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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| For males over 80 years old at risk for falls, are foot orthotics or traditional strength and balance training more effective at reducing falls? |

**AUTHOR**

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| **Prepared by** | Jason Bottoms | **Date** | 11/30/19 |
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**CLINICAL SCENARIO**

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| The patient is my 81-year-old grandfather. He has very few health problems given his age is doesn’t take any medications other than a daily multi-vitamin. He recently had a series of uncharacteristic falls while walking. Luckily, there were all minor falls and he did not injure himself. However, the increasing frequency of the falls led him to visit an MD where he was diagnosed with bilateral peripheral neuropathy in his lower extremities. He would like to reduce his fall risk to ensure he is safe with the outdoor activities he enjoys such as fishing, gardening, raising cattle, and playing with his dogs. In my experience, peripheral neuropathy can make it particularly difficult for patients to walk over uneven surfaces like those encountered walking outdoors. I’ve seen many patients with peripheral neuropathy and would treatment options for reducing falls in these patients. Falls are a major cause of injury, hospitalization and are often the start of a cascade of problems for older adults. I want to know the best evidence for preventing falls in this population.  |

**SUMMARY OF SEARCH**

[Best evidence appraised and key findings]

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| Eight articles were located that met inclusion/exclusion criteria including: 1 case study, 6 randomized controlled trials, and 1 systematic review.* The literature search did not reveal any studies that directly compared strength and balance training versus foot orthotic interventions on reducing falls in community dwelling older adults
* Exercise programs delivered by health care professionals can be effective in reducing falls in community dwelling elderly adults.
* Exercise programs focused on balance, gait and functional training and a combination of strength and balance training have the highest evidence to support reducing falls in community dwelling older adults.
* A multi-faceted podiatry approach including customized orthoses is effective at reducing falls in older adults with foot pain and an increased falls risk.
* Overall evidence regarding PT-implemented foot orthotic intervention is limited in quality and quantity.
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**CLINICAL BOTTOM LINE**

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| An 81-year-old male with a recent diagnosis of peripheral neuropathy and increased number of falls will benefit in a reduced risk of falling from an individualized exercise program focused on balance, gait, strength and functional training. It is unclear whether orthotic intervention will be beneficial due to the lack of current, high quality evidence. There is some evidence that a multi-faceted podiatry program may be effective but only if it includes an exercise program. Further research should be conducted on the efficacy and cost-effectiveness of orthotic intervention alone in reducing falls in elderly adults with peripheral neuropathy. |

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| ***This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor*** |

*The above information should fit onto the first page of your CAT*

**SEARCH STRATEGY**

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| **Terms used to guide the search strategy** |
| **P**atient/Client Group | **I**ntervention (or Assessment) | **C**omparison | **O**utcome(s) |
| “Peripheral neuropathy”“Diabetes”Older adults | OrthoticsShoe inserts | Strength trainingBalance training | Falls |

**Final search strategy (history):**

*Show your final search strategy (full history) from PubMed. Indicate which “line” you chose as the final search strategy.*

PubMed for Foot orthotics

1. peripheral neuropathy [MeSH Terms] AND lower extremity [MeSH Terms] (5052 results)
2. older adults (5183292 results)
3. physical therapy OR physiotherapy (176907 results)
4. orthotics AND lower extremity (175 results)
5. shoe inserts (6 results)
6. falls (15556 results)
7. ((((((((peripheral neuropathy[MeSH Terms]) AND lower extremity[MeSH Terms]) AND older adults) AND (physical therapy) OR physiotherapy)) AND (orthotics) AND lower extremity)) OR shoe inserts) AND falls

PubMed for traditional strength and balance training

1. peripheral neuropathy [MeSH Terms] AND lower extremity [MeSH Terms] (176 results)
2. adult onset diabetes mellitus [MeSH Terms] (11554 results)
3. older adults (48300 results)
4. physical therapy [MeSH Terms] OR physiotherapy (17006 results)
5. strength training [MeSH Terms] (700 results)
6. balance training (1247 results)
7. falls (5025 results)
8. Parkinson\* (696 results)
9. Timed up and go (389 results)
10. ((((((((((peripheral neuropathy[MeSH Terms]) AND lower extremities[MeSH Terms])) AND older adult) NOT adult onset diabetes mellitus[MeSH Terms]) AND ((physical therapy modalities[MeSH Terms]) OR physiotherapy)) AND strength training[MeSH Terms]) OR balance training) AND falls prevention) AND (timed up and go)) NOT parkinson\*

With filters for within 5 years, clinical trials and reviews, human subjects, English, males, aged 65+

*In the table below, show how many results you got from your search from each database you searched.*

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| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| **PubMed (FO)****PubMed (EP)****CINAHL (FO)** **CINAHL (EP)****Web of Science (FO)****Web of Science (EP)** | **17****1377****1****46****9****75** | **NA****Applied above filters and added NOT Parkinson\* and Timed up and go (37 results****NA****NA****NA****NA** |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| Patient population diagnosed with peripheral neuropathyStandardized outcome measures to assess falls riskRandomized controlled trialsStudy discusses efficacy of interventions on reducing falls risk in patient population |
| **Exclusion Criteria** |
| Not published in EnglishNarrative review articlesQuasi-experimental studies |

**RESULTS OF SEARCH**

**Summary of articles retrieved that met inclusion and exclusion criteria**

*For each article being considered for inclusion in the CAT, score for methodological quality on an appropriate scale, categorize the level of evidence, indicate whether the relevance of the study PICO to your PICO is high/mod/low, and note the study design (e.g., RCT, systematic review, case study).*

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| **Author (Year)** | **Risk of bias (quality score)\*** | **Level of Evidence\*\*** | **Relevance** | **Study design** |
| **Cockayne (2017)** | **PEDro: 6/10** | **1b** | **High** | **Cohort randomized control trial** |
| **Clemson (2012)** | **PEDro: 7/10** | **1b** | **High** | **Randomized control trial** |
| **Hawley-Hague (2017)** | **RoBANS:** **Selection of participants: high****Confounding variables: unclear****Intervention measurement: low****Blinding of outcome assessment: high****Incomplete outcome data: high****Selective reporting: low** | **4** | **Moderate** | **Case study/intervention evaluation**  |
| **Hirase (2015)** | **PEDro: 5/10** | **1b** | **High**  | **Multi-center controlled trial** |
| **Menant (2008)** | **AMSTAR: 4/8****(Unable to answer questions 6-8 due to inability to access list of articles to confirm whether the required information was provided. Scored out of 8 instead of 11.)** | **1a** | **High** | **Systematic review**  |
| **Sherrington (2019)** | **AMSTAR: 10/11** | **1a** | **High**  | **Systematic review of RTCs** |
| **Spink (2011)**  | **PEDro: 8/10** | **1b** | **High**  | **Parallel group randomized control trial** |
| **Sousa (2017)** | **PEDro: 6/10** | **2b** | **Moderate**  | **Randomized control trial** |

\*Indicate tool name and score

\*\*Use Portney & Watkins Table 16.1 (2009); if downgraded, indicate reason why

**BEST EVIDENCE**

The following 2 studies were identified as the ‘best’ evidence and selected for critical appraisal. Rationale for selecting these studies were:

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| * **Sherrington 2019 – This review was very well conducted to limit bias effectively. It provides a thorough review of the current literature in regards to exercise and its effect in reducing falls in the elderly population at risk for falls. Additionally, it examines other outcome measures and breaks down analysis on different types of exercise interventions on fall risk.**
* **Spink 2011 – This was a thoroughly conducted RTC eliminating as much chance for bias as reasonably possible with physical therapy interventions. It focused specifically on foot orthotics and footwear in general and compared the results with general podiatric care. This ost accurately reflects the intervention addressed in the PICO and compares it to a popular treatment option. While it is an RTC as opposed to a systematic review, the level of evidence for existing systematic reviews regarding orthotic intervention for falls prevention was lacking, making this RTC the best representation of the evidence on this intervention.**
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**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of (study title) by (authors, Year)**

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| **Aim/Objective of the Study/Systematic Review:** |
| Assess the benefits and harms of various exercise interventions on preventing falls in community-dwelling older adults. |
| **Study Design**[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| Systemic review of RTCsSearch strategy: The authors searched CENTRAL, MEDLINE, Embase, CINAHL, PEDro, Cochrane Bone, Joint and Muscle Trauma Group Specialised Register, up to as recently as May 2, 2018. An example of a search from CENTRAL is as follows:#1 MESH DESCRIPTOR Accidental Falls EXPLODE ALL TREES#2 (falls or faller\*):TI,AB,KY#3 #1 or #2#4 MESH DESCRIPTOR Aged EXPLODE ALL TREES#5 (senior\* or elder\* or old\* or aged or ag?ing or postmenopausal or community dwelling):TI,AB,KY#6 #4 or #5#7 #3 and #6Similar searches were used in the other listed databases. The authors also examined reference lists of other systematic reviews as well as contacting researchers in the field for assistance in identifying relevant ongoing trials. Selection criteria: pairs of authors (4 total) selected trials for inclusion* Inclusion: RCTs, effect of exercise on falls, community dwelling adults over the age of 60
* Exclusion: trials on a particular condition, quasi-randomized controlled trial, trials with more than 20% loss to follow-up (unable to be explained by the investigators of those studies)

Data extraction and quality assessment: pairs of authors (4 total) extracted data using a previously established data extraction form. Disagreement was resolved by a third party. Review authors were not blinded to authors or sources and did not assess their own trials. The following information was included in data extraction: general information, trial design, risk of bias assessment, participant demographics, interventions, outcomes measured, cost/cost effectiveness. In instances of missing data, the authors contacted the investigators in the study. |
| **Setting**[e.g., locations such as hospital, community; rural; metropolitan; country] |
| The authors were affiliated with the School of Public Health at the University of Sydney in Sydney, Australia. |
| **Participants**[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| * This systematic review included 108 trials involving 23,407 participants. All were RTCs with the majority being individually randomized and 9 being cluster randomized.
* These trials included 146 intervention arms and 84 control arms
* The authors used the Prevention of Fall Network Europe (ProFaNE) taxonomy to classify each exercise program (intervention arm) used in selected trials into one of the following categories: (1) gait, balance, coordination and functional task training (n=78), (2) strength/resistance training (n=9), (3) flexibility (n=1), (4) 3D exercise (n=15), (5) general physical activity (walking, n=6), (6) endurance (n=1), (7) multiple primary exercise programs (n=37).
* The median number of participants in each trial was 134 with a range of 20-1635
* The authors assessed risk of bias using Cochrane’s ‘Risk of Bias’ tool. Pairs of authors (4 total) assessed each study for bias.
* Risk of allocation bias was considered low in 72 trials, unclear in 36 trials and high in 0 trials
* Blinding of participants on performance bias was unclear in 97 studies (participants/assessors unable to be blinded to allocation due to constraints of study but impact on performance bias unclear), low in 5 studies, and high in 6 studies.
* Bias due to incomplete data was low in 57 trials, unclear in 22 trials and high in 29 trials
* Bias due to selective reporting was low in 12 trials, unclear in 43 trials and high in 52 trials
 |
| **Intervention Investigated**[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| 107 of the 108 RTCs specified a control group. Control was defined as usual care (no change in activity) or an intervention thought not to reduce falls (such as general health education, very gentle exercise, or 'sham' exercise not expected to impact on falls. |
| *Experimental* |
| Of the 108 RTCs included in this review, there were 146 intervention arms:* Balance and functional exercises versus control: 48
* Resistance exercises versus control: 7
* Flexibility versus control: 0
* 3D exercise (Tai Chi) versus control: 10
* 3D exercise (dance) versus control: 1
* General physical activity (walking program) versus control: 3
* Endurance training versus control: 0
* Multiple categories of exercise versus control: 21
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| **Outcome Measures**[Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| Primary outcome: rate of falls – falls per person per year – reported in 34 trials and could be calculated in another 43 trials bringing the total trials reporting rate of falls to 77.Secondary outcomes:* Number of people who experienced one or more falls (risk of falling): 77 trials
* Number of people who experienced one or more fall‐related fractures: 11 trials
* Number of people who experienced one or more falls that resulted in hospital admission: 2 trials
* Number of people who experienced one or more falls that required medical attention: 5 trials
* Number of people who experienced one or more adverse events: 39 trials
* Intervention adherence: 77 studies (proportion of classes attended in 53, proportion of scheduled sessions completed in 20, quantified amount of exercise performed in 3)
 |
| **Main Findings**[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. You may summarize results in a table but you must explain the results with some narrative.] |
| Due to the expansiveness of this review, the findings discussed her are those that most closely relate to the clinical scenario and clinical application of findingsExercise (all types)Rate of falls – The review found that in across 59 studies with 12,981 participants, exercise (all types) reduced number of falls by 23% (95% CI: 17%-29%) with a **high** certainty of evidence (ES [rate ratio]=0.77 95% CI=0.71-0.83.) Number of people experiencing one or more falls - The review found that in across 63 studies with 13,518 participants, exercise (all types) reduced number of people who experienced one or more falls by 15% (95% CI: 9%-11%) with a **high** certainty of evidence (ES [rate ratio]=0.85 95% CI=0.81-0.89.)The review found that **inconclusive or low** certainty evidence exercise (all types) may reduce fall that result in fracture (27% reduction, 95% CI: 5% to 44% reduction), falls that result in hospitalization (reduction 22%, 95% CI: 49% reduction to 18% increase), falls requiring medical attention (39% reduction, 95% CI: 21% to 53% reduction). Balance, gait and functional training Rate of falls – The review found that in across 39 studies with 7920 participants, balance, gait and functional training reduced number of falls by 24% (95% CI: 19%-30%) with a **high** certainty of evidence (ES [rate ratio]=0.76 95% CI=0.70-0.81.) Number of people experiencing one or more falls - The review found that in across 63 studies with 13,518 participants, balance, gait, and functional training reduced number of people who experienced one or more falls by 13% (95% CI: 9%-18%) with a **high** certainty of evidence (ES [rate ratio]=0.87 95% CI=0.82-0.91.)Resistance trainingRate of falls – The review found that in across 5 studies with 327 participants, resistance training reduced number of falls by 14% (95% CI: 33% reduction to 97% increase) with a **very low** certainty of evidence (ES [rate ratio]=1.14 95% CI=0.67-1.97.) Number of people experiencing one or more falls - The review found that in across 2 studies with 163 participants, resistance training reduced number of people who experienced one or more falls by 19% (95% CI: 43% reduction to 15% increase) with a **very low** certainty of evidence (ES [rate ratio]=0.81 95% CI=0.57-1.15.)Multiple types of exerciseThe most common form of the multiple exercise category was a combination of balance and strength exercises.Rate of falls – The review found that in across 11 studies with 1374 participants, multiple types of exercise training reduced number of falls by 34% (95% CI: 12%-15%) with a **moderate** certainty of evidence (ES [rate ratio]=0.66 95% CI=0.50-0.88.) Number of people experiencing one or more falls - The review found that in across 17 studies with 1623 participants, multiple types of exercise training reduced number of people who experienced one or more falls by 22% (95% CI: 4%-36%) with a **moderate** certainty of evidence (ES [rate ratio]=0.78 95% CI=0.64-0.96.)Comparing between exercise programsAnalysis did not find significant differences in fall prevention effects of different programs despite the trials being adequately powered to detect differences between the programs. |
| **Original Authors’ Conclusions**[Paraphrase as required. If providing a direct quote, add page number] |
| “Well‐designed exercise programmes reduce the rate of falls and the number of people experiencing falls amongst older people living in the community (high‐certainty evidence) Pg 5.” There is limited evidence for non-falls outcomes and falls resulting in fracture, hospitalization and need for medical care. The reporting of adverse events during exercise interventions was poor. Balance and functional exercise programs provided high certainty evidence at reducing falls rates and number of people who experience one of more falls. Programs that combine multiple exercises (mostly strength and balance training) provide moderate evidence for reducing falls rate and number of fallers and multiple fallers. |
| **Critical Appraisal** |
| **Validity**[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.] |
| AMSTAR: 10/11 a priori design provided: yes; two independent data extractors: yes; comprehensive search: yes; status of publication: no; list of studies: yes; characteristics of studies: yes; quality assessment: yes; quality assessment used in conclusions: yes; appropriate methods to combine studies: yes; publication bias assessed: yes; conflict of interest stated; yes.Strengths:* Study design: study selection and data extraction we undertaken by 2 pairs of researchers and designed to encompass as many studies as possible. The authors were blinded to each others results in screening and data extraction to minimize bias.
* Classification of exercise programs: with a review this large, classification of the studies into groups is crucial. The authors used ProFaNE guidelines to do this. They also performed sensitivity analysis to test the effect of categorizing certain studies and found no important affect on results
* Thorough discussion and reporting of many aspects of the study including conflicts of interest, potential sources of bias, resolution of disagreements and how the reviews results agree or disagree with existing literature.
* Use of quantitative data: This allows for greater statistical comparison and effect size calculations.

Weakness:* Limitation to RTCs: This limitation excluded some quasi-experimental studies and other systematic reviews that could have added to the comprehensiveness of the study
* In regards to this clinical scenario, the review does not find any studies on orthotic interventions indicting a blind spot in their search.
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| **Interpretation of Results**[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.] |
| This review provides high quality evidence that exercise programs can be effective at reducing falls in the community-dwelling elderly population. As the AMSTAR score indicates, this review was well designed to reduce chance for bias. It utilized quantitative data to allow for statistical analysis and interpretation of results. The review found high rate ratios for exercise of all types in reduction in fall rate and number of people who experience more than one fall, ES [rate ratio]=0.77 95% CI=0.71-0.83 and ES [rate ratio]=0.85 95% CI=0.81-0.89 respectively. Among the different exercise types examined, only programs focused on balance, gait and functional training and multiple types of exercises resulted in high to moderate certainty of falls prevention. These findings have high potential for clinical applicability due to reported ratio ratios at 95% CI. The review also found a dearth of reporting for adverse events as well as falls resulting in fractures, hospitalizations and medical attention. The review found no significant difference in falls prevention between the different exercise types examined.  |
| **Applicability of Study Results**[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.] |
| This review has moderate applicability to my clinic question. It does not examine orthotic interventions to reduce falls nor but it does examine different exercise programs’ effect on reducing falls in community dwelling elderly people. Importantly, it concludes that while balance training and multi-component exercise training (strength and balance training) are effective at reducing falls, resistance (strength) training alone was not shown to be effective with a high level of certainty. The review has moderate to high applicability to my clinical scenario in that it is comprehensive enough to include many participants with peripheral neuropathy, provides high level evidence on the efficacy of treatment options for these patients and includes patients in the appropriate age range. The review mentions 12 studies that discuss the cost effectiveness of implementing a falls prevention program. These studies provide limited evidence that fall prevention oriented exercise programs can be cost effective in the long-term and short-term. The exercise programs identified in the study are varied but many are simple and can be performed in the participant’s home making the, feasible and practical.  |

**(2) Description and appraisal of (study title) by (authors, Year)**

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| **Aim/Objective of the Study/Systematic Review:** |
| To examine the effectiveness of a multi-faceted podiatry intervention (foot orthoses, advice on footwear, $100 subsidy for footwear purchase, home-based programme of foot and ankle exercises, a falls prevention education booklet and routine podiatry care for 12 months) in preventing falls in community dwelling older adults with foot pain. |
| **Study Design**[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]Note: For systematic review, use headings ‘search strategy’, ‘selection criteria’, ‘methods’ etc. For qualitative studies, identify data collection/analyses methods. |
| * Parallel group randomised controlled trial
* A priori size calculation: 286 participants. Performed based on a 60% follow up rate in the control group, a 30% reduction of falls in the intervention group, a 15% dropout rate, 80% power and significance level of 5%
* Participants screened initially via phone, assed at baseline and at 6 months after baseline by an assessor blinded to group allocation
* Two physiotherapist assessors were used for the assessments, the same assessor was used for baseline and 6 month assessments for each participant
* After baseline assessment, participants were randomly assigned to either a control group (receiving routine podiatry care) of the multifaceted podiatry intervention group
* After randomization, routine care (control group) and multifaceted podiatry intervention are carried out by a single podiatrist
 |
| **Setting**[e.g., locations such as hospital, community; rural; metropolitan; country] |
| University health classes in Melbourne, Australia |
| **Participants**[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| * N=305
* Community dwelling, cognitively intact older adults with foot pain and increased falls risk
* Recruited between July 2008 and September 2009 by mail from a database of podiatry patients at La Trobe university Health Sciences Clinic in Victoria, Australia
* Average age was 73.9 years, 94 males and 211 females
* Average BMI of intervention group was 29.4, average BMI of control group was 29.7
* 82 out of the intervention group had fallen in the last 12 months (48 had fallen 2 or more times), 83 out of the control group (45 had fallen 2 or more times)
* Average duration of foot pain was 6.9 years
* Participants in each group were similar at baseline for key demographic variables listed above
* At 6 months, 86% of the intervention group and 94% of control group were present for follow up. Of the 19 intervention participants lost to follow up, 5 gave no reason, 13 were due to illness or injury and 1 due to lack of time. Of the 9 control participants lost to follow-up, 4 gave no reason, 3 were due to illness or injury and 2 were due to lack of time. No indication of cause of injuries but author’s report no adverse events occurred.
* At 12 months, 96% of the remaining intervention group and 98% of the remaining control group were present for follow up. Of the 6 intervention participants lost to follow up, 3 gave no reason, 3 were due to illness or injury. Of the 3 control participants lost to follow-up, 2 gave no reason and 1 participant died (unrelated to intervention or fall.)

\* The authors note that one participant was inadvertently included and allocated to the control group that should have been excluded due to Parkinson’s disease. This patient was included in analysis to satisfy intention to treat analysis |
| **Intervention Investigated**[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| Both control and experimental groups were instructed to continue with the podiatry treatment they were receiving. All participants were offered free podiatry treatment as La Trobe University Health Clinic for the duration of the trial to replace or supplement their current podiatry treatment. |
| *Experimental* |
| In addition to the above intervention of routine podiatry treatment, the experimental group received:Foot orthoses – prefabricated, full length, dual density orthoses were heat-moulded to each participant’s foot shape and then customized individually by a podiatrist. Footwear advice and provision – inappropriate footwear were identified as heel height greater than 4.5 cm, no fixation, no heel counter, overly soft heel counter, worn out sole or inappropriately narrow shoe heel. If identified as having inappropriate footwear, these participants were educated on the hazards of their footwear and provided information on what constitutes a safe shoe. They were advised to buy a safer shoe and provided with the equivalent of a $100 voucher.Home based foot and ankle exercise program – 30-minute exercise program to be performs three times per week for six months. Exercise program was not individualized and focused on stretching and strengthening foot and ankle muscles. It was self-progressed by the participants based on ability to perform the exercise with no pain and no muscle soreness the next day. The intervention podiatrist contacted each participant via telephone at 1,4,12 and 20 weeks to answer questions and promote adherence.Falls preventions education – booklet provided by the Australian Commonwealth Department of Health and Aging focused on risk factors and strategies to prevent falls. These were discussed with each patient.  |
| **Outcome Measures**[Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| The authors state that two physiotherapists were used for the assessments, the same assessor was used for baseline and 6 month assessments for each participantPrimary Outcomes:* Proportion of fallers
* Proportion of multiple fallers (more than 1 fall)
* Falling rate (falls per participant in the 12 month duration of study)
* Falls were defined as unexpected events that resulted in the participant ending up on the ground, floor or lower level
* Falls documented by patient reported fall calendars turned in monthly throughout the study.

Secondary Outcomes:* Foot Pain and Disability Index (MFPDI): 19-item questionnaire to assess foot pain with scores ranging from 0-34 with higher scores indicating greater levels of pain.
* Physiological Profile Assessment (PPA): used to assess physiological falls risk and consists of five assessment items testing vision, peripheral sensation, lower limb strength, reaction time and body sway. Scores range from -2 to 3 and are averaged across the 5 items with higher scores indicating higher risks of falling
* Falls Efficacy Scale – International (FES-I): 7-item Likert scale to assess fear of falling. Scores range from 7-28 with higher scores indicating higher fear of falling.
* Short form Health Survey (SF-12): the Mental (MCS-12) and Physical (PCS-12) Component Summary scores of the SF-12 to measure generic health related quality of life. Each subscale is scored from 0-100 with higher scores indicating higher function.
* Hand Held Dynamometry (HHD): average of three trials used to test ankle dorsiflexion, plantarflexion, inversion and eversion, hallux plantarflexion and lesser toe plantarflexion.
* Paper grip test: used to test toe plantarflexion strength, participant seated with knee and ankle at 90 degrees and instructed to hold 1 mm card onto ground with toe muscles. Examiner attempts to pull card from under toes while stabilizing at ankle. Inability to hold card on any of 3 attempts is a failure.
* Goniometer measurements for foot and ankle range of motion for great toe dorsiflexion and ankle inversion/eversion using standard landmark for reference points.
* Lunge test: used for ankle dorsiflexion and recorded using a digital inclinometer on the mid-point of the anterior tibial border, conducted with the knee extended and flexed.
* Lateral stability measured with sway meter that measures body’s displacement at the waist. Participants asked to stand in tandem for 30 seconds with preferred foot in front and maximal displacement recorded.
* Maximum balance test used to measure leaning balance. Sway meter used to measure maximal anterior and posterior lean possible without loss of balance. Tested barefoot and in shoes.
* Coordinated stability test used to measure leaning balance. Sway meter attached and used to track accuracy of participant as they rotate their hips in all directions to follow a convoluted path with the sway meter pen marked on a piece of paper. Total error score is calculated by number of times the pen strays outside the track. Tested barefoot and in shoes.
* Five times sit to stand test used to measure functional ability based on age predicted norms associated with high falls risk
* Alternate stepping test used to measure functional ability, participant is timed while placing each foot alternatively on a 19 cm step eight times. Scores based on age predicted norms associated with high falls risk.
* Walking speed over 6 meters calculated to measure functional ability. Scores based on age predicted norms associated with high falls risk.
 |
| **Main Findings**[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.] |
| Primary outcomes* 103 falls occurred in the intervention group, 161 falls occurred in the control group
* Fall frequency was 0.67 for the intervention group and 1.06 for the control group, a 36% fall reduction in the intervention group
* No significant difference was found for number of single or multiple fallers between groups.

Falls rate and proportion of single and multiple fallers in intervention and treatment group over 12 months

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| Outcome Measure | Intervention Group (n=153) | Control Group (n=152) | Falls risk ratio (CI=95%) | P value |
| Fall frequency per participant (range) | 0.67 (0-6) | 1.06 (0-15) | 0.64 (0.45-0.91) | 0.01 |
| Single falls | 64 | 75 | 0.85 (0.66-1.08) | 0.19 |
| One or more falls | 21 | 33 | 0.63 (0.63-1.04) | 0.07 |

Secondary outcomes- Significant improvements were found in ankle eversion strength, ankle dorsiflexion and inversion/eversion range of motion, and postural sway on the floor when barefoot and maximum balance range test wearing shoes.Secondary outcome measures at baseline and 6-month follow up for intervention and control groups (significant results only)

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| --- | --- | --- | --- | --- |
| Variables | Intervention Group (n=153) | Control Group (n=152) | Adjusted mean difference of improvement (CI=95%) | P value |
| Baseline | Follow-up | Baseline | Follow-up |
| Ankle eversion strength (Newtons) | 97.85 | 107.76 | 99.18 | 100.99 | 7.69 (2.87-12.51) | 0.002 |
| Ankle dorsiflexion ROM (degrees) | 30.91 | 32.81 | 30.41 | 31.06 | 1.37 (0.34-2.41) | 0.009 |
| Ankle inversion/eversion (degrees) | 32.56 | 36.12 | 32.63 | 33.51 | 2.66 (0.65-4.66) | 0.010 |
| Postural sway on floor, barefoot (mm2) | 137.82 | 94.43 | 114.37 | 119.58 | -28.63 (-49.08 to -8.17) | 0.003 |
| Max balance range, shoes on (mm) | 125.02 | 140.29 | 122.48 | 127.80 | 10.83 (5.48-16.19) | <0.001 |

The authors found a 36% reduction in number of falls over 12 months in the intervention group as compared to the control. This was calculated based on a fall frequency (number of falls per person over 12 month period) differences between groups. The intervention group had fall frequency of 0.67 compared to the control fall frequency of 1.06. This resulted in a falls risk ratio of 0.64 with a 95% CI of 0.45-0.91 indicating a 36% reduction in falls among the control group. The authors found no significant difference between groups for proportion of single fallers (42% in intervention, 49% in control) or multiple fallers (14% in intervention, 22% in control). For secondary outcomes, the authors found significant improvements in ankle eversion strength measured by HHD, ankle dorsiflexion measured by lunge test and inversion/eversion range of motion measured by goniometry, postural sway on the floor when barefoot measured by the postural sway section of the PPA and maximum balance range test wearing shoes measured by maximum balance test. They did not find significant difference between groups for any of the other 23 outcomes assessed.  |
| **Original Authors’ Conclusions**[Paraphrase as required. If providing a direct quote, add page number] |
| A multifaceted podiatry intervention is inexpensive and relatively simple to implement and is an effective falls prevention strategy for older individuals with foot pain and increased falls risk.  |
| **Critical Appraisal** |
| **Validity**[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.] |
| PEDro: 8/10Internal validity is improved in this study by use of groups that are similar at baseline being randomly allocated and this allocation being concealed by eligibility determiners. By using a podiatrist to administer the intervention and two physiotherapists as assessors, the authors were able to blind the assessors to the intervention. They maintained at least 85% losing only 14% to follow up throughout the study. They also used an intention to treat analysis further increasing validity by accounting for non-compliance in actual practice. External validity: The number of participants in this study were calculated using an a priori size calculation to ensure sufficient power and improve the applicability of the results (however, the authors due note that this calculation may have been affected due to overestimation of fall rate which could lead to the trial being underpowered for detecting difference in proportion of fallers). Additionally, the participants had a wide range of secondary conditions (diabetes, stroke, heart disease, OA, RA), varying levels of physical activity, large variations in number of falls and duration of foot pain that might be applicable to a wide variety of individuals.Strengths: A priori size calculation used to ensure the study was sufficiently large enough to ensure sufficient power to increase generalizability and reducing the chance of a type II error. For each participant, the same assessor was used for baseline and follow up reducing chance for measurement bias. Additionally, all interventions were delivered by a single podiatrist. The study had surprisingly completion rates (86% for intervention group and 94%) ensuring little data lost to follow up. Additionally, the authors performed am intention to treat analysis to further improve the validity of the study and minimizing type I error. Finally a rate ratio of 0.64 (95% CI: 0.45-0.91) indicates strong implications for clinical significance.Weaknesses: Due to the nature of intervention studies like this RTC, it was not possible to blind subjects to the treatment received leading to possibility of a placebo effect and type I error. The study is also at risk of selection bias as it may have selected highly motivated volunteers due to the longer 12-month nature of the study and required self-monitoring of the home exercise program. These highly motivated individuals may be more likely to be compliant with the intervention. In regards to physical therapy application, the interventions in this study were carried out by a podiatrist making it difficult to generalize to physical therapist delivered interventions. Finally, standard deviations (SD) are not provided for fall statistics making calculating standardized effect size difficult and therefore limiting the ability to comment on clinically significant implications and applicability of study results. Overall evidence quality of this study was improved by sound study design aimed at reducing bias and improving validity. The large, varied sample size improves the generalizability and the a priori calculation improves the power of the study and reduces chance of a type II error. However, the study is still limited by the possibility of selection bias, inability to blind subjects, inability to delineate intervention affects and overestimation of falls in the a prior size calculation. Despite these limitations, this is still a high quality study on the effectiveness of a multifaceted podiatry intervention in reducing falls in elderly people.  |
| **Interpretation of Results**[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.] |
| A multi-faceted podiatry approach consisting of customized orthoses, footwear evaluation and advice, a general foot and ankle exercise program, and falls education is effective at reducing falls in older adults with foot pain and an increased falls risk. It is difficult to delineate which of these specific interventions was most effective at reducing falls. A multi-faceted podiatry program was also effective an improving multiple factors associated with falls including ankle strength and ROM and postural stability. Due to the large sample size, risk ratio of 0.64 (95% CI: 0.45-0.91) for fall frequency, and varied population sample, these results should be considered when treating elderly patient with foot pain at high risk of falls.  |
| **Applicability of Study Results**[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.] |
| This study has low applicability to my clinical question because its participants were on average younger than my population and the intervention group included both of my proposed interventions without attempting to delineate the effectiveness of them. It does indicate the efficacy of an intervention that includes foot orthoses for reducing falls. However, it is applicable to my clinic scenario in that is demonstrates an effective treatment for older adults at risk for falls. Additionally, its population includes diabetic individuals with peripheral neuropathy which is a primary interest in my clinical scenario. |

**SYNTHESIS AND CLINICAL IMPLICATIONS**

[Synthesize the results, quality/validity, and applicability of the two studies reviewed for the CAT. Future implications for research should be addressed briefly. Limit: 1 page.]

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| **Synthesis of Evidence:** The results of this search indicate the low quality and quantity of research on PT-delivered orthotic intervention in reducing the falls in older adults. The randomized control trial by Spink et al does provide moderately generalizable evidence that a multi-faceted podiatry intervention that includes foot orthoses can be effective in reducing falls in elderly individuals with an increased falls risk. Conversely, the search also revealed the high level of evidence that exists supporting exercise programs for reducing falls in community dwelling elderly individuals. While many different types of exercises were found, the evidence suggests that exercise programs should be delivered by a health care professional and be focused on balance, gait, strength and functional training. The rigor with which the systematic review by Sherrington et al was conducted combined with the strong statistical analysis performed, indicates the strong clinical implications this study can have on PT practice. The review was well conducted and designed in order to be comprehensive in nature and include all relevant studies. The authors worked in independent pairs and were blinded to the other’s work during article selection and data extraction to decrease bias and improve internal validity. No systematic reviews were found examining or discussing foot orthoses as an intervention to reduce falls in older adults. However, the investigators in the Spink et al study reduced bias, attempted to ensure appropriate power, and maintained high completion rates in their study. Their results indicate that interventions that include foot orthoses may indeed reduce falls in older adults but did not attempt to delineate the effects of orthotic interventions from other podiatric interventions used.**Implications for clinical practice:** The existing evidence supports the current concepts of exercise prescription to reduce falls in at risk older adults. PTs are highly trained in balance, gait, and fall risk analysis as well as exercise prescription. As evident by the high quality systematic review by Sherrington et al, exercise programs should focus on strength, gait, balance and functional training to reduce falls in older adults. Importantly, the evidence indicates that balance and functional training in particular are vital aspects of a falls prevention exercise program as resistance training alone was not found to have clinical significance in preventing falls. Delivery of these exercise programs by highly trained medical professionals, such as PTs is also supported by the literature. It is unclear whether PT-delivered interventions focused on foot orthoses would be effective in reducing falls in older adults. While orthoses fabrication and implementation isn’t always thought of as a PT’s primary intervention method, it is within the PT scope of practice. The study by Spink et al indicates the possibility of the effectiveness of these interventions as a component of an intervention delivered by a podiatrist. At this time, the evidence suggests utilizing strength and balance exercise training over foot orthoses for older individuals at risk for falls.**Further Research**:This literature search revealed the need for further research on the efficacy of PT-delivered foot orthotic interventions on reducing falls in older adults. Secondary findings indicate the need to examine cost effectiveness of exercise interventions in reducing falls, the reporting of adverse events in studies on fall prevention exercise programs. Additionally, more research is need on falls prevention strategies specifically for adults with peripheral neuropathy.  |

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[List all references cited in the CAT]

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