



# **Relationship Between Falls And Physical Activity In Healthy Seniors**

## **A Focused Practice Question**

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## **1. ISSUE**

This research review seeks to understand the relationship between physical activity and falls in healthy community-dwelling seniors, in order to contribute to the built environment strategic priority and healthy aging in Peel. Falls are one of the leading causes of injury-related hospitalizations among seniors.<sup>1,2</sup> While falls among seniors can be preventable, the factors that can contribute to falls are complex.<sup>1</sup>

Regional Council has a vision for Peel to be an age-friendly community where seniors have access to supports that enable them to age safely, with dignity, and maximize their quality of life<sup>3</sup>. A well-designed, healthy and liveable community, while beneficial for all ages, is essential to the health and well-being of an aging population.

Peel Public Health (PPH) contributes to designing communities and environments that support healthy living. Healthy communities designed to encourage physical activity and walkability, provide many recognized health benefits, including contributing to lower diabetes and obesity rates. However, PPH has not fully explored the evidence examining the relationship between physical activity and falls, specifically to understand what types of activity demonstrate an association to falls, and whether supporting physical activity in the built environment has demonstrated any relationships to falls.

## **2. CONTEXT**

Canada and Ontario's population is aging rapidly. While Peel's population is currently younger than the national and provincial averages, growth among the aging population is expected over

the next 30 years.<sup>3</sup> Population projections developed by the Peel Data Centre show that Peel residents 65 years and older will grow from 10.5 per cent of the total population in 2011, to 21 per cent of Peel's population in 2041.<sup>3</sup>

Falls-related emergency department (ED) visits, hospitalizations and deaths increase with age. For Peel seniors, falls are the leading cause of injury-related ED visits and one of the top five causes of injury-related hospitalizations.<sup>4,2</sup> Still, Peel's 2013 rates for falls-related ED visits, hospitalization, and death among the seniors population are overall lower as compared to provincial rates. See Appendix A for a comparison of fall-related data between Peel and Ontario.

Falls can contribute to negative mental and physical health outcomes such as fear of falling, loss of autonomy and greater isolation, confusion, immobilization and depression.<sup>1</sup> The risk factors for falls among seniors are complex, and the reasons for falls among community-dwelling seniors may be different from those in institutional settings.<sup>1</sup> Some of the main factors that put seniors at risk for falls include:<sup>1</sup>

- Biological (e.g. balance or gait deficits, muscle weakness, impaired mobility)
- Chronic and acute health conditions (e.g. cognitive impairment, visual impairment, foot disorders, incontinence)
- Behavioural (e.g. history of falls, fear of falling, inappropriate assistive devices, lack of exercise, inappropriate footwear, alcohol and drug use/misuse)
- Socio-demographic (e.g., age, gender, ethnicity/cultural, low income, poor living conditions, lack of support networks and social interaction, lack of transportation)

- Environmental (e.g., absence of handrails/grab bars/rest areas, slippery or uneven surfaces, obstacles, home hazards, stairs, poor building design)

The Public Health Agency of Canada (PHAC) report, “Seniors’ Falls in Canada: Second Report”, notes lack of physical activity as a factor associated with risk of falling.<sup>1</sup> Statistics Canada estimates that only 12 per cent of Canadians between the ages of 60 to 79 years were meeting the Canadian Physical Activity Guidelines in 2012 and 2013.<sup>5</sup> PHAC’s “Tips to Get Active” encourages daily physical activity for older adults (65 years and older), noting the potential health benefits of being active: improving balance; reducing falls and injuries; helping one to stay independent longer; and helping to prevent heart disease, stroke, osteoporosis, type 2 diabetes, some cancers and premature death.<sup>6</sup>

While exercise is often considered a common approach to falls prevention, there may be types of exercise that are more effective than others, or may cause more harm than benefit.

Integrating fall-prevention evidence into practice is necessary for effective healthy public policies and prevention strategies.<sup>7</sup>

PPH contributes to seniors health in a wide range of programming, including falls prevention as mandated by the Ontario Public Health Standards. Currently, PPH falls prevention interventions focus on: working with key community partners (e.g. Mississauga-Halton Local Health Integration Network’s Exercise and Falls Prevention Collaborative, and GTA Public Health Falls Prevention Network) to promote evidence-based practice through networking, collaboration and engagement; increasing access to falls prevention information and resources to help older adults remain healthy and independent through the “Healthy Aging in Peel

Website”; and continuing to monitor data and trends for falls. Additionally, PPH’s built environment work supports universal design principles to create communities that are accessible for older adults to walk for utilitarian and recreational purposes.

**3. LITERATURE REVIEW QUESTION**

The original research question for the literature review was: “what is the relationship between built environment supported physical activity and falls in healthy seniors”. This question did not retrieve any relevant synthesized literature, and was deemed too specific. Subsequently, the question was re-worded to be: “what is the relationship between physical activity and falls in healthy seniors”.

The new PECO format was:

Population	healthy seniors (65+ years), community-dwelling
Exposure/Intervention	physical activity (general), exercise
Comparison	no comparison
Outcome	falls

**4. LITERATURE SEARCH**

A literature search was first conducted in May 2015 using the original research question, and did not return any relevant articles. A new search was conducted in June 2015 using the revised research question. Both searches were limited to only guidelines and synthesized reviews published between 2005-2015.

The new search included a library search of databases, as well as searching the grey literature. Included in the new search were: Medline, Global Health, Ageline, Healthstar, Cochrane, TRIP, NICE, National Guidelines Clearinghouse, and McMaster's Optimal Aging Portal. See Appendix B for the complete search strategy.

## 5. RELEVANCE ASSESSMENT

Article titles and abstracts, as well as full text where necessary, were reviewed, and two reviewers mutually agreed upon the most relevant articles. Papers were assessed based on the following criteria:

- *Inclusion criteria:* English language; published in the last 10 years (2005-2015); included community-dwelling seniors/healthy seniors/healthy older adults (65+ years); focused on physical activity/exercise (in general); assessed falls as an outcome
- *Exclusion criteria:* children/youth/young adults/frail elderly; populations with specific diseases/disorders or at risk of falls/recurrent falls/fall-induced injury; long-term care homes or palliative care settings; interventions/structured programs

## 6. RESULTS OF THE SEARCH

The new database search retrieved 153 results, and the grey literature search returned approximately 362 search results. Once duplicates were removed and abstracts/full text were reviewed, three papers were considered relevant to be assessed for quality. Of note, one review in particular, a Cochrane review<sup>8</sup>, while considered potentially a strong relevant review,

was excluded as a duplicate due to its inclusion in the “umbrella\* review” paper also being assessed for quality. See Appendix C for the relevance table.

## 7. CRITICAL APPRAISAL

Two reviewers independently assessed the quality of the three relevant reviews using the Health Evidence Quality Assessment Tool for Review Articles, and consensus was reached by discussion. Of the three reviews, one review (an umbrella review) rated “strong” quality (score of 9), one rated “moderate” (score of 7), and one rated “weak” (score of 4).

## 8. DESCRIPTION OF INCLUDED STUDIES

Two reviews were included for data extraction: one was an umbrella review (strong quality) and the other a systematic review/meta-analyses (moderate quality). Data extraction tables can be found in Appendix D.

1) Stubbs et al. (2015): *What works to prevent falls in community-dwelling older adults: umbrella review of meta-analyses of randomized controlled trials.*<sup>9</sup>

- This umbrella review, rated as strong quality, assessed meta-analyses of randomized controlled trials (RCTs) on the prevention of falls in community-dwelling older adults.
- Overall, it included 16 meta-analyses; seven meta-analyses specifically investigated exercise and falls.

2) Sherrington et al. (2011): *Exercise to prevent falls in older adults: an updated meta-analysis and best practice recommendations.*<sup>10</sup>

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\* Reviews of systematic reviews are referred to by several different names in the scientific literature including umbrella reviews, overviews of reviews, reviews of reviews, a summary of systematic reviews and also a synthesis of reviews; umbrella reviews are designed to incorporate all types of syntheses of research evidence.



- This meta-analysis, rated as moderate quality, is an update to a previously published systematic review by Sherrington et al. (2008): *Effective exercise for the prevention of falls: a systematic review and meta-analysis*.<sup>11</sup>
- This update includes 54 RCTs to determine the effects of exercise on falls.
- It provides more detailed conclusions as to the types/features of exercises effective for falls prevention, as well as on adverse events/harms, which are not concluded in the umbrella review.

## 9. SUMMARY OF FINDINGS

The results from the umbrella review (Stubbs et al. 2015) and meta-analysis/systematic review (Sherrington et al. 2011), have been summarized below.

### ***Exercise prevents falls***

- Both Stubbs et al. and Sherrington et al. concluded that exercise can prevent falls.
- Stubbs et al. concluded that exercise significantly reduces falls (including the risk, odds and rate of falls):
  - reduced risk of falling ranging from 13 per cent (RR=0.87; 95% CI=0.81-0.94) to 33 per cent (RR=0.67; 95% CI=0.52-0.85)
  - 22 per cent reduced odds of falling (OR=0.78, 95% CI=0.65-0.93)
  - 61 per cent reduced rate of falls (RaR=0.39, 95% CI=0.23-0.66) and rate of falls causing fracture
  - 37 per cent reduced rate of injurious falls (RaR=0.63, 95% CI=0.51-0.77); 30 per cent reduced rate of falls resulting in medical care (RaR=0.70, 95% CI=0.54-0.92);

and 43 per cent reduced rate of falls causing serious injury (RaR=0.57, 95% CI=0.36-0.90)

- Sherrington et al. updated review found that the pooled estimate of the effect of exercise on the rate of falls indicates a 16 per cent reduction (pooled rate ratio 0.84, 95% CI=0.77-0.91).

### ***Certain types of exercises are more effective in the prevention of falls***

- Sherrington et al. calculated that 64 per cent of the variability between different findings of included trials was explained by the inclusion of balance training, a higher dose of exercise, and walking training.
  - primarily exercises that challenged balance had the biggest effect on reducing falls; exercise must provide a “moderate or high challenge to balance” for effective falls prevention (22% reduction in falls in 43 studies with this component, 95% CI=14-30)
  - walking and strength training had a lesser effect on falls, and may be included in addition to balance, as these types of exercise do provide some benefits, however not at the expense of balance exercises
  - ongoing exercise is necessary, and exercise must be of a sufficient dose to have an effect (i.e. minimum of 2 hours per week)
- Stubbs et al. also concluded that endurance, balance, and strength type exercises could be recommended, noting that exercise focused on gait, balance or functional<sup>†</sup> training reduces the rate of falls (RaR=0.72; 95% CI=0.55-0.94).

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<sup>†</sup> Functional training is a classification of exercise which involves training the body for the activities/tasks performed in daily life; functional training attempts to adapt or develop exercises which allow individuals to perform the activities of daily life more easily and without injuries.

- While the exact type, duration, frequency, and setting of interventions showed variations in the effect of results, describing these variations in detail was out of scope for the umbrella review.

### ***Falls prevention exercise should target both general community and those at high risk***

- Both Stubbs et al. and Sherrington et al. note that exercise should be encouraged to community-dwelling older adults and those at high risk.
- Sherrington et al. comments on the potential harms of exercise on falls, concluding that:
  - generally, care should be taken to safely engage in exercise overall
  - specifically, high risk individuals should not be prescribed brisk walking and those at higher risk may require closer supervision when engaging in any type of exercise
- Stubbs et al. however acknowledged the lack of reporting of adverse events/harms associated with falls prevention as a limitation in the umbrella review. This limitation may possibly be due to the absence of such information in the original studies.
- Both Stubbs et al. and Sherrington et al. discuss tailoring exercise:
  - patients' preference should be considered as it can influence adherence to exercise
  - different groups of people will require different exercise delivery strategies
  - both group or home-based exercises may be undertaken for falls prevention

## **10. RELEVANCE TO PRACTICE**

This research review found that a relationship exists between physical activity and falls.

Exercise as a single intervention prevents falls. In particular, while exercise has many overall health benefits for older adults<sup>12</sup>, the evidence points towards certain types of exercise as more effective than others in the prevention of falls:

- Combined approaches that support endurance activities such as walking, as well as balance and strength training, or a combination of such types of activities included through functional training are beneficial to preventing falls.
  - generally, care should be taken when engaging in exercise to not increase risk of falls; for instance high risk individuals (as determined through appropriate risk assessment) should not be prescribed brisk walking
- Ongoing exercise and sufficient dose of exercise (at least 2 hours per week) is important for lasting benefits.
  - additionally for adherence it is important to find activities that are enjoyable
- Findings of this research review are overall consistent with the Canadian Physical Activity Guidelines for Older Adults<sup>12</sup> that recommends a combination of different types of activities (i.e. endurance, strength, balance) to achieve health benefits and improve functional abilities for adults aged 65 years and older.
  - for older adults, the Canadian Physical Activity Guidelines recommend 150 minutes of aerobic physical activity per week, supplemented by strengthening activities, and activities to enhance balance and prevent falls

Future work with the built environment can acknowledge that physical activity/exercise is beneficial for falls prevention in community dwelling (non-residential care) seniors, in addition to the many health benefits for long term health and well-being. Due to a lack of highly synthesized literature examining built environment related physical activity and the relationship to falls, any specific contributing factors of the built environment could not be accounted for through this research review.

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10. Sherrington C., Tiedemann A., Fairhall N., et al. (2011). Exercise to prevent falls in older adults: an updated meta-analysis and best practice recommendations. *New South Wales*. 22(3-4), 78-83.
11. Sherrington C., Whitney J.C., Lord S.R., et al. (2008). Effective exercise for the prevention of falls: a systematic review and meta-analysis. *Journal of American Geriatric Society*. 56, 2234-2243.
12. Canadian Society for Exercise Physiology. (2012). Canadian Physical Activity Guidelines. Retrieved from [www.csep.ca/guidelines](http://www.csep.ca/guidelines)

## **APPENDICES**

Appendix A: Comparison of Falls-Related Data (Peel and Ontario)

Appendix B: Search Strategy

Appendix C: Relevance Table

Appendix D: Data Extraction Tables

## APPENDIX A: Comparison of Falls-Related Data (Peel and Ontario)

### Emergency Department (ED) Visits Related to Falls by Age Group (2013)

Age Group	Peel - Count	Peel – Rate*	Ontario – Rate*
65-69 years	1396	2493.04	3066.22
70-74 years	1148	3056.85	3886.23
75-79 years	1054	3754.63	5360.66
80-84 years	1219	6512.1	7990.73
85+	1875	10737.6	13231.52

National Ambulatory Care Reporting System Data 2013, Canadian Institute for Health Information. IntelliHEALTH Ontario, Ministry of Health and Long-Term Care

Population Estimates 2013, Statistics Canada. IntelliHEALTH Ontario, Ministry of Health and Long-Term Care

\*Rate: for 100,000 population

### Hospitalizations Related to Falls by Age Group (2013)

Age Group	Peel - Count	Peel – Rate*	Ontario – Rate*
65-69 years	225	401.81	487.29
70-74 years	204	543.2	807.46
75-79 years	276	983.19	1356.16
80-84 years	409	2184.95	2578.19
85+	683	3911.35	4833.87

Hospital In-Patient Discharges Data 2013, Canadian Institute for Health Information. IntelliHEALTH Ontario, Ministry of Health and Long-Term Care

Population Estimates 2013, Statistics Canada. IntelliHEALTH Ontario, Ministry of Health and Long-Term Care

\*Rate: for 100,000 population

### Mortality Related to Falls by Age Group (2013)

Age Group	Peel - Count	Peel – Rate*	Ontario – Rate*
65-69 years	5	10.45	11.42
70-74 years	11	32.61	30.5
75-79 years	16	61.86	55.55
80-84 years	20	117.74	146.93
85+	54	353.84	444.81

Ontario Mortality Database 2011, Ontario Registrar General. IntelliHEALTH Ontario, Ministry of Health and Long-Term Care

Population Estimates 2011, Statistics Canada. IntelliHEALTH Ontario, Ministry of Health and Long-Term Care

\*Rate: for 100,000 population

## APPENDIX B: Search Strategy

### Original Library Database Search (May 2015):

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to April 2015>, Global Health <1973 to 2015 Week 20>, Ovid Healthstar <1966 to April 2015>, Ovid MEDLINE(R) <1946 to May Week 3 2015>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <May 22, 2015>

- 1 exp Aged/ (4344686)
- 2 exp "Aged, 80 and over"/ (1214200)
- 3 "aging population".ti,ab. (7980)
- 4 "old\* adult\*".ti,ab. (88691)
- 5 "senior\*".ti. (10507)
- 6 "elder\*".ti. (176864)
- 7 exp Walking/ (41091)
- 8 "walk\*".ti. (28823)
- 9 exp Leisure Activities/ (300743)
- 10 "built environment".ti,ab. (3020)
- 11 (community adj3 design).ti,ab. (3139)
- 12 "outdoor activit\*".ti,ab. (1947)
- 13 exp "Activities of Daily Living"/ (110534)
- 14 "environment\*".ti. (206543)
- 15 exp City Planning/ (3338)
- 16 exp Social Environment/ (183701)
- 17 "physical environment".ti,ab. (5085)
- 18 exp Residence Characteristics/ (91410)
- 19 exp Accidental Falls/ (32476)
- 20 "fall\*".ti. (46746)
- 21 exp "Wounds and Injuries"/ (1223499)
- 22 (outdoor adj3 fall\*).ti,ab. (118)
- 23 1 or 2 or 3 or 4 or 5 or 6 (4384968)
- 24 19 or 20 or 21 or 22 (1272850)
- 25 ("review\*" or "meta analys\*").ti. (615541)
- 26 7 or 8 or 9 or 12 or 13 (420415)
- 27 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 (568385)
- 28 26 and 27 (122591)
- 29 23 and 24 and 25 and 28 (127)
- 30 limit 29 to english language [Limit not valid in CDSR; records were retained] (117)



31 limit 30 to yr="2005 -Current" (86)

Database: Ageline (May 2015) = 1 result

Search ID#	Search Terms	Search Options	Actions
S7	S5 AND S6	Search modes - Boolean/Phrase	<a href="#">View Results (1)</a>
S6	TI "review*" OR "meta analys**"	Search modes - Boolean/Phrase	<a href="#">View Results (2,184)</a>
S5	S3 AND S4	Search modes - Boolean/Phrase	<a href="#">View Results (100)</a>
S4	(DE "Recreation") OR (DE "Walking") OR "walk*" OR "outdoor activit**"	Search modes - Boolean/Phrase	<a href="#">View Results (4,133)</a>
S3	S1 OR S2	Search modes - Boolean/Phrase	<a href="#">View Results (1,483)</a>
S2	TI "environment**"	Search modes - Boolean/Phrase	<a href="#">View Results (1,077)</a>
S1	"built environment" OR "community W3 design" OR "physical environment" OR "community infrastructure" OR "city plan*" OR "urban plan**"	Search modes - Boolean/Phrase	<a href="#">View Results (531)</a>

### **New Library Database Search (June 2015):**

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to May 2015>, Global Health <1973 to 2015 Week 23>, Ovid Healthstar <1966 to May 2015>, Ovid MEDLINE(R) <1946 to June Week 1 2015>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <June 15, 2015>

- 1 exp Aged/ (4364768)
- 2 exp "Aged, 80 and over"/ (1222056)
- 3 "aging population".ti,ab. (8039)
- 4 "old\* adult\*".ti,ab. (89714)
- 5 "senior\*".ti. (10561)
- 6 "elder\*".ti. (177606)
- 7 exp Walking/ (41431)
- 8 "walk\*".ti. (29013)
- 9 exp Leisure Activities/ (302224)
- 10 exp "Activities of Daily Living"/ (111078)
- 11 exp Exercise/ (233216)
- 12 "exercis\*".ti. (150554)
- 13 exp Motor Activity/ (320781)
- 14 "phys\* activit\*".ti,ab. (153393)
- 15 exp Accidental Falls/ (32671)
- 16 "fall\*".ti,ab. (267613)
- 17 exp "Wounds and Injuries"/ (1228543)
- 18 (outdoor adj3 fall\*).ti,ab. (119)
- 19 1 or 2 or 3 or 4 or 5 or 6 (4405555)
- 20 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 (781813)
- 21 15 or 16 or 17 or 18 (1476023)

- 22 19 and 20 and 21 (18405)
- 23 ("review\*" or "meta analys\*").ti. (620846)
- 24 22 and 23 (446)
- 25 limit 24 to (english language and yr="2005 -Current") [Limit not valid in CDSR; records were retained] (316)
- 26 remove duplicates from 25 (147)
- Database: Ageline (June 2015) = 6 results

<input type="checkbox"/> Select / deselect all <input type="button" value="Search with AND"/> <input type="button" value="Search with OR"/> <input type="button" value="Delete Searches"/>			
Search ID#	Search Terms	Search Options	Actions
<input type="checkbox"/> S12	S10 AND S11	Search modes - Boolean/Phrase	<a href="#">View Results (6)</a>
<input type="checkbox"/> S11	TI "review*" OR meta analys**	Search modes - Boolean/Phrase	<a href="#">View Results (67)</a>
<input type="checkbox"/> S10	S8 AND S9	Search modes - Boolean/Phrase	<a href="#">View Results (423)</a>
<input type="checkbox"/> S9	S5 OR S6	Search modes - Boolean/Phrase	<a href="#">View Results (2,074)</a>
<input type="checkbox"/> S8	S1 OR S2 OR S3 OR S4 OR S7	Search modes - Boolean/Phrase	<a href="#">View Results (5,132)</a>
<input type="checkbox"/> S7	TI "walk**"	Search modes - Boolean/Phrase	<a href="#">View Results (384)</a>
<input type="checkbox"/> S6	TI "accident*" W3 fall*	Search modes - Boolean/Phrase	<a href="#">View Results (152)</a>
<input type="checkbox"/> S5	DE "Falls"	Search modes - Boolean/Phrase	<a href="#">View Results (2,043)</a>
<input type="checkbox"/> S4	TI "phys* activit**"	Search modes - Boolean/Phrase	<a href="#">View Results (816)</a>
<input type="checkbox"/> S3	DE "Physical Activity"	Search modes - Boolean/Phrase	<a href="#">View Results (1,886)</a>
<input type="checkbox"/> S2	DE "Exercise" OR DE "Exercise Programs"	Search modes - Boolean/Phrase	<a href="#">View Results (3,142)</a>
<input type="checkbox"/> S1	DE "Walking"	Search modes - Boolean/Phrase	<a href="#">View Results (1,151)</a>

### Grey Literature Search (June 2015):

Website	Search Terms	Search Results
National Guidelines Clearinghouse <a href="http://www.guideline.gov/index.aspx">http://www.guideline.gov/index.aspx</a>	Falls and physical activity in healthy seniors	16
	Exercise and falls	7
	Exercise and falls and healthy seniors	16
	Exercise and falls in healthy seniors	15
	Exercise and falls and seniors	20
	Advanced search → falls; 65-79, 80+; prevention	32
NICE <a href="http://www.nice.org.uk/">http://www.nice.org.uk/</a>	Section: public health guidelines	56
TRIP	"(title:"aged" OR "senior*" OR "elder*" OR "older adult*")(title:"phys* activit*" OR "exercis*" OR "walk*")(title:"fall*" OR "injur*")", by quality	4

Website	Search Terms	Search Results
McMaster's Optimal Aging Portal <a href="http://www.mcmasteroptimalaging.org/">http://www.mcmasteroptimalaging.org/</a>	Section: Public Health Professional Database → falls and physical activity	21
	Section: Public Health Professional Database → exercise and falls	50
	Section: Public Health Professional Database → exercise and falls in healthy seniors	3
	Section: Public Health Professional Database → falls and physical activity in healthy seniors	3
	Section: Public Health Professional Database → physical activity and falls	2
	Section: Browse Topics → falls and injury prevention	37
	Section: Browse Topics → exercise	80

### APPENDIX C: Relevance Table

**Original PECO:** What is the relationship between built environment supported physical activity and falls in healthy seniors?  
**New PECO:** relationship between physical activity and falls in healthy seniors (65+ years of age)

Author	Title & Date	Criterion 1 <i>(type of study)</i>	Criterion 2 <i>(population or setting)</i>  <b>healthy seniors (65+) community-dwelling</b>	Criterion 3 <i>(exposure or intervention)</i>  <b>physical activity exercise</b>	Criterion 4 <i>(outcome)</i>  <b>falls</b>	Criterion 5 <i>(other, such as date of publication)</i>	Critical Appraisal <i>(Y/N)</i>	Data Extraction <i>(Y/N)</i>
Stubbs, B	What works to prevent falls in community-dwelling older adults: umbrella review of meta-analyses of randomized controlled trials	meta-analysis	community-dwelling older adults - over age 60	- fall prevention interventions (includes exercise)	- prevent falls - rate, risk and odds of falling	2015 English	Yes	Yes
Gillespie, LD	Interventions for preventing falls in older people living in the community (Cochrane Review)	systematic review	older people living in the community	effects of falls interventions includes: - exercise (single intervention) - multifactorial programmes - in general physical activity	- rate of falls - risk of falls	2012 English	Yes  (note: included in Stubbs umbrella review)	No
Sherrington, C	Exercise to prevent falls in older adults: an updated meta-analysis and best practice recommendations	meta-analysis	older adults - general community - those at high risk for falls	- exercise (single intervention) - features or types of exercise	- prevent falls	2011 English	Yes	Yes
Costello, E	Update on falls prevention for community-dwelling older adults: review of single and multifactorial intervention programs	review	community-dwelling older adults - over age 60	- effectiveness of fall prevention programs (includes exercise and balance)	- number of falls - number of fallers - rate of falls	2008 English	Yes	No
Sherrington, C	Effective exercise for the prevention of falls: a systematic review and meta-analysis	systematic review with meta-analysis	older people - general community - residential care	- effects of exercise - components of exercise programs	- falls prevention - fall rates	2008 English	No  (use updated article by same author)	No

**Original PECO:** What is the relationship between built environment supported physical activity and falls in healthy seniors?

**New PECO:** relationship between physical activity and falls in healthy seniors (65+ years of age)

<b>Author</b>	<b>Title &amp; Date</b>	<b>Criterion 1</b> <i>(type of study)</i>	<b>Criterion 2</b> <i>(population or setting)</i> <b>healthy seniors (65+) community-dwelling</b>	<b>Criterion 3</b> <i>(exposure or intervention)</i> <b>physical activity exercise</b>	<b>Criterion 4</b> <i>(outcome)</i> <b>falls</b>	<b>Criterion 5</b> <i>(other, such as date of publication)</i>	<b>Critical Appraisal</b> <i>(Y/N)</i>	<b>Data Extraction</b> <i>(Y/N)</i>
Karlsson, M	Prevention of falls in the elderly – a review	review	older people - living in the community - elderly living in hospital settings and nursing homes	- identify fall prevention strategies proven effective (includes physical activity/exercise)	- reducing falls - reducing number of fallers	2013 English	No (not systematic)	No
Arnold, C	Exercise for fall risk reduction in community-dwelling older adults: a systematic review	systematic review	community-dwelling older adults - over age 50	- exercise or physical activity interventions - influence of exercise programs and multicomponent	- reducing falls - reducing fall risk	2008 English	No (focus on interventions/ programmes and delivery)	No
Petridou, E	What works better for community-dwelling older people at risk to fall: a meta-analysis of multifactorial versus physical exercise-alone interventions	meta-analysis	community dwelling older people - at risk to fall	- compare and quantify the effectiveness of multifactorial versus exercise-alone interventions	- reducing recurrent falls	2009 English	No (focus on at risk for falls/recurrent falls)	No
Goodwin, V	Multiple component interventions for preventing falls and fall-related injuries among older people: systematic review and meta-analysis	systematic review and meta-analysis	older people	- effectiveness of multiple component interventions - effect sizes of particular intervention combinations	- fall rates - number of fallers - fall-related injuries	2014 English	No (focus on multiple interventions)	No
El-Khoury, F	The effect of fall prevention exercise programmes on fall induced injuries in community dwelling older adults: systematic review and meta-analysis of randomised controlled trials	systematic review and meta-analysis	older community dwelling people - over 60 years	fall prevention exercise interventions	- injurious falls - serious falls - fall-related fractures	2013 English	No (focus on fall induced injuries)	No

**Original PECO:** What is the relationship between built environment supported physical activity and falls in healthy seniors?

**New PECO:** relationship between physical activity and falls in healthy seniors (65+ years of age)

<b>Author</b>	<b>Title &amp; Date</b>	<b>Criterion 1 (type of study)</b>	<b>Criterion 2 (population or setting)</b> <b>healthy seniors (65+) community-dwelling</b>	<b>Criterion 3 (exposure or intervention)</b> <b>physical activity exercise</b>	<b>Criterion 4 (outcome)</b> <b>falls</b>	<b>Criterion 5 (other, such as date of publication)</b>	<b>Critical Appraisal (Y/N)</b>	<b>Data Extraction (Y/N)</b>
Choi, M	Effectiveness of intervention programs in preventing falls: a systematic review of recent 10 years and meta-analysis	systematic review and meta-analysis	older adults - community groups - nursing home setting	- effectiveness of fall prevention programs	- falls - fall rate	2012 English	No (from abstract not much on community)	No
Gates, S	Multifactorial assessment and targeted intervention for preventing falls and injuries among older people in community and emergency care settings: systematic review and meta-analysis	systematic review and meta-analysis	older people - community - emergency care - primary care	- effectiveness of multifactorial assessment and interventions	- number of fallers - fall related injuries - fall rate - admission to hospital - contacts with health services - move to institutional care - physical activity - quality of life	2007 English	No (excluded on settings and outcomes)	No
Michael YL	Interventions to prevent falls in older adults: an updated systematic review	systematic review	older adults - primary care settings - higher risk	- assess benefits and harms of interventions for reducing falls and improving health outcomes in older adults in primary care settings	- falls	2010 English	No (excluded on population)	No
Paterson, D	Ageing and physical activity: evidence to develop exercise recommendations for older adults	unsure	older adults (65+ years)	- exercise variables (intensity, type and volume) - physical activity	- falls - cardiorespiratory, functional capacity, independence	2007 English	No (from abstract not only falls)	No
Ferreira, M	Physical activity improves strength, balance and endurance in adults aged 40-65 years: a systematic review	systematic review	healthy adults (40-65 years)	- physical activity on enhancing strength and balance and prevent falls	- strength - balance - endurance - falls rate	2012 English	No (excluded on population)	No

**Original PECO:** What is the relationship between built environment supported physical activity and falls in healthy seniors?  
**New PECO:** relationship between physical activity and falls in healthy seniors (65+ years of age)

<b>Author</b>	<b>Title &amp; Date</b>	<b>Criterion 1</b> <i>(type of study)</i>	<b>Criterion 2</b> <i>(population or setting)</i> <b>healthy seniors (65+) community-dwelling</b>	<b>Criterion 3</b> <i>(exposure or intervention)</i> <b>physical activity exercise</b>	<b>Criterion 4</b> <i>(outcome)</i> <b>falls</b>	<b>Criterion 5</b> <i>(other, such as date of publication)</i>	<b>Critical Appraisal</b> <i>(Y/N)</i>	<b>Data Extraction</b> <i>(Y/N)</i>
Moyer, V	Prevention of falls in community-dwelling older adults: U.S. Preventive Services Task Force Recommendation Statement	clinical guideline	community-dwelling adults - aged 65 years or older at increased risk for falls	effectiveness and harms of primary care-relevant interventions, includes: - multifactorial clinical assessment - clinical management - clinical education or behavioural counseling - home hazard modification - exercise or physical therapy	- reduce falls and fall-related morbidity and mortality	2012 English	No (clinical focus)	No
U.S. Department of Health & Human Services	Falls: assessment and prevention of falls in older people	clinical guideline (NICE)	- all people aged 65 or older - at risk of falling	- assessment and prevention of falls in older people	- rate of falls - impact of falls and complications - mortality - patient satisfaction and experience of falls prevention, interventions and strategies	2013 English	No (clinical focus)	No

## APPENDIX D: Data Extraction Tables

Items Reviewed	“What works to prevent falls in community-dwelling older adults: umbrella review of meta-analyses of randomized controlled trials”
<b>General Information &amp; Quality Rating for Review</b>	
1. Author(s) and Date	Stubbs B., Brefka S., Denking M.D., 2015
2. Country (of authorship)	United Kingdom
3. Quality Rating	<ul style="list-style-type: none"> <li>• Rated strong quality (9/10) using Health Evidence Quality Assessment Tool; the article lost points for the following reason:               <ul style="list-style-type: none"> <li>- did not indicate 2 search strategies from second column (only mentions reference lists and databases)</li> </ul> </li> </ul>
4. Objectives of Review	<ul style="list-style-type: none"> <li>• To conduct a comprehensive umbrella review of all systematic reviews containing meta-analyses of randomized controlled trials (RCTs) on the prevention of falls (fall prevention interventions) in community-dwelling older adults.</li> </ul>
<b>Details of Review</b>	
5. Number of Studies (reviews) Included	<ul style="list-style-type: none"> <li>• Overall 16 separate meta-analyses reporting 47 pooled analyses were included in this umbrella review</li> <li>• Specifically 7 meta-analyses on exercise included the following # of RCTs and # of participants:               <ol style="list-style-type: none"> <li>1. Gou et al, 2014 = 22 RCTs (n=4,912)</li> <li>2. El-Khoury et al, 2013 = 17 RCTs (n=4,305)</li> <li>3. Petridou et al, 2009 = 15 RCTs (n=3,146)                   <ul style="list-style-type: none"> <li>- 10 RCT (n=2,549) → exercise and multifactorial</li> <li>- 5 RCTs (n=597) → exercise only</li> </ul> </li> <li>4. Gillespie et al, 2012 = 32 RCTs (n=6,655)                   <ul style="list-style-type: none"> <li>- 16 RCTs (n=3,622) → group exercise</li> <li>- 7 RCTs (n=951) → home-based exercises</li> <li>- 5 RCTs (n=1,563) → tai chi</li> <li>- 4 RCTs (n=519) → gait, balance or functional training</li> </ul> </li> <li>5. Michael et al, 2010 = 18 RCTs (n=3,568)</li> <li>6. Thomas et al, 2010 = 6 RCTs (n=1,466); 1 study was CCT</li> <li>7. Weatherall, 2004 = 5 RCTs (n = 860)</li> </ol> </li> </ul>
6. Types of Studies	<ul style="list-style-type: none"> <li>• Meta-analyses of RCTs (combined narratively due to heterogeneity in population, interventions and/or outcomes across included meta-analyses)</li> </ul>
7. Search Period	<ul style="list-style-type: none"> <li>• Systematic search of databases from inception to August 2014 (reviews date back to 2004)</li> </ul>
8. Databases searched	<ul style="list-style-type: none"> <li>• Two independent authors conducted a systematic search of: MEDLINE, EMBASE, CINAHL, AMED, BNI, PsycINFO, Cochrane Library, PubMed, PEDro</li> <li>• Also reviewed reference lists of relevant articles</li> </ul>
9. Inclusion and Exclusion Criteria	<p><b>Inclusion:</b></p> <ul style="list-style-type: none"> <li>• Population: community-dwelling older adults (i.e. living in the community), mean age of 60+ years</li> <li>• Interventions: any intervention that sought to prevent falls</li> <li>• Outcome measures: rate of falls or number of fallers (considered any type of falls including recurrent and injurious falls)</li> <li>• Meta-analyses must contain at least 1 pooled analysis with 3 or more RCTs (meta-analyses including some controlled trials were included if 80% or more of the</li> </ul>



	<p>included studies within the pooled analysis were RCTs)</p> <ul style="list-style-type: none"> <li>• Any language</li> </ul> <p><b>Exclusion:</b></p> <ul style="list-style-type: none"> <li>• Population: living in long-term care facility, studies conducted in hospitals or long-term care facilities, specialist populations (e.g. stroke, Parkinson)</li> <li>• Meta-analyses not informed by a systematic review</li> </ul>
<b>Details of Interventions</b>	
10. Description of interventions	<p><b>Single Interventions:</b></p> <ul style="list-style-type: none"> <li>• Exercise interventions – 7 meta-analyses <ul style="list-style-type: none"> <li>- Overall the methodological quality of exercise meta-analyses was moderate to high</li> <li>- Interventions: exercise only; exercise vs control; group exercise vs control; home-based exercises vs control; tai chi; gait, balance or functional training; exercise/physical therapy; exercise program</li> </ul> </li> <li>• Vitamin D interventions – 7 meta-analyses</li> <li>• Environmental interventions (e.g. home adaptations and modifications) – 3 meta-analyses</li> <li>• Surgery (cardiac pacing) – 2 meta-analyses</li> <li>• Education – 1 meta-analyses</li> <li>• Single interventions combined – 1 meta-analyses</li> </ul> <p><b>Multifactorial and Multicomponent Interventions:</b></p> <ul style="list-style-type: none"> <li>• Individually tailored multifactorial interventions – 6 meta-analyses</li> <li>• Nurse-led falls prevention – 1 meta-analyses</li> <li>• Education and exercise combined – 1 meta-analyses</li> <li>• Multicomponent interventions (not individually tailored) – 1 meta-analyses</li> </ul>
11. Intervention settings	<ul style="list-style-type: none"> <li>• Not reported</li> </ul>
12. Target groups	<ul style="list-style-type: none"> <li>• Participants over 60 years of age</li> <li>• Where indicated reviews include community-dwelling older adults</li> </ul>
13. Outcomes	<ul style="list-style-type: none"> <li>• Rate of falling</li> <li>• Risk of falling</li> <li>• Odds of falling</li> <li>• Rate of injurious falls</li> </ul>
<b>Results of Review</b>	
14. Quality of Included Meta-analyses	<ul style="list-style-type: none"> <li>• Based on AMSTAR scores, overall the methodological quality of the 7 included exercise meta-analyses: <ul style="list-style-type: none"> <li>- 6 were rated moderate-high quality; 1 rated low quality</li> </ul> </li> </ul>
15. Main Results of Review	<p><b>Exercise and Falls:</b></p> <ul style="list-style-type: none"> <li>• There is consistent evidence to support the effectiveness of exercise as single intervention to prevent falls <ul style="list-style-type: none"> <li>- In the 7 exercise meta-analyses, which included 14 pooled analyses, 6 of the 7 exercise meta-analyses found that exercise significantly reduces falls (rate, risk, odds, and including those that cause injury); 1 meta-analyses of low quality found non-significant reduction in falls</li> <li>- 13 of 14 pooled analyses demonstrated that exercises significantly reduces falls</li> </ul> </li> <li>• Detailed results from the included exercise meta-analyses report that exercise was responsible for: <ul style="list-style-type: none"> <li>- reduced risk of falls (RR=0.87; 95% CI=0.81-0.94; number of trials=18; number of participants= 3,568) and reduced risk of falls (RR=0.67; 95% CI=0.52-0.85)</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>- reduced odds of falling (OR=0.78; 95% CI=0.65-0.93; number of studies=22; number of participants=4,912)</li> <li>- reduced rate of falls (RaR=0.39; 95% CI=0.23-0.66; number of trials=6) and reduced rate of falls causing fracture (RaR=0.39; 95% CI=0.23-0.66; number of trials=6; I<sup>2</sup>=0%)</li> <li>- reduced rate of injurious falls (RaR=0.63; 95% CI=0.51-0.77; number of trials = 10; I<sup>2</sup> = 50%)</li> <li>- reduced rate of falls resulting in medical care (RaR=0.70; 95% CI=0.54-0.92; number of trials = 8; I<sup>2</sup>=20%)</li> <li>- reduced rate of falls causing serious injury (RaR=0.57; 95% CI=0.36-0.90; number of trials=7; I<sup>2</sup>=46%)</li> </ul> <ul style="list-style-type: none"> <li>• 1 review established that exercise focused on gait, balance or functional training reduces the rate of falls (RaR=0.72; 95% CI=0.55-0.94; number of trials=4; number of participants=519; I<sup>2</sup>=0)</li> <li>• 1 review found exercise reduced the rate of falls regardless of it being conducted in a group setting (RaR=0.71; 95%CI=0.63-0.82; number of trials=16; number of participants=3,622; I<sup>2</sup>=48%) or at home (RaR=0.68; 95% CI=0.58-0.80; number of trials=7; number of participants=951; I<sup>2</sup>=0%)</li> </ul> <p><i>(RaR = rate of falls; RR = risk ratios/relative risk; OR = odds of having a fall)</i></p>
<p>16. Recommendations / Comments / Limitations</p>	<p><b>Recommendations:</b></p> <ul style="list-style-type: none"> <li>• A balanced program including endurance, balance, and strength exercises could be recommended</li> <li>• Exercise should be provided to community-dwelling older adults to prevent falls</li> <li>• Older people at risk for falling or known to fall should be encouraged to exercise</li> <li>• Patients' preference also should be considered as it can influence adherence to exercise</li> </ul> <p><b>Comments:</b></p> <ul style="list-style-type: none"> <li>• The exact type (e.g. balance, strengthening, tai chi), duration, frequency, and setting of such interventions do show some variations in the effect of the results, but describing these variations in greater detail is beyond the scope of this review</li> <li>• It could be hypothesized that exercise also largely accounts for the effect seen in multifactorial/multicomponent programs</li> <li>• Future research should investigate the frequency, intensity, and type of intervention and setting, and test their effectiveness in clinical practice</li> </ul> <p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>• The meta-analyses often did not publish specific details regarding the included studies so not always possible to determine clinical homogeneity</li> <li>• Several meta-analyses may have included similar studies in their analyses</li> <li>• Very few meta-analyses reported on the harms associated with falls prevention interventions (unclear if the lack of adverse events reported in the included meta-analyses is due to the absence of these in the original studies)</li> </ul>

Items Reviewed	“Exercise to prevent falls in older adults: an updated meta-analyses and best practice recommendations”
<b>General Information &amp; Quality Rating for Review</b>	
1. Author(s) and Date	Sherrington C., Tiedemann A., Fairhall N., Close C.T., Lord S., 2011
2. Country (of authorship)	Australia
3. Quality Rating	<ul style="list-style-type: none"> <li>• Rated <u>moderate</u> quality (7/10) using Health Evidence Quality Assessment Tool; the article lost points for the following reasons:               <ul style="list-style-type: none"> <li>- Inadequate search strategy</li> <li>- No quality assessment of additional studies included in the update</li> <li>- No assessment of quality by multiple reviewers</li> </ul> </li> </ul>
4. Objectives of Review	<ul style="list-style-type: none"> <li>• To determine the effects of exercise on falls prevention in older people.</li> <li>• An update to previously published systematic review “Effective exercise for the prevention of falls: a systematic review and meta-analysis”, Sherrington (2008).               <ul style="list-style-type: none"> <li>- as the review refers to methods from the 2008 versions, sections of the original 2008 article were reviewed and included</li> </ul> </li> </ul>
<b>Details of Review</b>	
5. Number of Studies (reviews) Included	<ul style="list-style-type: none"> <li>• The 2011 update includes 54 randomized controlled trials (RCTs):               <ul style="list-style-type: none"> <li>- 44 RCTs previously assessed from the original article (2008) plus 10 additional trials included in this update (2011)</li> </ul> </li> </ul>
6. Types of Studies	<ul style="list-style-type: none"> <li>• Randomized controlled trials (RCTs)</li> </ul>
7. Search Period	<ul style="list-style-type: none"> <li>• This updated review used the same approach to searching electronic databases as in the original 2008 review</li> <li>• 2008 original search conducted in May 2007; databases for the update were searched up to May 2010</li> <li>• Studies date back to 1992</li> </ul>
8. Databases searched	<ul style="list-style-type: none"> <li>• OVID was used to search MEDLINE, EMBASE, CINAHL</li> <li>• Search was supplemented with searches of PubMed, Physiotherapy Evidence Database, SafetyLit, and Prevention of Falls Network Europe</li> <li>• Checked reference list of the Cochrane review and other reviews, and the updated search results provided by the trial search coordinator of the Cochrane Bone, Joint and Muscle Trauma Group</li> </ul>
9. Inclusion and Exclusion Criteria	<ul style="list-style-type: none"> <li>• The methodology used in the original review (2008) was used to determine eligibility for inclusion in this updated review</li> <li>• To determine eligibility of identified trial reports, two investigators independently scanned titles and abstracts</li> </ul> <p><b>Inclusion:</b></p> <ul style="list-style-type: none"> <li>• Published randomized trials conducted in older people in which the primary intervention being evaluated was exercise and the outcome was number of falls, number of fallers, or rate of falls</li> </ul> <p><b>Exclusion:</b></p> <ul style="list-style-type: none"> <li>• Trials were ineligible if non-exercise interventions were a major (&gt;25% of time) component of the intervention being evaluated</li> <li>• If the control group received exercise or the intervention involved substantial (&gt;25% of time) additional non-exercise interventions, the study was excluded</li> </ul>
<b>Details of Interventions</b>	
10. Description of interventions	<ul style="list-style-type: none"> <li>• The 2011 article did not describe the 10 additional eligible trials included in this update</li> <li>• The original 2008 article described the 44 RCTs included in both reviews (2008 and 2011)</li> <li>• Features of exercise components assessed in the interventions (displayed in the original 2008 article) include:               <ul style="list-style-type: none"> <li>- Moderate or high intensity strength training/high intensity strength training</li> <li>- Moderate or high challenge balance training/high challenge balance training</li> <li>- Stretching</li> </ul> </li> </ul>

	<ul style="list-style-type: none"> <li>- Walking (any)</li> <li>- Supervised exercise</li> <li>- Adherence</li> <li>- Length of exercise program</li> </ul>
11. Intervention settings	<ul style="list-style-type: none"> <li>• Not described</li> </ul>
12. Target groups	<ul style="list-style-type: none"> <li>• The included 44 trials (from 2008) involved a total of 9,603 participants; majority of trials with community-dwelling older people</li> <li>• # of participants in 10 additional trials was not reported</li> </ul>
13. Outcomes	<ul style="list-style-type: none"> <li>• Reduction in falls</li> <li>• Fall rates</li> <li>• Number of fallers</li> <li>• Number of falls</li> </ul>
<b>Results of Review</b>	
14. Main Results of Review	<p><b>2011 meta-analysis/systematic review:</b></p> <ul style="list-style-type: none"> <li>• Exercise as a single intervention can prevent falls</li> <li>• The findings of this update remain essentially unchanged from the original review (2008)</li> <li>• The pooled estimate of the effect of exercise on the rate of falls indicates a 16% reduction (pooled rate ratio from random effects meta-analysis 0.84, 95% CI 0.77-0.91, 54 trials)</li> <li>• There was a moderate amount of variability between the findings of the included trials (<math>I^2 = 56\%</math>)</li> <li>• The meta-regression analysis confirmed that features of exercise program design and trial population can explain some of this between-trial variability</li> <li>• 64% of the variability (calculated by statistical program used for meta-regression) between different findings of included trials was explained by the inclusion of balance training, higher dose of exercise and walking training <ul style="list-style-type: none"> <li>- 21% reduction in falls in studies with combination of components of balance training, walking training, higher exercise dose (95% CI=11-30, 14 studies)</li> </ul> </li> <li>• Exercise for falls prevention should provide a moderate or high challenge to balance <ul style="list-style-type: none"> <li>- 22% reduction in falls in studies with this component (95% CI 14-30, 43 studies)</li> <li>- exercises that do not aim to challenge balance are not effective in preventing falls</li> </ul> </li> <li>• Walking and strength training associated with lesser effect on falls (and not crucial for effect on falls), however these types of exercises have many benefits, and may be included in addition to balance training but not at the expense of balance training <ul style="list-style-type: none"> <li>- 10% reduction in falls in studies with walking component (95% CI 0-22; 30 studies); 23% reduction in falls in studies without walking component (95% CI 11-32; 30 studies)</li> <li>- high risk individuals should not be prescribed brisk walking programs</li> <li>- 1 trial found that fast walking programs for people at high risk of falls can increase the rate of falls</li> </ul> </li> <li>• Exercise must be of sufficient dose to have an effect (at least 2 hours a week) and ongoing exercise is necessary</li> <li>• Care should be taken with exercise to not increase risk of falling (noted with walking, balance)</li> <li>• Exercise can prevent falls in group or home-based setting</li> <li>• Different groups of people will require different exercise delivery strategies</li> <li>• High risk groups may require smaller group sizes and closer supervision</li> </ul>

15. Recommendations /  
Limitations

**Recommendations:**

- 2011 update includes best practice recommendations:
  - Exercise must provide a moderate or high challenge to balance
  - Exercise must be of a sufficient dose to have an effect
  - Ongoing exercise is necessary
  - Falls prevention exercise should be targeted at the general community as well as those at high risk for falls
  - Falls prevention exercise may be undertaken in a group or home-based setting
  - Walking training may be included in addition to balance training but high risk individuals should not be prescribed brisk walking programs
  - Strength training may be included in addition to balance training
  - Exercise providers should make referrals for other risk factors to be addressed

**Limitations:**

- No limitations for the 10 additional trials discussed in 2011 update
- Limitations discussed in the 2008 article (44 trials) include:
  - Inferences cannot be made about the effects of the characteristics of individuals (e.g. presence of risk factors in individual participants)
  - Despite multivariate adjustment, there is possibility that the conclusions are subject to confounding by unmeasured variables or by failure to adjust completely for measured variables

