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.

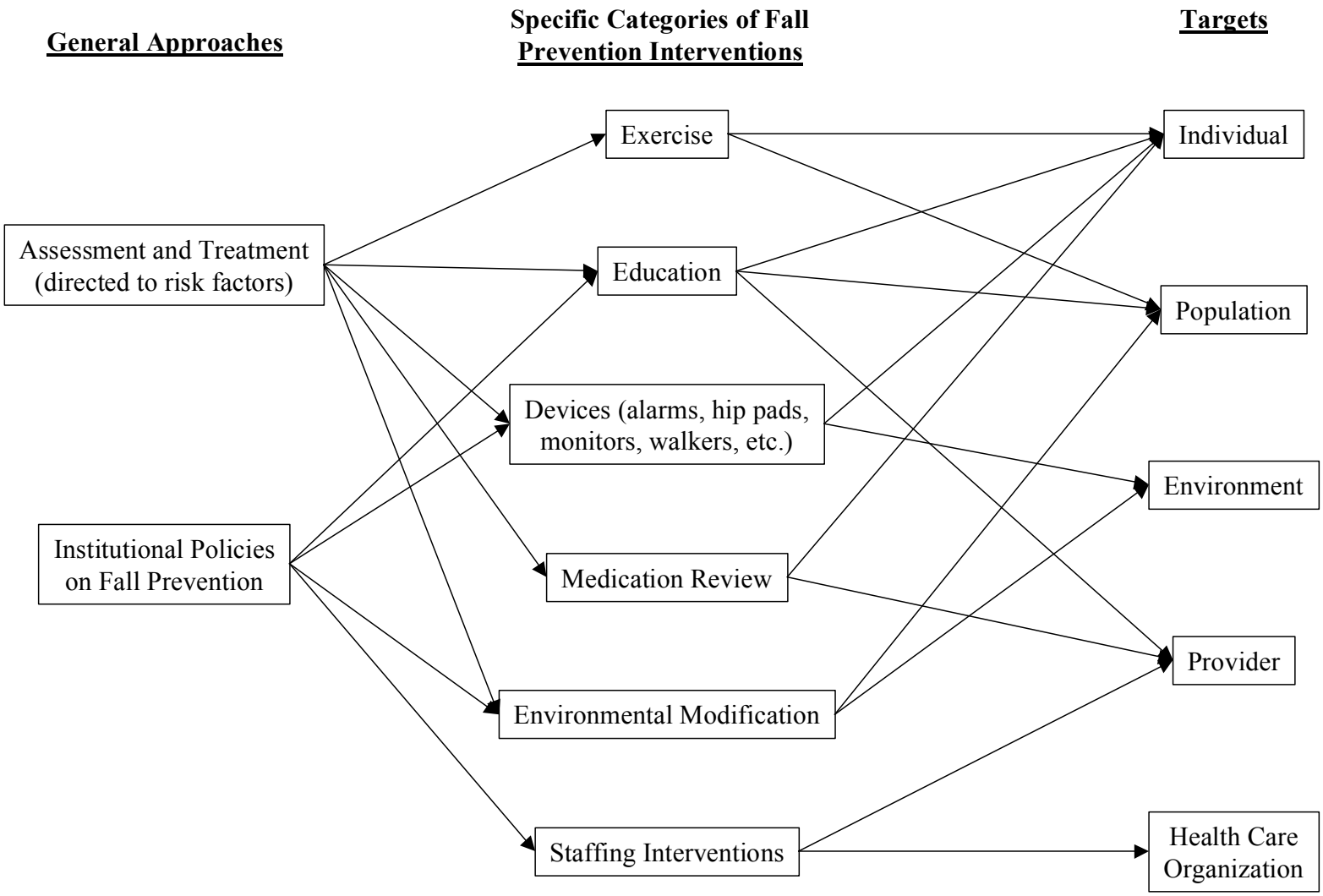
Medication / Medication Review. This category includes two approaches. First, physicians should review patient records to evaluate whether side effects of any medication may contribute to falls. Second, treatment with hormone replacements, calcium, and vitamin D can be used to increase strength in an 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 ELDERS 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 heath care interventions. The Cochrane Library contains both a database of systematic reviews and a controlled-trials registry. The library receives additional material continually to ensure that reviews are maintained through identification and incorporation of new evidence. The Cochrane Library is available on CD-ROM, by subscription.

The Cochrane files contained 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

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 :

1. Fall*
2. Elderly
3. Aged
4. Older
5. Senior*
6. exp ACCIDENTAL FALLS/
7. (2 or 3 or 4 or 5) and (1 or 6)

In CINAHL, the search strategy was:

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, it
4. 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 8
10. 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 13
15. 14 not 9
16. 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 17
21. 18 or 19
22. 20 and 21
23. 9 and 22
24. 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.

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, Albarede 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.

Campbell AJ, Robertson MC, Gardner MM. Elderly people who fall: Identifying and managing the causes. Br J Hosp Med 1995 54:(10)520-3.

Campbell JA. Drug treatment as a cause of falls in old age. A review of offending agents. Drugs Aging 1991 1:289-302.

Chandler JM, Hadley EC. Exercise to improve physiologic and functional performance in old age. Clin Geriatr Med 1996 12:(4)761-84.

Clemson L, Fitzgerald MH, Heard R. Content validity of an assessment tool to identify home fall hazards: the Westmead Home Safety Assessment. Br J Occup Ther 1999 62:(4)171-9.

Commodore DI. Falls in the elderly population: a look at incidence, risks, healthcare costs, and preventive strategies. Rehabil Nurs 1995 20:(2)84-9.

Coombs F. Engineering technology in rehabilitation of older adults. Exp Aging Res 1994 20:(3)201-9.

Table 2. Review and Background Articles

Cumming RG. Epidemiology of medication-related falls and fractures in the elderly. Drugs Aging 1998 12:(1)43-53.

Dishman RK. Compliance/adherence in health related excercise. Health Psychology 1988 1:237-267.

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.

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.

Hoskin AF. Fatal falls: trends and characteristics. Stat Bull Metrop Insur Co 1998 79:(2)10-5.

Josephson KR, Fabacher DA, Rubenstein LZ. Home safety and fall prevention. Clin Geriatr Med 1991 7:707-731.

Kiel DP. The evaluation of falls in the emergency department. Clin Geriatr Med 1993 9:(3)591-9.

King MB, Tinetti ME. Falls in community-dwelling older persons. J Am Geriatr Soc 1995 43:1146-1154.

Table 2. Review and Background Articles

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.

Leipzig RM, Cumming RG, Tinetti ME. Drugs and falls in older people: a systematic review and meta-analysis: II. Cardiac and analgesic drugs. J Am Geriatr Soc 1999 47:(1)40-50.

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, Mcllroy WE. Control of compensatory stepping reactions: age-related impairment and the potential for remedial intervention. Physiother Theory Pract 1999 15:(2)69-92.

Mihalko S. Strength training in older women: Does self-efficacy mediate improvements in physical function? University of Illinois at Urbana-Champaign. 1997.

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.

Nickens H. Intrinsic factors in falling among the elderly. Arch Intern Med 1985 145:1089-1093.

Norton R. Preventing falls and fall-related injuries among older-people. Austral J A 1999 18:(4)160-166.

Oakley AE, France Dawson M, Holland J, Arnold S, Cryer C, Doyle Y, et al. Preventing falls and susequent injury in older people. Qual Health Care 1996 5:243-9.

Table 2. Review and Background Articles

Oliver D, Hopper A, Seed P. Do hospital fall prevention programs work? A systematic review. J Am Geriatr Soc 2000 48:(12)1679-89.

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.

Province MA, Hadley EC, Hornbrook MC, Lipsitz LA, Miller JP, Mulrow CD, et al. The effects of exercise on falls in elderly patients. A preplanned meta- analysis of the FICSIT Trials. Frailty and Injuries: Cooperative Studies of Intervention Techniques. JAMA 1995 273:(17)1341-7.

Rawsky E. Review of the literature on falls among the elderly. Image J Nurs Sch 1998 30:(1)47-52.

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.

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.

Rubenstein LZ, Josephson KR, Robbins AS. Falls in the nursing home. Ann Intern Med 1994 121(6):442-51.

Sattin RW. Falls among older persons: A public health perspective. Annu Rev Public Health 1992 13:489-508.

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.

Sorock GS. Falls among the elderly: Epidemiology and prevention. Am J Prev Med 1988 4:282-288.

Table 2. Review and Background Articles

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.

Tinetti ME, Speechley M. Prevention of falls among the elderly. N Engl J Med 1989 320:1055-1059.

Udani JK, Ofman JJ. Tai Chi for the prevention of falls in the elderly. Integr Med 1998 1:(4)167-169.

Vandervoort AA. Ankle mobility and postural stability. Physiother Theory Pract 1999 15:(2)91-103.

Wagner SG, Pfeifer A, Cranfield TL, Craik RL . The effects of ageing on muscle strength and function: a review of the literature. Physiother Theory Pract 1994 10:(1)9-16.

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/VO_2Max, mood/depression/affect, risk of fracture)
- Exercise, utilization/costs ☐ **(Answer 9)**
- Unsure ☐
- None of the above ☐

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

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: _____
(Last Name Only)

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

Description (if more than one study):_____

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

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

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

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

4. Is the study described as randomized? (circle one)
   - Yes ..... 1 **(ANSWER #5, #6, #7)**
   - No ..... 2 **(SKIP to #8)**

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 **(ANSWER #9)**
   - Single blind, patient ..... 2 **(SKIP to #10)**
   - Single blind, outcome assessment ..... 3 **(SKIP to #10)**
   - Open ..... 4 **(SKIP to #10)**
   - Blinding not described ..... 8 **(SKIP to #10)**

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)

Intervention(s)

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

17. Intervention modality (check all that apply) :

Assistive device ❑
Balance training ❑
Environmental modification ❑
Falls risk factor identification ❑
Gait training ❑
General physical activity ❑
Medication/ Medication review ❑
Patient education:
Individual counseling ❑
Community intervention ❑
Group Counseling ❑
Strength training ❑
Surgery ❑
Vision impairment correction ❑

Other (specify:_____) ❑
Other (specify:_____) ❑

Usual Care - with no attempt to control for non-specific effects ❑
Usual Care - with attempt to control for non-specific effects (e.g. use of placebo) ❑

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

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

19. Setting of the intervention(s): (check all that apply)

Community center (senior center, day program) ❑
Physician's office ❑
Outpatient physical therapy clinic ❑
Rehabilitation hospital ❑
Hospital (inpatient) ❑
Nursing Home ❑
Patient's home (home-provided services) ❑
Other (specify:_____) ❑
Not described ❑

20. Was the intervention setting also described as: (check all that apply)

Academic (Teaching) ❑
Non-academic ❑
Other (specify:_____) ❑
Not described ❑

21. Was there a protocol for the intervention? (circle one)

Yes 1
No 2
Not reported 8
Not applicable 9

22. Is the frequency of the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

23. Is the duration of the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

24. Are contraindications for the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

25. Are adherence rates for the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

26. Types of providers performing the intervention(s): (check all that apply)

Physicians ❑
Physical therapists/occupational therapists ❑
Nurses ❑
Pharmacists ❑
Social workers ❑
Family ❑
Other (specify:_____) ❑
Not described ❑
Not applicable ❑

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

Intervention(s)

If study has a control group, then enter data for that group here.
Otherwise, enter data for each group in order of first mention.
Arm 2 of ____ Description: _____

17. Intervention modality (check all that apply) :

Assistive device ❑
Balance training ❑
Environmental modification ❑
Falls risk factor identification ❑
Gait training ❑
General physical activity ❑
Medication/ Medication review ❑
Patient education:
Individual counseling ❑
Community intervention ❑
Group Counseling ❑
Strength training ❑
Surgery ❑
Vision impairment correction ❑

Other (specify:_____) ❑
Other (specify:_____) ❑

Usual Care - with no attempt to control for non-specific effects ❑
Usual Care - with attempt to control for non-specific effects (e.g. use of placebo) ❑

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

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

19. Setting of the intervention(s): (check all that apply)

Community center (senior center, day program) ❑
Physician's office ❑
Outpatient physical therapy clinic ❑
Rehabilitation hospital ❑
Hospital (inpatient) ❑
Nursing Home ❑
Patient's home (home-provided services) ❑
Other (specify:_____) ❑
Not described ❑

20. Was the intervention setting also described as: (check all that apply)

Academic (Teaching) ❑
Non-academic ❑
Other (specify:_____) ❑
Not described ❑

21. Was there a protocol for the intervention? (circle one)

Yes 1
No 2
Not reported 8
Not applicable 9

22. Is the frequency of the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

23. Is the duration of the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

24. Are contraindications for the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

25. Are adherence rates for the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

26. Types of providers performing the intervention(s): (check all that apply)

Physicians ❑
Physical therapists/occupational therapists ❑
Nurses ❑
Pharmacists ❑
Social workers ❑
Family ❑
Other (specify:_____) ❑
Not described ❑
Not applicable ❑

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

Intervention(s)

If study has a control group, then enter data for that group here.
Otherwise, enter data for each group in order of first mention.
Arm 3 of ____ Description: _____

17. Intervention modality (check all that apply) :

Assistive device	❑	Medication/ Medication review	❑
Balance training	❑	Patient education:	
		Individual counseling	❑
Environmental modification	❑	Community intervention	❑
Falls risk factor identification	❑	Group Counseling	❑
Gait training	❑	Strength training	❑
General physical activity	❑	Surgery	❑
		Vision impairment correction	❑

Other (specify:_____) ❑
Other (specify:_____) ❑

Usual Care - with no attempt to control for non-specific effects ❑
Usual Care - with attempt to control for non-specific effects (e.g. use of placebo) ❑

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

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

19. Setting of the intervention(s): (check all that apply)

Community center (senior center, day program) ❑
Physician's office ❑
Outpatient physical therapy clinic ❑
Rehabilitation hospital ❑
Hospital (inpatient) ❑
Nursing Home ❑
Patient's home (home-provided services) ❑
Other (specify:_____) ❑
Not described ❑

20. Was the intervention setting also described as: (check all that apply)

Academic (Teaching) ❑
Non-academic ❑
Other (specify:_____) ❑
Not described ❑

21. Was there a protocol for the intervention? (circle one)

Yes 1
No 2
Not reported 8
Not applicable 9

22. Is the frequency of the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

23. Is the duration of the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

24. Are contraindications for the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

25. Are adherence rates for the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

26. Types of providers performing the intervention(s): (check all that apply)

Physicians ❑
Physical therapists/occupational therapists ❑
Nurses ❑
Pharmacists ❑
Social workers ❑
Family ❑
Other (specify:_____) ❑
Not described ❑
Not applicable ❑

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

Intervention(s)

If study has a control group, then enter data for that group here.
Otherwise, enter data for each group in order of first mention.
Arm 4 of ____ Description: _____

17. Intervention modality (check all that apply) :

Assistive device	❑	Medication/ Medication review	❑
Balance training	❑	Patient education:	
		Individual counseling	❑
Environmental modification	❑	Community intervention	❑
Falls risk factor identification	❑	Group Counseling	❑
Gait training	❑	Strength training	❑
General physical activity	❑	Surgery	❑
		Vision impairment correction	❑

Other (specify:_____) ❑
Other (specify:_____) ❑

Usual Care - with no attempt to control for non-specific effects ❑
Usual Care - with attempt to control for non-specific effects (e.g. use of placebo) ❑

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

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

19. Setting of the intervention(s): (check all that apply)

Community center (senior center, day program) ❑
Physician's office ❑
Outpatient physical therapy clinic ❑
Rehabilitation hospital ❑
Hospital (inpatient) ❑
Nursing Home ❑
Patient's home (home-provided services) ❑
Other (specify:_____) ❑
Not described ❑

20. Was the intervention setting also described as: (check all that apply)

Academic (Teaching) ❑
Non-academic ❑
Other (specify:_____) ❑
Not described ❑

21. Was there a protocol for the intervention? (circle one)

Yes 1
No 2
Not reported 8
Not applicable 9

22. Is the frequency of the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

23. Is the duration of the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

24. Are contraindications for the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

25. Are adherence rates for the intervention described? (circle one)

Yes 1
No 2
Not applicable 9

26. Types of providers performing the intervention(s): (check all that apply)

Physicians ❑
Physical therapists/occupational therapists ❑
Nurses ❑
Pharmacists ❑
Social workers ❑
Family ❑
Other (specify:_____) ❑
Not described ❑
Not applicable ❑

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)**
    - No ..... 2 **(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
    - No 2
    - 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".)		*Patient [P], assessor [A], or laboratory (or medical record) [L] rated? (ND=not described)*			
Balance	❑	**P**	**A**	**L**	ND
Body composition measurements (Height, Weight, BMI)	❑	**P**	**A**	**L**	ND
Cardiovascular measurements (Heart Rate, BP, VO_2 max)	❑	**P**	**A**	**L**	ND
Costs	❑	**P**	**A**	**L**	ND
Falls	❑				
Falls risk	❑	**P**	**A**	**L**	ND
Functional status (General Health)	❑	P	**A**		ND
Functional status (Physical)	❑	P	**A**		ND
Gait	❑	**P**	**A**	**L**	ND
Injury rate/Fracture rate	❑	**P**	**A**	**L**	ND
Mortality	❑		**A**	**L**	ND
Psychological status/ fear of falling/self-efficacy	❑	**P**	**A**		ND
Quality of life (SF-36, SF-12, SIP, QWB)	❑	**P**			ND
Strength/Endurance	❑	**P**	**A**	**L**	ND
Utilization	❑	**P**	**A**	**L**	ND
Other (specify: _____)	❑	**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	❑	❑	❑
Increased musculoskeletal problems	❑	❑	❑
Increased injuries (not fracture)	❑	❑	❑
Increased number of fractures	❑	❑	❑
Other complications	❑	❑	❑
Other (specify: _____)	❑	❑	❑
None described			❑

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 SAS[13] 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 effects[23] pooled log risk ratio across all studies in our analysis. We also present the chi-squared test for heterogeneity p-value[24] 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 Stata[14] 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 effects[23] pooled log incidence rate ratio across all studies in our analysis. We also present the chi-squared test for heterogeneity p-value[24] 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 test[28] and a regression asymmetry test[29] 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 FICSIT [15]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-analysis[15] 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.