

## CRITICALLY APPRAISED TOPIC

### FOCUSED CLINICAL QUESTION

For patients 80 years or older at risk of falls- as determined by performance on the TUG, 30 second chair stand, or 4-stage balance tests- is the Otago exercise program more effective than a strengthening program alone in preventing falls over follow-up periods of at least 6 and up to 12 months.

### AUTHOR

<b>Prepared by</b>	Jonathan Earles	<b>Date</b>	03 December 2019
<b>Email address</b>	<a href="mailto:Jonathan_earles@med.unc.edu">Jonathan_earles@med.unc.edu</a>		

### CLINICAL SCENARIO

The patient was an 82 year-old male with a recent history of 1 fall within the last 12 months. The patient was independent with home and community ambulation both up to and following his fall. This patient could stand with feet together but could not achieve semi-tandem stance. This patient achieved 12 repetitions on the 30 second chair stand test, and completed the Timed Up and Go (TUG) test in 14 seconds.

The Otago exercise program (OEP) features progressive strengthening and balance retraining exercises performed over the course of a year. The OEP also incorporates aerobic exercise in the form of progressive weekly walking sessions. The patient described above is a candidate for referral for the OEP because he is above the age of 80 and shows signs of an increased risk for falls in his high ( $\geq 12$  seconds) TUG score and performance on the four-stage balance test.<sup>1</sup>

With as many as one in four Americans over the age of 65 falling each year, falls prevention in older adults is an important element of geriatric care.<sup>2</sup> Identifying effective falls prevention interventions is necessary, as is differentiating between proposed mechanisms of balance, strengthening, and aerobic training. Determining whether the patient above would benefit more from the OEP or a strengthening program alone would impact both his and other older adults' plan of care in falls prevention.

### SUMMARY OF SEARCH

[Best evidence appraised and key findings]

This CAT includes eight articles that met inclusion and exclusion criteria, including 1 systematic review, 4 randomized controlled trials, 1 non-randomized clinical trial, 1 non-randomized cohort study, and 1 non-randomized comparison study.

- This literature search yielded virtually no recent studies comparing the OEP directly to strengthening programs. A majority of the groundwork studies that compared OEP to more traditional balance interventions like strengthening were conducted during the late 1990's, at the time of the OEP's inception, and were therefore inappropriate for this CAT.
- The RCTs included largely used either normal activities or health education as controls.
- Several RCTs were downgraded when assessing quality due to low follow-up numbers, suggesting high dropout among older adults in exercise programs used in research. Future research could examine long-term adherence to the OEP among subjects.
- Another problem with the studies included is how inconsistently they assess actual falls prevention, with some reporting inadequate power to compare falls reduction between OEP and control groups.

### CLINICAL BOTTOM LINE

There is imperfect, but adequate, evidence presented here to support the use of the Otago exercise program vs. normal activity to reduce falls risk in patients over the age of 80 over 6 and 12 month follow-up periods. There is limited recent evidence comparing the OEP to other strengthening programs. The OEP appears to be similarly effective at preventing falls when compared to Tai-Chi, while producing greater gains in strength. It appears that early trials compared the OEP to other interventions in finding the utility of the program, and in so doing "the original OEP trials provide strong effectiveness of the programme for reducing falls."<sup>3</sup>

*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

Terms used to guide the search strategy			
Patient/Client Group	Intervention (or Assessment)	Comparison	Outcome(s)
Older adult	Otago exercise program	"Strengthening program"	Falls
80 years old	"Otago"	"Resistance training"	Falls prevention
Fall risk		"Strength"	Follow-up
TUG			6 months
Timed up and go			1 year
30 second chair stand			
4 stage balance test			

### Final search strategy (history):

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

**Builder**

All Fields  [Show index list](#)

AND All Fields  [Show index list](#)

[Search](#) or [Add to history](#)

#	Action	Search Query	Results	Time
#17	Add	Search (((((((Older adult) OR (Aged, 80 and over)) OR Aged) OR Frail elderly)) AND (((Fall) OR Accidental fall) OR Fall risk)) OR (((Timed up & go) OR (Timed up and go)) OR TUG)) OR ((4-stage balance test) OR Four-stage balance test)) OR ((30 second chair stand test) OR 30 second sit to stand test)) AND ((Resistance training) OR Strengthening)) Sort by: Best Match	690	12:51:53
#16	Add	Search ((Resistance training) OR Strengthening) Sort by: Best Match	89062	12:51:36
#15	Add	Search (((Resistance training) OR Strengthening) OR Strength) Sort by: Best Match	418173	12:51:21
#14	Add	Search (Otago exercise program) Sort by: Best Match	34	12:51:06
#13	Add	Search (Otago exercise program) OR Otago Sort by: Best Match	21673	12:50:21
#12	Add	Search (30 second chair stand test) OR 30 second sit to stand test Sort by: Best Match	332	12:50:05
#11	Add	Search ((30 second chair stand test) OR 30 second sit to stand test) Sort by: Best Match	110	12:49:54
#10	Add	Search ((30 second chair stand test) OR 0 second sit to stand test) Sort by: Best Match	154	12:49:33
#9	Add	Search ((Four stage balance test) OR 4-stage balance test) OR Four-stage balance test Sort by: Best Match	313	12:49:17
#8	Add	Search ((4-stage balance test) OR Four-stage balance test) Sort by: Best Match	17	12:48:44
#7	Add	Search (((Timed up & go) OR (Timed up and go)) OR TUG) Sort by: Best Match	4862	12:48:16
#6	Add	Search (Timed Up AND Go) OR TUG Sort by: Best Match	5294	12:48:04
#5	Add	Search ((Fall) OR Accidental fall) OR Fall risk Sort by: Best Match	128500	12:47:37
#4	Add	Search (((Older adult) OR (Aged, 80 and over)) OR Aged) OR Frail elderly Sort by: Best Match	517709	12:47:08

**History** [Download history](#) [Clear history](#)

Search	Add to builder	Query	Items found	Time
#19	Add	Search (((((((Older adult) OR (Aged, 80 and over)) OR Aged) OR Frail elderly)) AND (((Fall) OR Accidental fall) OR Fall risk)) AND (((Timed up & go) OR (Timed up and go)) OR TUG)) OR ((4-stage balance test) OR Four-stage balance test)) OR ((30 second chair stand test) OR 30 second sit to stand test)) AND ((Resistance training) OR Strengthening)) Sort by: Best Match	47	12:52:23
#18	Add	Search (((((((Older adult) OR (Aged, 80 and over)) OR Aged) OR Frail elderly)) AND (((Fall) OR Accidental fall) OR Fall risk)) OR (((Timed up & go) OR (Timed up and go)) OR TUG)) OR ((4-stage balance test) OR Four-stage balance test)) OR ((30 second chair stand test) OR 30 second sit to stand test)) AND (Otago exercise program) AND ((Resistance training) OR Strengthening)) Sort by: Best Match	4	12:52:11

1. The above images display the exact order and step-by-step creation of a search on PubMed. There are a couple of mistakes (The search ("30 second chair stand test") OR "30 second sit to stand test" left off a quotation mark, for example), but searches stuck to the original search strategy fairly closely. The three basic searches used on PubMed are as follows (differences highlighted, final search strategy shown in **bold**):

- **((((((((Older adult) OR (Aged, 80 and over)) OR Aged) OR Frail elderly)) AND (((Fall) OR Accidental fall) OR Fall risk)) AND (((Timed up & go) OR (Timed up and go)) OR TUG)) OR ((4-stage balance test) OR Four-stage balance test)) OR ((30 second chair stand test) OR 30 second sit to stand test)) AND ((Resistance training) OR Strengthening)) – returned 47 results**
- (((((((Older adult) OR (Aged, 80 and over)) OR Aged) OR Frail elderly)) AND (((Fall) OR Accidental fall) OR Fall risk)) OR (((Timed up & go) OR (Timed up and go)) OR TUG)) OR ((4-stage balance test) OR Four-stage balance test)) OR ((30 second chair stand test) OR 30 second sit to stand test)) **OR "Otago exercise program"** AND ((Resistance training) OR Strengthening)) – Returned 690 results
- (((((((Older adult) OR (Aged, 80 and over)) OR Aged) OR Frail elderly)) AND (((Fall) OR Accidental fall) OR Fall risk)) OR (((Timed up & go) OR (Timed up and go)) OR TUG)) OR ((4-stage balance test) OR Four-stage balance test)) OR ((30 second chair stand test) OR 30 second sit to stand test)) **AND "Otago exercise program"** AND ((Resistance training) OR Strengthening)) – Returned 4 results

2. Advanced search option on PEDro, using drop down options for "subdiscipline" and "gerontology," and entering "Otago exercise program" produced 15 results.
3. CINAHL, using the same search used on the third PubMed example (above) produced 4 results. However, all 4 were different than the 4 produced by the identical search on PubMed.
4. Cochrane Library through UNC, using "Otago exercise program" AND falls prevention as terms.

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

<b>Databases and Sites Searched</b>	<b>Number of results</b>	<b>Limits applied, revised number of results (if applicable)</b>
1. PubMed	1. 47	1. Reduced Otago-related searches to "Otago exercise program" (vs "Otago exercise program" OR "Otago"). 2. None. 3. Simplified overall search based on PubMed search parameters to "Otago exercise program" AND "falls prevention." Found 25 results after revision. 4. None.
2. PEDro	2. 15	
3. CINAHL	3. 4	
4. Cochrane	4. 39	

#### **INCLUSION and EXCLUSION CRITERIA**

<b>Inclusion Criteria</b>
<ul style="list-style-type: none"> <li>• Population: older adults aged 80 or older OR older adults aged 65 or older with demonstrable falls risk (especially prior history of falls)</li> <li>• Population: patients able to complete Otago independently at home or in a group setting</li> <li>• Intervention: Otago exercise program</li> <li>• Comparison: resistance/strength training, standard care</li> <li>• Outcome: incidence of falls at 6 and/or 1 year follow-up periods</li> <li>• RCT, systematic review</li> <li>• English-language articles, not country-of-origin specific (Otago originated in New Zealand, so I'm prepared to find studies from abroad)</li> <li>• PTs in the study must have received standard Otago training</li> </ul>
<b>Exclusion Criteria</b>
<ul style="list-style-type: none"> <li>• Case studies</li> <li>• Meta-syntheses, narrative reviews, other qualitative studies</li> <li>• Poster presentations</li> <li>• Follow-up periods of less than 6 months used</li> <li>• Population: Patients used do not demonstrate falls risk or are unable to participate in Otago</li> </ul>

## 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).*

Author (Year)	Risk of bias (quality score)*	Level of Evidence**	Relevance	Study design
Binns E, Taylor D. (2011) <sup>3</sup>	Downs and Black Checklist: 17/29	2b	Low. This study did use TUG and chair stand test as outcomes; but did not use falls as an outcome measure. This study did not use strength training as a control group, and group assignment was not randomized. The authors wonder if 6 months is too short for OEP participants to demonstrate improved strength.	Clinical Trial
Liu-Ambrose T, Donaldson M, Ahamed Y, et al. (2008) <sup>4</sup>	PEDro Scale: 7/10	2b Downgraded because only 70.2% of subjects were present at follow-up	High. Mean age for both groups was over 80, the intervention was OEP, the control group was assigned exercises (though the authors state none of the control participants consistently completed them by follow-up), and "falls" and TUG were outcome measures.	Randomized Control Trial
Son N, Ryu YU, Jeong H, Jang Y, Kim H. (2016) <sup>5</sup>	PEDro Scale: 8/10	1b	Moderate-High. Mean age for both groups was in the low 70's, the intervention was OEP while the control group did Tai-Chi (not "strengthening," per se), "falls," TUG, and chair stand tests were outcome measures, but the study explicitly states that it did not determine falls prevention differences between groups.	Randomized Comparison Trial (Tai Chi listed as a second exercise choice, not a control)
Kocic M, Stojanovic Z, Nikolic D, et al. (2018) <sup>6</sup>	PEDro Scale: 6/10.	2b Downgraded because only 78% of	Moderate-High. Mean age for all participants was over 78. The	Randomized Control Trial

		subjects were present at follow-up	intervention was OEP, but control group performed no strengthening, instead continued normal activities. "Falls," TUG, and chair stand test were outcome measures.	
Thomas S, Mackintosh S, Halbert J. (2010) <sup>7</sup>	AMSTAR: 9/11	1a	<u>Moderate-High</u> . All trials used OEP as experimental treatment, and all trials used some variation of "standard care" as control intervention. All but one of the 7 trials used in this SR included 12 month follow ups and included information about compliance. The SR did not provide information about outcome measures outside of mortality and falls rate (ie nothing about TUG, etc).	Systematic Review; Meta-Analysis
Yang X, Hill K, Moore K, et al. (2012) <sup>8</sup>	PEDro Scale: 7/10	2b Downgraded because only 73% of subjects were present at follow-up	<u>Moderate-Low</u> . While subjects 65+ were recruited, mean age for all participants was over 80. The intervention was OEP, but the control group performed no strengthening and instead continued normal activities. Outcome measures included 5x sit-stand. "Falls" were measured retrospectively and the authors state that the "study was not powered to evaluate falls."	Randomized Control Trial
Shubert T, Goto L, Smith M, et al. (2017) <sup>9</sup>	Downs and Black Checklist: 16/29	2b	<u>Moderate-Low</u> . This study changed delivery of the OEP such that PTs only interacted with "high risk" other study staff providing the bulk of the intervention. The study changed the frequency of the OEP such that participants received more visits than is usual in the	Non-randomized cohort study (authors label it "translational study of implementation")

			6-month program. This study used the TUG, chair stand, AND 4-stage test as outcomes but "was not powered to detect a change in falls or fall-related injuries."	
Dadgari A, Hamid T, Hakim MN, et al. (2016) <sup>10</sup>	PEDro Scale: 5/10	2b Downgraded because only 70.2% of subjects were present at follow-up	<b>Moderate.</b> Mean participant age for both experimental and control group <71 yo. The intervention was OEP, but the control group performed no strengthening and instead received "general health training." Outcome measures did include TUG, chair stand test, and incidence of falls.	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:

- Liu-Ambrose T, Donaldson M, Ahamed Y, et al. Otago Home-Based Strength and Balance Retraining Improves Executive Functioning in Older Fallers: A Randomized Controlled Trial. *Journal of the American Geriatrics Society*. 2008;(5)6:1821-1830. doi:10.1111/j.1532-5415.2008.01931.x<sup>4</sup>
- While Liu-Ambrose et al. focus on the potential cognitive benefits of the Otago, therefore including among their outcome measures cognitive measures like the Stroop Color-Word Test, this study is highly applicable to the PICO of this CAT. For example, study participants included community-dwelling older adults (criteria was 70+ compared to PICO definition of 80+, but the mean age of participants in both groups was 80+). Also, the intervention in the experimental group was the OEP, and the control group was given "guideline care," which included falls assessment, lifestyle recommendations, and specific exercise recommendations for about half of control group participants (the authors indicate that regular exercise was not reported among the control group). The study does use the TUG as an outcome measure, and reports changes over a 6-month follow-up. Finally, Liu-Ambrose et al. assessed changes in falls at a 1-year follow-up, using prospective data gathered from daily calendars given to participants.
- Thomas S, Mackintosh S, Halbert J. Does the 'Otago exercise programme' reduce mortality and falls in older adults?: a systematic review and meta-analysis. *Age and Ageing*. 2010;39,(6):81-687. <https://doi.org/10.1093/ageing/afq102><sup>7</sup>
- This systematic review represents a higher level of evidence than the RCTs included in this CAT, and gives a pooled estimate of a total of 759 OEP and 546 control participants that found a reduction in falls rate among OEP participants across 12 month follow-ups. In fact, 6 of the 7 studies used at least 10 month follow-ups, with only one (the Binns article, #1 in the above list) using a 6 month follow-up period. Drawbacks include the authors acknowledgement of wide CI when comparing mortality, and overall low numbers of participants across studies and high numbers of drop-outs among the studies included. The study does not explicitly discuss outcomes measures mentioned in the PICO of this CAT (TUG, etc).

## SUMMARY OF BEST EVIDENCE

### (1) Description and appraisal of (Otago Home-Based Strength and Balance Retraining Improves Executive Functioning in Older Fallers: A Randomized Controlled Trial) by (Liu-Ambrose et al, 2008).<sup>4</sup>

<b>Aim/Objective of the Study/Systematic Review:</b>
<ul style="list-style-type: none"><li>To examine the relationship between implementation of the OEP and falls risk in community-dwelling adults over the age of 70 who had recently experienced a fall.</li><li>This study sought to elucidate the mechanisms by which the OEP works – whether it influences falls risk by changing physiologic factors like strength or cognitive factors like executive functioning, or both.</li></ul>
<b>Study Design</b> [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.
<ul style="list-style-type: none"><li>Randomized Control Trial.</li><li>Outcome measurements occurred at baseline and after a 6-month follow-up. In addition, falls incidence was monitored for a full 12 month follow-up period.</li><li>Single-blind design, with assistants who conducted outcome measurements and called participants blinded to group allocation.</li></ul>
<b>Setting</b> [e.g., locations such as hospital, community; rural; metropolitan; country]
<ul style="list-style-type: none"><li>Two “dedicated referral-based falls clinics” in Vancouver, British Columbia, Canada (pg 1822).</li></ul>
<b>Participants</b> [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.
<ul style="list-style-type: none"><li>N = 74, mean baseline age of 82.2 years.</li><li>Men and women in the Vancouver area who were referred to one of two local “falls clinics” by their primary care provider or emergency department following a recent fall and who were considered to be at risk for falls.</li><li>179 patients initially considered eligible- meeting age, falls history, falls risk, and performance measure criteria for inclusion.</li><li>105 either declined or were not reachable prior to beginning the study.</li><li>Randomized into OEP (N = 36) and Control (N = 38) groups:<ul style="list-style-type: none"><li>31 members of the OEP group assessed in baseline measurements (5 lost to refusal or new onset of exclusion condition).</li><li>28 members of control group assessed in baseline measurements (10 lost to refusal or new onset of exclusion condition).</li></ul></li><li>At 6-month follow-up N=52, as OEP (N = 28) and control (N = 24):<ul style="list-style-type: none"><li>3 members of the OEP group lost to death, insufficient baseline measurement, or “visual impairment.”</li><li>4 members of the control group lost to death, dropout, insufficient baseline measurement.</li></ul></li><li>No significant differences between groups in regards to age, gender, falls history, previous falls treatments.</li></ul>
<b>Intervention Investigated</b> [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]
<i>Control</i>
<ul style="list-style-type: none"><li>Received standard care recommendations based on the American Geriatrics Society/British Geriatrics Society/American Academy of Orthopaedic Surgeons Falls Prevention Guidelines, which the authors of the study identify as their “guideline care.” This included vitamin D supplements, exercise</li></ul>

recommendations, but not supervised exercise. The authors note that “No participants in the control group took up the recommendation to exercise.” No additional information was provided as to the frequency of check-ups in the falls risk clinics.

### *Experimental*

- Two PTs delivered the OEP according to OEP instructions, including prescribing exercises from a set list of strengthening and balancing exercises.
- Participants were instructed to attempt exercises 3x/week for 30 minutes each session, and to walk an additional 2x/week.
- Participants were given illustrations of each exercise, and ankle weights to provide resistance as appropriate.
- PTs visited each OEP group participant’s home to initiate the program and prescribe exercises, then returned 4 times (once every other week within the first 6 weeks, then once more at the 6-month mark). These follow-up meetings allowed PTs to assess adherence, encourage participation, and give progression recommendations as appropriate.
- Less than 70% (68%) of participants in the OEP group reported adhering to OEP exercises at least once per week, and only 25% completed the OEP exercises the recommended 3x/week.

### **Outcome Measures**

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

- Physiological Profile Assessment (PPA) z-score: assesses physiological fall risk. Produces a standard score with “mild fall risk” if z-score  $\geq 1$ , and “marked fall risk” if z-score  $\geq 3$ . Includes 5 domains which contribute to standardized score: “postural sway, hand reaction time, quadriceps strength, proprioception, and edge contrast sensitivity”(pg 1822). Measured at baseline and at 6-month follow-up at the fall clinic by research assistants.
- TUG: a measure of functional mobility. Participants stand from a chair with armrests, walk 3 meters and turn, returning to the chair to sit. Fall risk” if completed in  $\geq 15$  seconds. Measured at baseline and at 6-month follow-up at the fall clinic by research assistants.
- Measures of Executive Function – all were assessed at baseline and at 6 months by research assistants.
  - Trail Making Test Part B: assesses “set shifting” and cognitive flexibility. Participants are given a page with numbers 1-13 and letters A-L scattered and are asked to draw a “trail” connecting numbers and letters in order, beginning with connecting the number 1 to the letter A and the letter a to the number 2. The shorter the time taken to complete the trail, the better, though no minimum score was provided.
  - Verbal Digits Backward Test: measures working memory. Participants are given incrementally longer strings of digits, read aloud, that they must repeat in reverse order, out loud. The first string is 3 digits, the maximum string is 9 digits, and participants have two trials per string, resulting in a maximum score of 14 and a minimum score of 0.
  - Stroop Color-Word Test: Measures response inhibition, with longer times reflecting poor concentration. Participants were given a piece of paper with 112 color names printed in various primary colors that did not match the name printed (“yellow” printed in green ink). Participants were asked to identify the color of the ink of each word. No minimum score provided.
- Falls incidence and adherence to OEP via monthly calendars, which were mailed via prepaid envelope.

### **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.]

**Table 2. Physiological Falls Risk, Functional Mobility, and Executive Functions at Baseline and 6-Month Follow-Up (N = 52)**

Outcome Measures	OEP Group (n = 28)		Control Group (n = 24)	
	Baseline	Six Months	Baseline	Six Months
	Mean ± Standard Deviation			
Physiological Profile Assessment z-score	2.0 ± 1.3	1.9 ± 1.2	1.9 ± 1.3	1.9 ± 1.2
Timed Up and Go Test, seconds	14.2 ± 4.6	13.6 ± 4.3	17.4 ± 10.4	18.1 ± 10.5
Trail Making Test Part B, seconds	222.4 ± 200.1	203.1 ± 262.3	224.7 ± 106.4	232.9 ± 127.1
Verbal Digits Backward Test (maximum 14 points)	3.8 ± 2.0	3.9 ± 2.3	3.1 ± 1.8	2.8 ± 1.8
Stroop Color-Word Test, seconds	157.6 ± 83.0	137.4 ± 49.5	151.7 ± 44.0	167.2 ± 103.4*

\* Significantly different from Otago Exercise Program (OEP) group at  $P = .05$ .

Table 2. pg 1827

This study used an alpha value of  $P \leq .05$  for all results and used “full analysis set” analysis, which the authors define as being “as close as possible to the intention-to-treat ideal of including all randomized participants” (pg 1825).

- **PPA:** All mean PPA values, for both groups and at both baseline and follow-up fell between 1 and 2, indicating “moderate risk” (pg 1823). The mean difference between the PPA z-scores of the OEP and control groups at the 6-month follow-up was zero, with a large p-value of  $P = .98$  demonstrating no significant difference between groups for physiological falls risk across the 6 months of the study.
- **TUG:** The mean difference between the TUG times of the OEP group and control group at 6 months was 4.5 seconds. The effect size was 0.56, a moderate effect size. However, this difference does not show statistical significance with  $P = .36$ .
- **Measures of Executive Function:**
  - **Trail Making Test Part B:** Neither the Trail Making Test nor the Verbal Digits Backwards Test produced significant between-groups improvements, with both  $P \geq .09$ . Mean difference for the OEP group relative to the control group at follow-up was 29.8 seconds, and the effect size was 0.14, a small effect size.
  - **Verbal Digits Backward Test:** Mean difference for the OEP group relative to the control group at follow-up was 1.1 points, and the effect size was 0.53, a moderate effect size. As previously mentioned, these differences were not statistically significant.
  - **Stroop Color-Word Test:** This produced a significant between-groups difference where  $P = .05$  in this measure of response inhibition. Mean difference for the OEP group relative to the control group at follow-up was 29.8 seconds, and the effect size was 0.26, a small effect size.

**Table 4. Proportion of Participants Experiencing One or More Falls over the 1-Year Observation Period (N = 52)**

Number of Falls	Otago Exercise Program Group (n = 28)	Control Group (n = 24)
	n (%)	
0	16 (57.1)	8 (33.3)
1	7 (25.0)	7 (29.2)
2	1 (3.6)	5 (20.8)
3	2 (7.1)	0
≥4	2 (7.1)	4 (16.7)

n (%) = number and percentage of “yes” cases within each group.

Table 4. pg 1828

- **Falls incidence:** The authors report removing two outliers from their samples – individuals who experienced 18+ falls each over the 1 year period (each had medical factors that contributed to falls risk). Following this, the unadjusted incidence rate ratio for falls was 0.56 for the OEP group compared to the control group with a 95% CI = 0.26-1.2. This indicates that, before adjustment, the OEP group experienced falls at a rate of 0.56 that of the control group. The adjusted incidence rate ratio was 0.47 with a 95% CI = 0.24-0.96.

**Original Authors’ Conclusions**

[Paraphrase as required. If providing a direct quote, add page number]

The authors discussion states, as previously seen in other studies and as shown by the incidence rate ratios of falls in this study, that the OEP is effective at reducing falls in community-dwelling older adults. This reduction occurred after a full year follow-up, despite physiological falls risk (PPA) and functional mobility (TUG) not significantly improving over the first 6-month follow-up. Instead, the OEP subjects demonstrated improvement in executive processing, as measured in response inhibition by the Stroop Color-Word Test. They conclude that the OEP (because it is comprised of balance, strength, and walking training) improves the executive functioning of older adults which may in turn reduce 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 Scale: 7/10. Random allocation: Yes, Concealed allocation: Yes, Groups comparable at baseline: Yes, Subjects blind: No, Therapists blind: No, Assessors blind: Yes, Adequate follow-up: No, Intention-to-treat analysis: Yes, Between-group comparisons: Yes, Point estimates and variability: Yes.

Internal Validity: Strengths: The study used random and concealed allocation, comparable groups at baseline, blinded assessors at baseline and follow-up, intention-to-treat analysis, compares between groups, and includes both mean and standard deviation values, all of which boost confidence in the internal validity of the results.

Weaknesses: Inability to blind the subjects and therapists delivering the intervention, and the fact that there were high dropout rates and therefore inadequate follow-up at 6 months. Another weakness is the small sample size: The authors state that "the study did not provide adequate sample size to ascertain the contribution of the observed change in executive functioning to the reduction of falls in our participants" (pg 1828-9). This small sample may have overemphasized the role of executive functioning on falls risk, thereby increasing the odds of a Type I error.

External Validity: Weaknesses: The authors identify limited sampling as a cause for concern about the generalizability of their results, as less than half of the eligible patients from the two falls clinic over the time period of sampling were included in the study. Their population may have been either more or less prone to falls than the general population, and it would be difficult to say due to inadequate representation. Strengths: The authors clearly state the eligibility criteria that they used in their sampling, which does lend strength to the generalizability of their findings, should future studies use similar criteria.

Overall: This study provided decent evidence that the Otago Exercise Program reduces falls rate in community-dwelling older adults when compared to a fairly hands-off control. The authors hypothesize that this is due to changes in executive functioning in OEP subjects, but acknowledge that their sample size limits the ability to show concrete relationships between executive functioning, the OEP, and falls.

### 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 study found moderate or minimal effect sizes for all of its primary outcome measures, but did find statistically significant improvements in response inhibition among the OEP participants. This study reinforces previous literature that shows decreased falls risk for older adults, as the subjects who performed the OEP were less likely to fall in the one-year follow-up period than were subjects in the control group. The small sample size, low follow-up, and relatively low adherence to the OEP all limit the generalizability of the findings of this sample, but it is reasonable to conclude that performing OEP strengthening, balance training, and walking are likely to reduce falls risk in older adults when compared to inactivity.

### 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.]

Practicality and Feasibility: The Otago Exercise Program, as described in this study, is very feasible from a therapist's point of view: it is primarily home-based and patient-driven, only supplemented by initial in-person meetings and periodic phone calls. Materials are limited to print-outs, ankle weights, and phone access, none of which are prohibitively expensive. This study demonstrates that finding motivating factors to produce consistent exercise is pivotal when attempting to implement an independent, months-long exercise program. Neither the control nor the OEP group may really be said to have consistently exercised multiple times per week, and some members of the OEP group exercised even less than once per week on average.

Applicability: While this study supports the notion that the OEP reduces falls risk for patients like the patient in the case example – 82 years old, community dwelling, independently mobile – it does not show statistically

significant improvements in physiological or functional measures over time with use of the OEP. The authors do discuss whether the PPA is an adequate measurement for capturing physiological changes, or is sensitive enough, especially over a 6-month period. Additional research would be valuable in investigating the role of the OEP in executive functioning and the utility of the PPA as an outcome measurement.

**(2) Description and appraisal of (Does the 'Otago exercise programme' reduce mortality and falls in older adults?: a systematic review and meta-analysis) by (Thomas et al, 2010).<sup>7</sup>**

<p><b>Aim/Objective of the Study/Systematic Review:</b></p>
<ul style="list-style-type: none"> <li>• This systematic review sought to determine the role of the Otago Exercise Program (OEP) on reducing falls, falls resulting in injury, and risk of death from falls in community-dwelling older adults over the age of 65 years.</li> <li>• This review also examined how closely older adults in OEP studies adhere to OEP programming.</li> </ul>
<p><b>Study Design</b></p> <p>[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]</p> <p>Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.</p>
<ul style="list-style-type: none"> <li>• Systematic review and meta-analyses of OEP studies.</li> </ul> <p><u>Search Strategy:</u> A literature search was performed in the Cochrane, CINAHL, TRIP, AARP Ageline, INFORMIT, Prevention of Falls Network Europe, and PEDro databases. Citations were subsequently searched on Web of Science. Searches typically included dates from 1990-September 2008, though the AARP search ended in August 2008 and the INFORMIT search reached back to 1970 for results; and results were not restricted by language. The authors do not include the specific terms or phrases used in their search.</p> <p><u>Selection Criteria:</u> Two of the three authors independently identified eligible articles based on their titles and abstracts, then acquired full articles for their list and double-checked inclusion criteria before including them in the review. The third author contributed to discussions surrounding any disagreements of opinion regarding inclusion.</p> <ul style="list-style-type: none"> <li>• <u>Inclusion criteria:</u> 1) RCTs, 2) other controlled trials with "masked assessment of outcome" (pg 682), 3) published before 1990, 4) OEP as an intervention AND inclusion of a control group which did not undergo a "significant intervention" (pg 682) 5) "Conference proceedings and reference lists of articles were also accessed" (pg 682).</li> <li>• <u>Exclusion criteria:</u> 1) duplicated articles, 2) summaries of trials already included 3) exercise intervention other than OEP used, 4) OEP altered, whether by not following OEP protocol or by being used along with a second intervention 5) systematic review of systematic reviews.</li> </ul> <p><u>Data Extraction:</u> The authors used the following information from eligible studies: study design, participants, intervention, outcome measures, sample sizes, incidents rates, and number of adverse events. The authors also reached out to RCT authors as necessary to clarify or gather additional information as needed.</p> <p><u>Quality Assessment:</u> Two authors (a combination different than that of the selection pairing) independently scored each RCT using the PEDro scale, compared findings, and discussed differences of opinion to resolution.</p>
<p><b>Setting</b></p> <p>[e.g., locations such as hospital, community; rural; metropolitan; country]</p>
<p>The authors of this systematic review operate out of Flinders University and the University of South Australia, in Adelaide, South Australia, Australia.</p>
<p><b>Participants</b></p> <p>[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]</p> <p>Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the</p>

study. You can find this descriptive information in the text and tables in the article.

- Participants from all studies were community-dwelling older adults without recent history of physical therapy appointments.
- Mean age of all participants = 81.6±3.9 years.
- This review included seven studies with total participants N = 1,305.
- OEP participants N = 759.
- Non-OEP participants N = 546.
- Five studies included both male and female participants, two studies used female participants only.
- The authors report that participants were randomly allocated to groups in all studies and that baseline characteristics were similar both within each individual study and across all seven studies.
- Dropout rates were reported as “low,” and a measure for at least one outcome measure at follow-up was recorded for more than 80% of the meta-analysis population (pg 685).
- This review and meta-analysis included the Liu-Ambrose article discussed above.

### **Intervention Investigated**

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

#### *Control*

- “The control intervention was usual care or social visits only in each of the seven studies analysed” (pg 684).

#### *Experimental*

- The OEP was used, “in its original form,” as the experimental intervention in all seven studies included in this review (pg 684).
- One of the seven studies combined the OEP with “a reduction in psychotropic medications” as an intervention in one of their four groups, but found no interaction between the two and labeled the results from this group as only OEP vs control, thereby omitting the portion of the intervention that included psychotropic medication modification.
- Another of the seven studies combined the OEP with a home safety check in one group and vitamin D supplements in all experimental groups. The authors of this review indicate that, because an interaction effect was noted between home modification and the OEP, the results of that particular group were not included in their review. The OEP only (and vitamin D) group was still compared to the control group, because the authors argue that vitamin D supplements would not impact adherence to the OEP and mortality.

### **Outcome Measures**

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

- The seven studies included in this review all used falls rate, injurious falls, mortality, and adherence or compliance to the OEP as outcome measures; and four studies included adverse events.

### **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.]

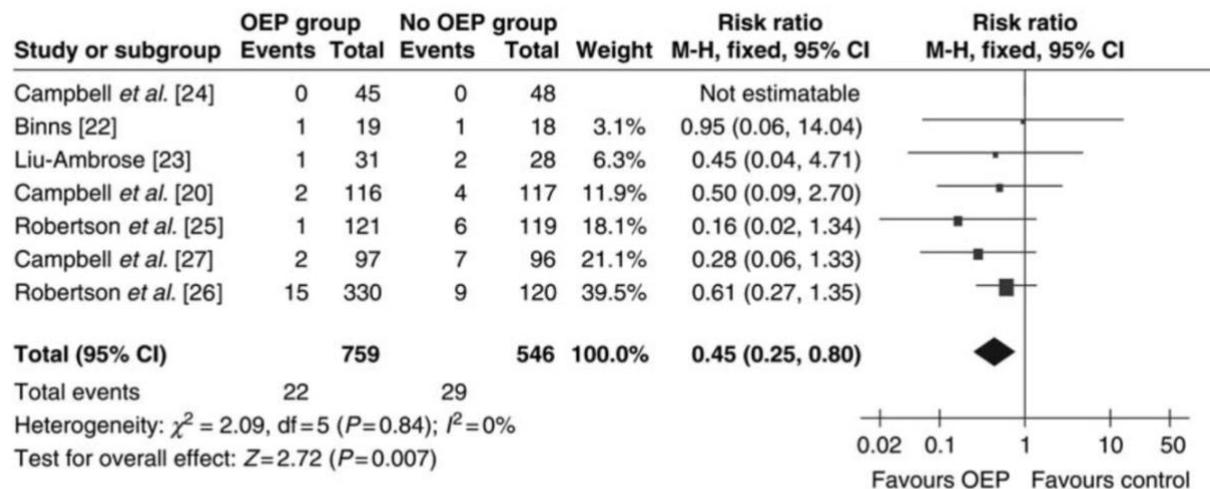


Figure 2. Forest plot of comparison: ‘OEP’ versus ‘no exercise’; outcome: mortality.

- Figure 2. Pg 685.
- The pooled population of the included studies demonstrate homogeneity as seen in the low measure of statistical heterogeneity,  $I^2 = 0\%$ .
- **Mortality:** seen in the figure above, The pooled risk ratio = 0.45 with a 95% CI = 0.25-0.80 and  $P = 0.007$ , indicating that the OEP significantly reduces the risk of death from falls in community-dwelling older adults. The authors state that this used a fixed-effects model.
- **Falls Rate:** Again using fixed-effects model, pooled estimate of incidence rate ratio = 0.68 with a 95% CI = 0.56-0.79 and  $P < 0.00001$ . This supports the idea that the OEP may help reduce falls rate among community-dwelling older adults.
- **Injurious Falls:** The authors report that there was no significant difference in fall severity between OEP and control groups.
- **Adherence/compliance:** The authors used the 6 studies which used 12-month follow-up periods to randomize a total of 843 participants into a group of OEP participants to assess compliance. 747 participants were present at 12-month follow-ups in their respective studies. Of this number,  $36.7 \pm 15.8\%$  were exercising at least three times/week and  $55.9 \pm 14.8\%$  were exercising at least two times/week at the 12-month follow-up.
- **Adverse Events:** Only four studies included adverse reactions, which produced a total of six adverse reactions: three falls, one “episode of pain due to exercising,” one “moderate injury,” and two reports of low back pain (pg 685).

### Original Authors’ Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

- The author’s state that the OEP “significantly reduces the risk of death in the 12 months after it has first been initiated in older community-dwelling individuals” (pg 685). They state that the OEP also significantly reduces the rate of falls in this population.
- The authors attribute the inability to identify a significant reduction of injurious falls following OEP intervention to their lack of access to data from individual participants.
- They hypothesize that adhering to OEP exercises at least twice per week may still produce the results mentioned above, though the recommendation is at least three times/week.

### 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 score: 9/11. 1) A priori design provided: yes; Duplicate study selection and data extraction: yes; comprehensive literature search: yes; status of publication an inclusion criterion: yes; list of both included and excluded studies: no; characteristics of included studies: yes; quality assessment: yes; quality assessment used in conclusions: yes; appropriate methods to combine studies: yes; publication bias assessed: no; conflict of interest stated; yes.

#### Strengths:

- **Selection and Publication Biases:** Two authors independently searched multiple databases as noted above, and discussed disputes with the third author. No restrictions were made by language, and the authors included grey literature like conference proceedings in their search strategy.

- **Quality assessment and Study Quality:** The authors used the PEDro Scale to assess all included studies. The PEDro scale is a reliable tool for assessing RCT quality. According to the PEDro site, of the 32,300 complete trials available on the site as of January 2019, the average PEDro score is  $5.1 \pm 1.5$ .<sup>11</sup> Four of the seven included studies meet PEDro “moderate to high” quality scores of  $\geq 6/10$ , two of the seven scored 5/10, and one scored 4/10.
- **Internal Validity:** All studies used the same experimental (OEP), and similar control (normal care) interventions; and used the same outcome measures. This, along with the relative homogeneity of the overall population, allowed for pooling.

**Weaknesses:**

- **Search strategy:** The authors do not include the actual search terms used for each database.
- **Selection Bias:** There is no citation list of excluded articles, only a flow chart discussing why *groups* of studies were excluded (i.e. 135 studies excluded for not using OEP as primary intervention).
- **Publication bias:** The authors do not include an assessment of publication bias, as with a funnel plot.
- **External validity:** The authors of this review point out that several of their included studies were conducted by the same researchers and therefore may include similar samples. While this participant homogeneity allowed for confidence in completing a meta-analysis, “the homogeneity of the sample also means that the results should be interpreted with caution when considering using the programme in groups of participants who *are not community-dwelling or normally independently ambulatory*” (emphasis added. pg 686)..

**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.]

While limited in generalizability by study participant homogeneity, this is a well-organized systematic review and meta-analysis which inspires confidence in its findings by virtue of the quality of its included studies, pooled estimates of falls rates and mortality, and consistency across studies of OEP use. This review indicates that selecting the OEP is preferable to “standard care” when attempting to address an older adult’s falls risk, but cannot be used to compare the OEP to other interventions.

**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.]

**Practicality and Feasibility:** This systematic review includes no information that contradicts the idea that the OEP is a feasible falls-prevention program. Thomas et al. did find limited participant adherence in their included studies, with only 37% of pooled participants completing the recommended three sessions of OEP exercise per week. They hypothesize that, as over half of participants completed at least two sessions per week, and OEP participants demonstrated significant improvements in falls rate and mortality, achieving adherence of at least two sessions per week may be beneficial. This is a feasible goal, though it would require patient motivation and self-efficacy to maintain adherence when not supervised.

**Applicability:** The limited generalizability of this review does not limit its application to the clinical case – the authors specify that their findings are most applicable to community-dwelling, independently mobile individuals, which is appropriate for the above clinical case. As the stated goals of this patient’s plan of care is falls risk reduction, this review supports the use of the OEP as an intervention, though as mentioned it unfortunately does not help distinguish between the OEP and another strengthening intervention.

**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.]

**Results and Quality**

The studies by both Thomas et al. and Liu-Ambrose et al. present evidence that the Otago Exercise Program is an effective intervention in reducing falls risk in community-dwelling, independently mobile, older adults above the age of 65. The Liu-Ambrose RCT introduces improved executive functioning among its OEP population as a potential mechanism for reducing falls rate among older adults.<sup>4</sup> It is important to note that the OEP is compared to standard care, and not an alternative strengthening program, in both the RCT and systematic review presented in this CAT. Much of the formative research investigating the OEP and comparisons to other interventions appears to have been conducted in the mid-to-late 1990’s, as evidenced in part by Thomas et al. including four studies published between 1997-2001.<sup>7</sup> Despite this, their systematic review does not include studies with control groups using strengthening programs other than the OEP. Son et al., as mentioned, found that the OEP compares favorably to Tai Chi in terms of falls risk reduction, and may produce

greater strength gains than Tai Chi.<sup>5</sup> A limitation in both the Liu-Ambrose and Thomas articles is the relatively low rate of adherence to standard OEP weekly exercise recommendations. The Liu-Ambrose RCT is limited by a small sample size, while the Thomas systematic review's generalizability is limited by a homogenous study population.

#### Applicability

The populations of both Thomas et al. and Liu-Ambrose et al. represent the clinical case presented in this CAT fairly well. It is evident that clinicians may consider the OEP for older adults who are independently mobile both at home and in the community, but who have a recent history of falls or are at risk for falls as determined by performance on functional measures such as the TUG. The low adherence rates reported across studies indicate that clinicians should discuss motivation, support, and habit-forming strategies when assigning the OEP as an intervention.

#### Future Research

Liu-Ambrose et al. found that, despite receiving generalized recommendations to exercise, the control group reported not exercising at follow-up. This supports the possibility that the OEP should be compared to standard care which does not include a separate intervention, as this may more closely resemble many older adults' experience with exercise. There is a potential need for additional research into whether or not the OEP produces improvements in physiological or functional outcome measures, neither of which were shown in the Liu-Ambrose study.<sup>4</sup> Thomas et al. specifically recommend more falls prevention research include mortality as an outcome after their findings suggest that the OEP may reduce mortality.<sup>7</sup> Finally, the low follow-up exhibited in several studies raises the question of whether follow-up is due to patient-specific factors, or if there is something about the design of the OEP that limits follow-through by subjects.

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