this modeling exercise, we assume CMS will reimburse the detailed evaluation at an average of \$95 (this will of course vary greatly depending on the particular type and number of specialist referrals necessary), \$280 for the rehabilitation program (\$35 per session for 8 paid sessions, 2/week for 2 weeks then 1/week for 4 weeks), and \$40 for the follow-up visit. Given such reimbursement rates, it is estimated that the falls prevention rehabilitation benefit will cost Medicare \$272 million in 2002. In return for this payment, the number of falls with injury is expected to decrease by 542,000. This results in an average cost to Medicare of about \$500 to prevent a fall with injury. The costs to Medicare vary by age, with a cost of \$376 million for persons aged group 65-74 and a savings of \$104 million for persons aged 75 and older (Table 13). Since Medicare only pays a portion of total direct costs (we assumed 60% in this analysis), the effect of the falls prevention rehabilitation program on total direct costs is even more advantageous. We estimate the proposed program would actually result in a net savings of \$1.7 billion when total direct health care costs are considered.

Sensitivity Analyses. To assess the robustness of our findings to underlying assumptions, we substituted more conservative estimates for five critical parameters. First, we lowered the share of direct medical costs borne by Medicare to 50%. Second, we assumed the intervention would reduce fall rates by only 18% (the lower bound of the 95% confidence interval) rather than the 40% estimate in our base case analysis. Third, we lowered the

penetration rate by assuming only 80% of older Medicare beneficiaries with a previous fall would receive the intervention in a given year. Fourth, we increased the percentage of Medicare beneficiaries who would need fall rehabilitation to 70%. Fifth, we raised the cost of fall rehabilitation to CMS from \$280 to \$350 per beneficiary.

Using more conservative estimates, the costs to Medicare become \$770, \$1,915, \$242, \$573, and \$724 million respectively, in each case of a more conservative assumption of parameters (Tables 14-18). However, given the large number of fall-related injuries prevented (542,000 in base case, and 244,000 in the lower bound case scenario), the falls prevention rehabilitation benefit can be considered a cost-effective intervention.

Table 13. Cost Analysis Base Case Estimation

Baseline Estimation	Age 65-74	Age 75 and older
Population	18,660,102	16,937,631
Number of people fall	5,598,030 (30%)	6,351,612 (38%)
Number of fall injuries	1,159,763	1,851,571
Medicare cost per fall injury	\$5,509	\$5,509
Medicare cost for all fall injuries	\$6,389,632,621	\$10,201,103,173
Number of reduced falls with injury	208,757	333,283
Reduced Medicare cost	(\$1,150,133,872)	(\$1,836,198,571)
Intervention cost	\$ 1,526,582,913	\$ 1,732,084,459
Medicare cost for fall injuries after intervention	\$6,766,081,662	\$10,096,989,060
Cost (savings) to Medicare	376,449,041	(\$104,114,112)

Table 14. Cost Analysis Sensitivity Analysis 1

Sensitivity Analysis 1: Medicare's share = 50% of direct cost of fall injuries

Baseline Estimation	Age 65-74	Age 75 and older
Medicare cost per fall injury	\$4591	\$4591
Medicare cost for all fall injuries	\$5,324,693,851	\$8,500,919,311
Reduced Medicare cost	(\$958,444,893)	(\$1,530,165,476)
Cost (savings) to Medicare	\$568,138,020	\$201,918,983

Table 15. Cost Analysis Sensitivity Analysis 2

Sensitivity Analysis 2: Intervention effectiveness at lower bound of meta-analysis result = 18%

Baseline Estimation	Age 65-74	Age 75 and older
Number of reduced falls with injury	93,941	149,977
Reduced Medicare cost	(\$517,560,242)	(\$826,289,357)
Cost (savings) to Medicare	\$1,009,022,670	\$905,795,102

Table 16. Cost Analysis Sensitivity Analysis 3

Sensitivity Analysis 3: Intervention penetration rate = 80%

Baseline Estimation	Age 65-74	Age 75 and older
Number of reduced falls with injury	185,562	296,251
Reduced Medicare cost	(\$1,022,341,219)	(\$1,632,176,508)
Intervention cost	\$ 1,356,962,589	\$ 1,539,630,630
Cost (savings) to Medicare	\$334,621,370	(\$92,545,878)

Table 17. Cost Analysis Sensitivity Analysis 4

Sensitivity Analysis 4: Fall rehabilitation rate = 70%

Baseline Estimation	Age 65-74	Age 75 and older
Intervention cost	\$ 1,667,653,281	\$ 1,892,145,069
Cost (savings) to Medicare	\$517,519,409	\$55,946,498

Table 18. Cost Analysis Sensitivity Analysis 5

Sensitivity Analysis 5: Cost of fall rehabilitation = \$350

Baseline Estimation	Age 65-74	Age 75 and older
Intervention cost	\$ 1,738,188,465	\$ 1,972,175,374
Cost (savings) to Medicare	\$588,054,593	\$135,976,803

These are admittedly crude estimates. They do not take into account any costs Medicare might have to pay as a result of implementing the plan developed from the falls prevention rehabilitation benefit (although such costs - for a change in medications, or new eyeglasses, or home environmental modifications, etc. - are not usually paid for by Medicare). Neither do these estimates account for any additional benefits beyond falls reduction that may accrue from the intervention. Exercise, for example, has also been associated with other health benefits. Still, these simple estimates support the hypothesis that falls prevention programs may be very cost-effective from Medicare’s perspective, or even cost-saving from a total direct medical cost perspective.

QUESTION 6. SHOULD FALLS PREVENTION PROGRAMS BE TARGETED TOWARD HIGH-RISK INDIVIDUALS? ARE THERE A FEW BASIC QUESTIONS TO IDENTIFY THESE INDIVIDUALS? CAN THIS BE DONE THROUGH SELF-IDENTIFICATION?

We did not find evidence supporting the hypothesis that falls prevention programs are most effective in high risk populations, although in theory this should be true, and for

other kinds of healthcare interventions there is empirical evidence that it is true. We assessed the efficacy of the two most effective interventions, multifactorial falls risk assessment and management program and exercise, in studies that enrolled high risk or non-high risk populations. No statistically significant differences in efficacy between groups was detected (Table 19).

Table 19. Intervention by Population Type

Intervention	Population Type	Subject who Fell at Least Once		Monthly rate of falling	
		Number of studies (arms)	Adjusted Risk Ratio (95 % CI)	Number of studies (arms)	Adjusted Incidence Rate Ratio (95 % CI)
Multifactorial falls risk assessment and management program	High Risk Population	8 (8)	0.82 (0.69, 0.97)	7 (7)	0.60 (0.45, 0.81)
Multifactorial falls risk assessment and management program	Not High Risk Population	2 (2)	0.60 (0.41, 0.89)	0 (0)	NR
Exercise	High Risk Population	5 (5)	0.81 (0.61, 1.08)	10 (10)	1.09 (0.84, 1.42)
Exercise	Not High Risk Population	7 (8)	0.82 (0.75, 1.12)	9 (10)	0.71 (0.58, 0.88)

That being said, interventions targeted to high and low risk populations have been different in most studies. For example, post-fall assessments and low-intensity exercise programs have been mostly targeted to frail and high-risk populations, while high intensity exercise programs have been targeted to broader populations (often excluding high-risk participants because of poor endurance). Therefore, comparing trials that focused on either high or low risk populations is not possible without some confounding by intervention variation.

Though not proven, it makes clinical and scientific sense that comprehensive post-fall assessments and fall risk assessments should be targeted to persons at higher risk. Because of their increased fall risk, they have the most to gain and would tend to have the largest effect size. In terms of identifying individuals at high risk for falls, there are a number of instruments, of varying length and complexity, with greater and lesser degrees of sensitivity and overall accuracy. From a practical standpoint, a simple identifier or set of questions is better, as long as it is reasonably accurate. With this in mind, the American Geriatrics Society evidence-based clinical guideline for prevention of falls (co-chaired by Laurence Rubenstein with considerable input from the Healthy Aging Project) recommended the following persons to have a comprehensive fall evaluation (risk assessment): 1) older persons presenting for medical attention with one or more falls, 2) older persons who report recurrent falls (2 or more in a 6 month period), or 3) older persons with abnormalities of gait and/or balance.²¹

QUESTION 7. ARE THERE SPECIFIC FALLS PREVENTION EXERCISES RECOMMENDED FOR SENIORS?

Exercise is effective in falls prevention programs. A variety of reviews and meta-analyses describing effective exercise interventions for falls prevention for seniors are found in the current literature.^{15, 123-127} We found too few studies that directly compared different exercise programs to support a pooled analysis, therefore, our meta-analysis was indirect, in that we compared the efficacy of different types of exercise to usual care. We did not find conclusive evidence supporting a recommendation for specific fall prevention exercises. Our results regarding exercise need to be interpreted in light of the results of the meta-analysis previously conducted of the Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT) trials. The meta-analysis of the FICSIT trials on the effect of exercise on falls in elderly patients showed that subjects in groups with exercise interventions had an estimated 10% lower risk of falling than control subjects (adjusted fall incidence ratio was 0.90, 95% CI [0.81, 0.99] p=0.04). Exercise interventions included training in one or more of the following: endurance, flexibility, balance platform, Tai Chi, and resistance.¹⁵ Our meta-analysis also showed that exercise interventions reduced the risk of falls, in this case by 12% (pooled risk ratio: 0.88, 95% CI [0.78, 1.00]) and the rate of falls by 19% (pooled risk ratio: 0.81, 95% CI [0.72, 0.92]). While both the FICSIT meta-analysis and our meta-analysis (Table 9) suggested some trends in differing effectiveness among exercises, these results were not consistent. The FICSIT meta-analysis concluded that balance exercises had the strongest effect, while our own meta-analysis showed that endurance exercise was the only exercise type to have statistical significance in reducing subjects who fell at least once, while balance exercises were most effective in reducing monthly rate of falling. As in the FICSIT meta-analysis, our 95% confidence intervals for the estimates of efficacy overlap, indicating that there are no statistically significant differences between groups.

QUESTION 8. ARE FALLS PREVENTION PROGRAMS ACCEPTABLE TO SENIORS?

We did not find any direct evidence to answer this question, in the form of surveys, focus groups, or other methods that directly assess the general acceptability of falls prevention interventions among seniors. Some indirect evidence can be obtained from the clinical trials of falls prevention interventions. About half of the studies reported the "refusal rate" of those contacted and eligible for the intervention. These data are presented in Table 20 and represent a mix of studies that attempted to enroll subjects from large populations or small specialty clinics. Thus the variation in the "refusal rates" may represent populations in different stages of "readiness to change." Furthermore, these refusal rates include people who refused for reasons other than the acceptability of the intervention. For example, people may refuse to participate in any clinical trial because they equate this with "experimentation." As a result of factors like these, the average "refusal rate" is 30.5%. Furthermore, among the studies that reported both the number of persons beginning the study and those completing the study, the average "dropout" rate was 16%. Taken together, these data suggest that the proportion of seniors for whom falls prevention programs are acceptable, while not precisely known, is likely substantial.

Table 20. Refusal Rate of Persons Eligible to Participate in Randomized Clinical Trials of Falls Prevention Interventions

Author, Year	Text Description	Statistic Provided	Refusal Rate (percent)
Carpenter GI, 1990 ID#443	Refused	59/602	9.8 %
Fabacher D, 1994 ID#444	declined to participate	94/348	27 %
Hornbrook MC, 1994 ID#445	declined to participate	5341/8680	61.5 %
Lord SR, 1995 ID#446	declined (in exercise group)	41/100	41 %
Mayo NE, 1994 ID#448	refused consent	71/431	16 %
Means KM, 1996 ID#450	ineligible, unwilling, or unable	55/154	35.7 %
Mulrow CD, 1994 ID#451	Refused	58/252	23 %
Sherrington C, 1997 ID#457	Declined	13/85	15 %
Wolfson L, 1996 ID#477 Judge JO, 1994 ID#478	dropped out before randomization/ decided not to participate or did not complete baseline test	164/274	59.8 %
Campbell AJ, 1997 ID#483 Campbell AJ 1999a ID#1504	chose not to participate	359/592	60.0 %
Rubenstein LZ, 1990 ID#492	Refused	45/205	22 %
Tinetti ME, 1994 ID#494 Tinetti ME, 1996 ID#497	Refused	54/355	15.2 %
Vetter NJ, 1992 ID#501	Refused	14/664	2.1 %
Wagner EH, 1994 ID#502	Refused	701/2260	31 %
Crilly RG, 1989 ID#522	Refused	10/60	16.7 %
Judge JO, 1993 ID#543	did not wish to participate or did not complete the screening process	30/114	26.3 %
Lord SR, 1996a ID#555	participation rate of eligible subjects in the intervention group	70.9%	29.1 %

Table 20. Refusal Rate of Persons Eligible to Participate in Randomized Clinical Trials of Falls Prevention Interventions

Author, Year	Text Description	Statistic Provided	Refusal Rate (percent)
Armstrong AL, 1996a ID#576	Declined	114/230	49.5 %
Buchner DM, 1997 ID#616	Refused	2445/13866	17.6 %
Ebrahim S, 1997 ID#1204	Refused	8/165	4.8 %
Coleman EA, 1999 ID#1510	Refused	84/253	33 %
Close J, 1999 ID#1524	Refused	124/521	23.8 %
Campbell AJ, 1999b ID#1593	chose not to participate	400/493	81.1 %
Pomeroy VM, 1999 ID#1595	informed consent could not be obtained	10/91	10.9 %
Chandler JM, 1998 ID#1622	not interested	202/302	66.8 %
Cumming RG, 1999 ID#1699	refused the intervention	70/264	26.5 %
Wallace JI, 1998 ID#1767	Declined	39/139	28 %
Rubenstein LZ, 2000 ID#1988	Refused	84/361	23.2 %
Kannus P, 2000 ID#3089	refusal to continue in the intervention	71/446	15.9 %
		Mean of Means	30.5 %

LIMITATIONS

The primary limitation of this systematic review, common to all such reviews, is the quantity and quality of the original studies. Heterogeneity is another major issue. Even more so than in reviews of single therapies (e.g., coronary revascularization for coronary artery disease, pharmaceutical therapy for rheumatoid arthritis), the studies presented here are heterogeneous in terms of the interventions tested and populations included. Furthermore, many of the study-level variables are highly idiosyncratic and inter-correlated (e.g., all studies of restraints take place in institutions). Many interventions have multiple components, making the assessment of the effect of the individual components challenging. Furthermore, the populations studied were heterogeneous in that some enrolled population-based samples of patients, while others enrolled attendees at a special clinic or even respondents to advertisements. Our assessment of the relative effectiveness of individual components was made using indirect methods, as we did not find any direct comparisons of individual components. Such indirect comparisons are not as powerful as direct comparisons. However, the convergent results of our two meta-analyses lend validity to our conclusions.

We gave equal importance to all studies that met our minimum criteria (RCTs that measured the percent of a group with at least one fall or the number of falls per person). We made no attempt to give greater importance to some studies based on "quality." The only validated assessment of study quality includes criteria not possible in falls prevention trials (double-blinding). As there is a lack of empirical evidence regarding other study characteristics and their relationship to bias, we did not attempt to use other criteria.

Our results regarding exercise need to be interpreted in light of the results of the pre-planned meta-analysis of the FICSIT trials. FICSIT included seven RCTs that assessed a variety of exercise interventions, including endurance, flexibility, platform balance, Tai Chi, and resistance. The meta-analysis used individual patient-level data. We could include only two of the individual FICSIT trials in one of our meta-analyses (subjects who fell at least once)^{16, 17} because we did not have access to the individual patient-level data. However, all but one FICSIT study contributed data to our second meta-analysis. Our results of exercise studies are in general agreement with the central FICSIT meta-analysis result: exercise programs help prevent falls (FICSIT pooled effect: 0.9, 95% CI [0.81, 0.99]; our pooled effect for percent with at least one fall 0.89, 95% CI [0.81, 0.98] and for monthly rate of falling 0.77, 95% CI [0.68, 0.87]). FICSIT also reported pooled effects for balance that were greater than (but not statistically different from) the overall effect. Our analysis assessing monthly rate of falling also found this result, however our analysis assessing number of subjects who fell at least once did not.

Regarding study populations, few studies of falls prevention stratified results by gender or ethnicity. Most studies either did not report the ethnic composition of the sample or used predominantly Caucasian samples. Thus, without further evidence, it should not be assumed such interventions will be similarly effective among all ethnic groups.

CONCLUSIONS

1. Falls prevention programs as a group have been shown to reduce the risk of experiencing a fall by 11% and monthly rate of falling by 23%.
2. Because few studies of single falls prevention interventions exist, statistical models were used to examine the independent effects of the four interventions with sufficient evidence to synthesize – multifactorial falls risk assessment and management; exercise; environmental modification; and education. Evidence supports a multifactorial falls risk assessment and management program as the most effective intervention. Exercise is the next most effective independent intervention. Thus, the evidence suggests that to be successful, falls prevention interventions should either use a multifactorial falls risk assessment and management program or exercise. However, the best approach to preventing falls is likely to use both a multifactorial falls risk assessment and management program along with exercise.
3. Falls risk assessments must be coupled with individually-tailored follow-up interventions to be effective.
4. Risk factor identification, which is one component of a multifactorial falls risk assessment and management program, may be self administered or administered by a professional. Both population-based public health approaches and medical model approaches are effective.
5. Our meta-analyses showed that exercise interventions reduce the risk of falls by 12% and the number of falls by 19%. While numerous exercise programs have been recommended to help prevent falls, there are insufficient data to identify the most effective exercises.
6. Successful falls prevention interventions have been delivered by a variety of providers, including exercise instructors, nurses, physical therapists, social workers, and teams of multiple providers. There is currently insufficient evidence to conclude that one provider type is preferable over another.
7. While not conclusive, the evidence suggests that falls prevention programs provided to seniors have the potential to be highly cost-effective compared with current practice. We estimate that a falls prevention rehabilitation program as a new Medicare benefit would be highly cost effective (even cost-saving in persons older than age 75) by preventing Medicare costs from injuries due to falls.
8. In the absence of new resources, it seems unlikely that much progress will be made in getting seniors to receive the benefits of falls prevention activities.

RECOMMENDATIONS

1. There is strong evidence that falls prevention programs are effective at preventing falls, and therefore ways are needed to better integrate these programs into the current care received by seniors.
2. There is strong evidence to support adding a falls prevention rehabilitation program as a new Medicare benefit. Such a program would be eligible to beneficiaries who have fallen, and would encompass a multifactorial risk assessment with a supervised exercise program.

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Evidence Tables