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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| Is vestibular rehabilitation or standard balance training more effective in reducing the frequency of falls and improving balance and fatigue in ambulatory adults with relapse-remitting or progressive multiple sclerosis? |  |

**AUTHOR**

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**CLINICAL SCENARIO**

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| This patient scenario stems from my clinical rotation at the International Multiple Sclerosis Management Practice. The patient is a female in her late 70s with secondary progressive multiple sclerosis (MS). She currently uses a rollator to navigate community and household distances, but uses a cane to assist with transfers and short household distances. One of her greatest deficits is lack of flexibility in her hamstrings and calves, secondary to her spasticity. She has severely decreased gait speed and step length and is unable to react timely or appropriately to perturbations. She has a long-standing history of dizziness, which exacerbated by rotational head motions and cervical extension, further increasing her risk for falls. She tested negatively for benign paroxysmal positional vertigo and did not improve with Epley’s technique. She recently underwent a brain MRI that identified lesions in her cerebellum and brainstem.  People with MS are able to endure symptoms of vestibular dysfunction due to central disturbance, such as lesions within the cerebellum; however, vestibular rehabilitation is not commonly performed with the MS population.1,2 Even when it is included in treatment, vestibular rehabilitation is not standardized or uniform. Since people with MS are subject to increasing physical disability and progressive muscle wasting, I am interested as to whether vestibular rehabilitation or standard balance training is more effective in the reducing falls and improving balance in those who report dizziness. While the balance centers of the brain are frequently affected by lesions occurring due to active disease, current treatment interventions focus on improving general balance without specific vestibular rehabilitation. Typical vestibular rehabilitation is most commonly utilized in persons with peripheral sources of vestibular dysfunction (inner ear).2 Since people with MS often suffer from a broad spectrum of symptoms, vestibular dysfunction frequently goes unnoticed or untreated. The MS lesions affecting the cerebellum and brainstem are examples of central vestibular dysfunction, and while it is not largely researched, individuals with MS with lesions in these two areas may benefit from vestibular rehabilitation to recalibrate their central vestibular system and induce cortical reorganization.2 |

**SUMMARY OF SEARCH**

[Best evidence appraised and key findings]

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| Eight studies were identified that met the inclusion/exclusion criteria including 7 randomized controlled trials and 1 cross-over study. For individuals with MS:   * Combined vestibular rehabilitation and conventional balance training allow for greater and more efficient improvements of vestibular and balance impairments than either performed in isolation. * Individualizing vestibular training regimens to person-specific deficits helps maximize improvements. * People who are moderately to severely disabled also benefit from vestibular rehabilitation in terms of fatigue, balance, and ADL performance. * Vestibular function and balance can be improved in a relatively short period (~4 weeks) of training. * Significant improvements are seen in people with and without brainstem/cerebellar involvement, indicating generalizability of vestibular training to people with MS who have impaired balance. |

**CLINICAL BOTTOM LINE**

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| Incorporating vestibular rehabilitation into balance training programs for ambulatory adults with MS who report dizziness or symptoms of vestibular dysfunction can maximize improvements of balance, dizziness, and fatigue. Individualizing the program to reflect the patient’s specific deficits can further expedite clinically significant results. Vestibular rehabilitation is both a feasible and affordable intervention to consider in the MS population. Further research is needed to identify the longevity of the results, as well as determine safe continuation of independent vestibular training. |

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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) |
| Ambulatory adults with multiple sclerosis (non-specific to progressive or relapse remitting) who report symptoms of vestibular dysfunction or dizziness | Vestibular rehabilitation | Standard neuromuscular balance and/or lower extremity strength, coordination, and gait training | **Primary**: Frequency of falls  **Secondary**: balance, fatigue, markers of vestibular function |

**Final search strategy (history):**

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

((vestibular rehabilitation OR vestibular physiotherapy OR vestibular physical therapy) AND (balance training OR balance) AND (multiple sclerosis) AND (young OR recently diagnosed OR recent diagnosis OR low disability OR high function\*)) 🡪 6 results

((vestibular rehabilitation OR vestibular physiotherapy OR vestibular physical therapy) AND ((multiple sclerosis) AND (young OR recently diagnosed OR recent diagnosis OR low disability OR high function\*))) 🡪 8 results

((vestibular rehabilitation OR vestibular physiotherapy OR vestibular physical therapy OR gaze stability) AND (balance training OR balance) AND ((multiple sclerosis) AND (young OR recently diagnosed OR recent diagnosis OR low disability OR high function\*))) 🡪 6 results

((vestibular rehabilitation OR vestibular physiotherapy OR vestibular physical therapy OR gaze stability) AND (balance training OR balance) AND (multiple sclerosis)) 🡪 28 results

((((vestibular rehabilitation) OR (vestibular physiotherapy) OR (vestibular physical therapy) OR (gaze stability) OR (eye movements)) AND ((balance training) OR (balance)) AND (multiple sclerosis))) 🡪 45 results

**Final search strategy:**

((((vestibular rehabilitation) OR (propriocept\*) OR (vestibular physiotherapy) OR vestibular physical therapy) OR (gaze stability) OR (eye movements)) AND ((balance training) OR (balance)) AND (multiple sclerosis))))

🡪 79 results

*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 | 79 | Full-text articles, RCTs and systematic reviews only, last 15 years, English texts only |
| Web of Science | 90 | RCTs and systematic reviews only, English texts only |
| PEDro | 13 | Abstract & Title: multiple sclerosis  Therapy: neurodevelopmental therapy, neurofacilitation  Problem: motor incoordination  Subdiscipline: Neurology  Method: clinical trial |
| EMBASE | 0 |  |
| EBSCO | 3 | RCTs and systematic reviews only, past 10 years, English texts only |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| RCTs, systematic reviews, meta-analyses  Ambulatory adults with multiple sclerosis   * EDSS (Expanded Disability Status Scale) score of 6.5 or less (participants are able to walk with up to two assistive devices, and are not restricted to wheelchair use as primary means of mobility) * Must have history or risk of fall(s) * Participants are allowed to use assistive device(s) for ambulation * Report of dizziness of symptoms of vestibular dysfunction   Vestibular rehabilitation – both static and dynamic interventions  Reported outcomes of frequency of falls, gait speed, measures of balance, sensory processing, neuroplastic changes in the brain measured by EEG or MRI, other falls data (near-falls, subsequent injuries), and/or reliance on assistive device(s) for ambulation  Long-term follow-up (at least 2 months post-study)  6 weeks or greater length of intervention  Must be published in English |
| **Exclusion Criteria** |
| Case reports, case studies, narrative reviews  EDSS score of 7 or greater (reliant upon wheelchair as primary means of mobility)  Diagnosis of benign paroxysmal positional vertigo (BPPV) – looking for studies that improve central vestibular dysfunction due to MS-caused lesions in the brain  Non-ambulatory adults with multiple sclerosis   * Not allowed to use FES or straight leg brace as assistive device for ambulation   Aquatic therapy for balance or gait training  Lack of long-term follow-up  Studies with interventions that last shorter than 6 weeks |

**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)**  **: PEDro Scale** | **Level of Evidence\*\*** | **Relevance** | **Study design** |
| **Hebert et al., 2011**3 | **10/11** | **1b** | **High** | **3-arm, 14-week, single-blinded, stratified blocked RCT** |
| **Ozgen et al., 2016**4 | **9/11** | **1b** | **Mod**  **(no standard balance comparison group)** | **2-arm, 8-week, single-blinded RCT** |
| **Afrasiabifar et al., 2018**5 | **9/11** | **1b** | **High** | **3-arm, parallel RCT** |
| **Hebert et al., 2018**6 | **10/11** | **1b** | **High** | **16-week, examiner-blinded RCT** |
| **Tramontano et al., 2018**7 | **7/11** | **1b** | **Mod**  **(inclusion of highly disabled participants)** | **2-arm, 4-week, single-blind RCT** |
| **Prosperini et al., 2010**8 | **6/11** | **2b/3b** | **High** | **Single group cross-over pilot study** |
| **Cattaneo et al., 2007**9 | **10/11** | **1b** | **High** | **3-arm, double blinded RCT** |
| **Brichetto et al., 2015**10 | **9/11** | **1b** | **Mod** | **2-arm, examiner-blinded RCT** |

\*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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| * **Afrasiabifar et al., 2018**: Comparing the effect of Cawthorne-Cooksey and Frenkel exercises on balance in patients with multiple sclerosis   This study has high relevance to the PICO question, is a high level of evidence (1b), and scored well (9/11) on the PEDro quality scale. Its comparison of three randomized groups separates it from the other studies included in the CAT in addition to its recent publication year.   * **Hebert et al., 2018**: Efficacy of Balance and Eye-Movement Exercises for Persons with Multiple Sclerosis   This study has high relevance to the PICO question, is a high level of evidence (1b), and scored well (10/11) on the PEDro quality scale. Its use of individualized vestibular rehabilitation distinguished it from other studies, as well as its recent publication year. |

**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of** Comparing the effect of Cawthorne-Cooksey and Frenkel exercises on balance in patients with multiple sclerosis: a randomized controlled trial **by** Afrasiabifar et al., 2018

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| **Aim/Objective of the Study/Systematic Review:** |
| The objective of this randomized controlled trial was to evaluate the effect of Cawthorne-Cooksey exercises, a series of vestibular rehabilitation exercises, and Frenkel exercises, which include a series of conventional exercises targeting balance deficits and strength, on the balance abilities of patients with multiple sclerosis. |
| **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. |
| This was a 12-week, 3-arm, parallel, randomized controlled trial. The three intervention groups were the group completing Cawthorne-Cooksey exercises, another group completing Frenkel exercises, and a third group (control) that received routine care. The study used a blocked randomization process to divide the participants into respective groups.5  The primary outcome measure was the Berg Balance Scale (BBS) to measure improvements in both static and dynamic balance.  Outcomes were measured at baseline, after the first 6 weeks of the intervention, and after the final week of the intervention (week 12). All assessors were blinded as to group allocation. The blocked randomization process was performed by a blinded and uninvolved statistician.5 |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| The study took place at an outpatient clinic at the University Hospital (Yasuj University of Medical Sciences) in Iran. |
| **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. |
| 75 eligible participants with multiple sclerosis were included in the study, 72 of which completed the study.  “Inclusion criteria consisted of a confirmed diagnosis of [multiple sclerosis] by a neurologist at least six months from onset, being in remission period, being between 15 and 55 years, ability to stand for 30 seconds and to walk at least 6 meters without any assistance, to have a Berg Balance Score of 21 to 40 points, no previous participation in a rehabilitation program, and not suffering from any other diseases other than multiple sclerosis”5 (p. 58).  Exclusion criteria consisted of unwillingness or inability to take part in the intervention, and an MS relapse occurring during the study period.5  Participants were recruited from the medical records of the society of special diseases of the Vice Chancellor in treatment affairs of Yasuj University of Medical Sciences in Iran, in which patients received phone calls with information about the study and inviting them to participate. The goal of this recruitment process was to gain a random selection of people with multiple sclerosis that is unbiased aside from geographic location and volunteering and willingness to participate in the study; however, their method is considered convenience sampling.5  Key demographics:   * Mean age = 32.7 years of age (p=0.7) * Gender = 77.8% female (p=0.7) * Mean Duration of illness/disease = 27.6 years (p=0.9)   At baseline, all key demographic variables and outcome measures were insignificant when compared across all three groups.  There were 3 participants that dropped out of the study; one from the Cawthorne-Cooksey group because of inability to regularly participate and two from the Frenkel group because of inability to regularly participate (1) and disease relapse (1). The 72 participants who completed the study followed up after 6 and 12 weeks.5 |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| The control group received routine care with no planned exercise program. Participants only had to come to the outpatient clinic at baseline testing, after 6 weeks, and at the termination of the study (after 12 weeks).  At the end of the study, all participants in the control group received information about how to perform both Cawthorne-Cooksey and Frenkel exercises.5 |
| *Exercise Control (Frenkel exercises)* |
| Participants completed 12 weeks of Frenkel exercises, which consisted of “a series of slow, repetitious motions that were performed in different positions when lying down, sitting, and standing”5 (p. 59). These exercises work to improve function of the cerebellum as the balance control center of the brain. Exercises were completed three times per week, alternating days for approximately 60 minutes per session. There were two 30-minute sessions with a 15-minute rest break in between and after each bout of exercise. Exercises were gradually made more difficult throughout the course of the study. Exercises were performed at the outpatient clinic of the university hospital. The study did not state which author provided the treatment.5 |
| *Experimental (Cawthorne-Cooksey)* |
| Participants completed 12 weeks of Cawthorne-Cooksey exercises through the standardized program protocol. This series of exercises “consists of repetitive, gradually getting more difficult, eye, head, and trunk movements in sitting and upright position both with an opened and closed eye for new arrangements of peripheral sensorial information, to stimulate the vestibular system and improve balance”5 (p. 59). The goal of these exercises was to engage the vestibular system to elicit cortical reorganization and recalibration of the central vestibular system (brainstem and cerebellum, compared to the peripheral vestibular system, which consists of the inner ear and pathways that lead to the brainstem). Similar to the Frenkel exercises, these exercises gradually increased in difficulty throughout the course of the study. Exercises were completed three times per week, alternating days for 60 minutes per session. There were two 30-minute session bouts with a 15-minute rest break in between and after each bout of exercise. Exercises were performed at the outpatient clinic of the university hospital. The study did not state which author provided the treatment.5 |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| The Berg Balance Scale (BBS) was the primary outcome measure administered by Shahla Najafi Doulatabad (secondary researcher) at the outpatient clinic of the university hospital. The BBS was re-measured in the same location by the same assessor, Shahla Najafi Doulatabad, who was blinded to group allocation. The maximum score possible in the BBS is 56 points. Participants enrolled in the study initially scored between 21 and 40 points, indicating reduced balance abilities and increased risk of falls.5 |
| **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.] |
| Interaction of Time:  There were significant differences from baseline to the 6-week and 12-week time periods in the Cawthorne-Cooksey group. After 6 weeks, this group improved BBS significantly (p=.001) as well as after 12 weeks (p=.001) when compared to pre-intervention scores. After the 12-week study, BBS scores improved by a mean of 8.9 points with a standard deviation of 1.8 points. Mean scores at pre-intervention to post-intervention were 30.9 and 39.8 points, respectively. 95% confidence intervals for the final point score ranged from 37.9 and 41.7.5  The Frenkel exercise group saw a mean improvement in BBS score of 0.9 points with a standard deviation of 0.8 and 2.3 points with a standard deviation of 0.9 after 6 and 12 weeks, respectively.  The control group saw worsened results over the course of the intervention with a mean decrease in score of 0.5 points and 1.2 points after 6 and 12 weeks, respectively.  Between-Group Changes:  There were significant differences identified between the three groups after 12 weeks when comparing the Cawthorne-Cooksey group to both the control and the Frenkel exercise groups (p-values=0.001 for both comparisons). There was also a significant difference between the Frenkel exercise and control groups after 12 weeks (p=0.01).5  Summary Table of Results:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | Baseline (week 0) | | Week 6 | | Week 12 | | | Mean BBS Score (SD) | Δ Group (p-value) | Δ Time, SD,  p-value\*\* | Δ Group, (95% CI) p-value | Δ Time (SD), p-value | Δ Group, (95% CI), p-value | | Cawthorne-Cooksey Group  (vestibular rehab) | 30.9 (5.6) | p=0.9 | +3.0 (0.9), **p=.001** | 1.4,  (-2.8-5.5), p=0.7 | +8.9 (1.3), **p=.001** | 5.9,  (1.9-9.9), **p=.001** | | Frenkel Exercise Group  (strength and standard balance) | 31.6 (5.1) | +0.9 (0.8) | +2.3 (0.9) | | Control Group\*  (no intervention) | 30.3 (6) | p=0.9 | -0.5 (0.6) | **p=.001** | -1.2 (1.05) | **p=.001** |   \*p-values in this row are comparing between Cawthorne-Cooksey and Control Group  \*\*p-values were not always provided in the change over time parameters  Overall, the Cawthorne-Cooksey group demonstrated the most significant improvements in balance over the course of the 12-week study with a mean improvement in BBS score of 8.9 points compared to a 2.3-point improvement in the Frenkel exercise group and -1.2 points in the control group. |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| The authors concluded that the study determined that only the Cawthorne-Cooksey exercises made statistically significant improvements in participants’ balance as measured by the Berg Balance Scale, and should be a recommended treatment in combination with medical intervention to improve balance in individuals with MS. They stated that this study was unable to identify clinically or statistically significant improvements in balance with the use of Frenkel exercises. One finding that they emphasized was the decrease in balance seen in the control group, which they theorize is due to the absence of a routine exercise schedule, and could demonstrate the progressive worsening course of the disease. Lastly, the lack of adverse events, affordability, and non-invasive characteristics demonstrate its safety.5 |
| **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.] |
| Internal validity:  This study has high internal validity based on its random allocation of participants to the three intervention groups and the blinding and concealment of all assessors and statisticians as to what participants’ group assignments were. In addition, the study compared demographic variables and baseline characteristics including outcome measure scores between the groups, identifying no significant differences, which reduces the risk of group assignment interfering with the effects of the study.5  External validity:  Participants were identified and contacted from the medical records of the Yasuj University of Medical Sciences Hospital. The goal of this was to gain a random selection of people with multiple sclerosis that is unbiased aside from geographic location and volunteering and willingness to participate in the study; however, it is difficult to consider people who volunteer for studies as unbiased. The method of participant selection is considered convenience sampling, which is oftentimes the most feasible option, but is still biased in terms of participant inclusion.5  Strengths:  This study was a randomized controlled trial, indicating level 1b evidence, which is very high. It had three arms, and the inclusion of a complete control group further strengthens the findings of the study. Blinding the assessors and using a consistent assessor for the Berg Balance Scale testing improves consistency and helps eliminate inter-rater error. Use of blocked randomization also helps prevent group differences in demographics or clinical measures at baseline.5  Weaknesses:  This study had a relatively small sample size, which is a weakness affecting the power of the study. In addition, the study did not take into account the variable of fatigue, which can greatly influence both strength and balance. Therefore, fatigue could be a confounding factor in this study, which the authors recognized. While standard deviations and confidence intervals were provided for each effect of time and between-group comparison with p-values indicating significance, there were no effect size calculations performed. The study also labelled columns of Tables 3 with standard deviations at each time interval, but none were provided. Another weakness of the study was the inability to blind the participants, which is always difficult with physical or exercise-based interventions.5 |
| **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.] |
| The p-values of the Cawthorne-Cooksey exercise group indicate significant improvements over time within the group and between groups after 12 weeks (p=.001 for all values). At 6 weeks, the Cawthorne-Cooksey group was not significantly more improved compared to the Frenkel exercise group despite the p-value of less than .05. The confidence interval includes zero, therefore, the vestibular-based intervention was not significantly better or more efficient until the 12-week assessment when the confidence interval did not include zero. The comparison of the experimental group to both a standard balance group and a control group strengthens the validity of the results; however, effect size and power calculations were not performed. Additionally, the improvement of 8.9 points on the Berg Balance Scale in the Cawthorne-Cooksey exercise group is both statistically and clinically significant, and as a physical therapist, the clinical significance is the more important measure of change. These results indicate that not only can vestibular rehabilitation improve balance thereby reducing the risk of falls, but it is also a more efficient means of doing so compared to conventional balance training currently employed in outpatient neurologic physical therapy. The improvements seen over the course of the intervention were within 12 weeks, which is an acceptable period of time to see a neurologic patient in outpatient physical therapy. One of the major limitations of the study is a long-term follow-up assessment to evaluate whether these improvements in balance and reduced risk of falls is maintained over time, and how best patients should maintain their improved balance.5 |
| **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 a high relevance to the question at hand because of its direct comparison of vestibular rehabilitation to conventional balance training. While it focused on balance measured by the Berg Balance Scale as the primary outcome, the BBS has data determining what scores indicate an increased risk of falls, which can then be directly applied to the patient case under research. The study focused on people with multiple sclerosis with balance deficits and a falls risk, but who were ambulatory, which is the specific MS population of interest. In addition, the intervention comprised a relatively normal amount of time that could be translated into an outpatient physical therapy clinic. There was no special equipment required to perform the exercises, which adds to the affordability of applying Cawthorne-Cooksey exercises in the clinic. |

**(2) Description and appraisal of** Efficacy of Balance and Eye-Movement Exercises for Persons with Multiple Sclerosis **by** Hebert et al., 2018

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| **Aim/Objective of the Study/Systematic Review:** |
| The objective of this study was to “determine whether a multifaceted vestibular-related rehabilitation program consisting of balance and eye-movement exercises improves balance in persons with multiple sclerosis and whether there are differences in outcomes based on brainstem and/or cerebellar lesion involvement”6 (p. e797). |
| **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. |
| This was a 16-week, 2-arm, examiner-blinded, stratified, randomized controlled trial. Participants were stratified by evidence of brainstem and/or cerebellar lesions (although this portion was not powered by the study, and therefore, definite conclusions cannot be made from this stratification of data). The two arms of the study were the experimental group receiving the balance and eye-movement exercises (Balance Eye-Movement Exercises for Persons with Multiple Sclerosis; BEEMS) and a control group that received no additional treatment. The study had three phases: “a 2-week baseline phase, 6-week treatment phase 1, and 8-week treatment phase 2”6 (p. e798). The examiners and team members administering measures were blinded as to group allocation, but participants were aware of group assignment. Randomization was “computer-generated … and concealed by an investigator not involved in testing or treatment”6 (p. e799). The team members who instructed and worked with participants on the balance and eye-movement exercises were blinded to all outcomes.  All outcomes were measured twice during the baseline phase, 2 weeks apart to better encompass baseline values, and at 6 weeks (end of phase 1) and 14 weeks (end of phase 2) of the intervention. Randomization of participants was computer-generated and concealed by an investigator not involved in testing or treatment.6 |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| The study took place at the University of Colorado Rocky Mountain MS Center, an outpatient setting. |
| **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. |
| 88 participants were deemed eligible for the study and randomized. 76 participants completed the trial. Six participants dropped out from the experimental group due to distance needed to drive (1), an MS relapse (2), or unknown reason or inability to be contacted (3). Six participants dropped of the control group due to MS relapse (3) or unknown reason or inability to be contacted (3).  Inclusion criteria included “clinically definite MS, ambulation of 100 meters with no greater than intermittent or unilateral constant use of an assistive device, age of 18 to 60 years, a CDP-SOT score of </= 82 of 100, and MFIS total score of >/= 22 out of 84”6 (p. e798).  Exclusion criteria included “non-ambulation, lower extremity orthoses, lower extremity spasticity >1 on the Modified Ashworth Spasticity Scale, another neurologic disorder contributing to balance problems, relapse within 3 months of enrolment, contraindication to physical activity, and participation in exercise specifically designed to improve balance or visual stability within 12 weeks of enrolment”6 (p. e798-9).  “Participants were recruited through the Rocky Mountain MS Center, the University of Colorado, and by community-based advertisement”6 (p. e798). The type of sampling used by this study is convenience sampling.  Key Demographics:   * Mean age: 44.75 years (p=0.1) * Gender: 85% female (p=0.76) * Mean duration of illness/disease: 8.44 years (p=0.69)   All participants demonstrated balance deficits and scored “below the clinically meaningful 8-point difference below the mean for healthy adults [on the CDP-SOT at baseline]”6 (p. e801).  There were no significant differences in any demographic variables or outcome measures at baseline between the experimental and control groups; however, there was a significant difference between the CDP-SOT composite and summed conditions 3 through 6 scores (p=0.03) at baseline between the experimental group participants who were stratified based on presence of brainstem/cerebellar involvement, which was to be expected.6 |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| The control group received no treatment, and only attended the two baseline assessments and outcome  measure reassessments at 6 weeks and 14 weeks.6  All outcomes were measured on site by the same blinded assessor. |
| *Experimental (BEEMS)* |
| The experimental balance and eye-movement exercises group attended two weekly sessions with supervision and daily home exercise during the first phase of the trial (first 6 weeks). In the second phase of the trial, participants in this group attended 1 supervised session weekly and performed daily home exercise (second 8 weeks).6  The three primary components of the balance and eye-movement exercises were “standing balance on difference surfaces, mobility-based balance in walking with and without head movements, and visual stability,” the last of which consisted of “voluntary saccadic eye, smooth pursuit movements, and dynamic gaze fixation.”6 Visual (1), somatosensory (2), and vestibular (3) input alterations were applied including (1) “absent, eyes closed; conflicting, head and body movements without gaze fixation; visual field movement and hand eye coordination, ball tossing and catching, eyes open,” (2) “base of support, progressive narrowing, progressive complexity of surface,” and (3) “stimulation of peripheral end organs in yaw and pitch directions, and body movements in elevation and translation”6 (p. e799). Which author provided the treatment was not explicitly stated.  All supervised balance and eye-movement exercise sessions were performed on site. |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| The primary outcome measures consisted of the various components of balance as measured by the SMART Balance Master Computerized Dynamic Posturography-Sensory Organization Test (CDP-SOT), which is a reliable and valid measure of balance in persons with MS. The test includes six conditions: “eyes open with no platform or visual surround sway reference, eyes closed with no platform or visual surround sway reference, eyes open with visual surround sway reference, eyes open with platform sway reference, eyes closed with platform sway reference, and eyes open with platform and visual surround sway reference”6 (p. e799). The total composite test is scored from 0 to 100, in which 0 indicates a fall and 10 is the best possible score.6 The test is also broken down into parts 1 and 2 (static balance measures scored out of 200 points) and parts 3 through 6, which resemble dynamic balance and are scored out of 400 points.  The secondary outcomes included Modified Fatigue Impact Scale (MFIS), the Dizziness Handicap Inventory (DHI), and the Perceived Deficits Questionnaire (PDQ) and the Short Form-36 Health Status Questionnaire (SF-36) from the Multiple Sclerosis Quality of Life Inventory. The MFIS scores between 0 and 84 points, with higher scores indicating greater fatigue. It has three subscales including physical, cognitive, and psychosocial, which can be individually assessed as well. The DHI scores between 0 and 100, with 100 indicating maximum perceived disability. The DHI is also capable of distinguishing between fallers and non-fallers in the MS population and is able to identify individuals who will benefit from vestibular rehabilitation.6 The SMART Balance Master was used for two additional measures including Gaze Stability and Dynamic Visual Acuity. Lastly, walk speed was measured by the Timed 25-Foot Walk.6  The same team member performed all primary and secondary SMART Balance Master, and Timed 25-Foot Walk outcome measures and was blinded as to group assignment. The rest of the outcome measures are self-report and were administered by the same team member.6  All outcomes were measured on site. |
| **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 Outcome: SMART Balance Master CDP-SOT Test  Interaction of Time: Mean (SD)  In the experimental group, the mean CDP-SOT score improved from 62.8 (13.3) points to 73.1 (13.0) points after 6 weeks and to 76.3 (10.4) points after 14 weeks. In the control group, the total change in CDP-SOT score was 61.5 (14.2) to 66.1 (15.3).6  There were significant improvements in CDP-SOT composite scores from baseline to 6 weeks in the experimental group.6  Between-Group Changes:  There was a significantly greater improvement in CDP-SOT after 6 weeks in the experimental group compared to the control group (p=0.006). There was a significantly greater improvement in CDP-SOT from baseline to 14 weeks in the experimental group compared to the control group (p<0.0001).6  Secondary Outcomes: MFIS, DHI, Composite CDP-SOT Scores, Gaze Stabilisation Test, Dynamic Visual Acuity Test, SF-36, PDQ, and the Timed 25-Foot Walk  Interaction of Time: Mean (SD)  In the experimental group, the DHI improved from 40.9 (23.6) to 26.8 (18.3) and 21.7 (18.2) over the course of the study, while the MFIS improved from 49.9 (13.1) to 35.9 (12.0) and 32.7 (13.8). Total change in these two measures in the control group were from 41.4 (24.5) to 36.4 (23.9) and 48.7 (14.7) to 43.7 (16.8), respectively. In the experimental group, the PDQ improved from 37.8 (12.9) to 28.9 (13.7) over the course of the study, while the SF-36 physical and mental component scores improved from 35.8 (8.70) to 41.3 (8.75) and from 42.6 (10.5) to 48.4 (9.7), respectively. In the control group, the PDQ changed from 37.6 (15.1) to 35.9 (15.3), while the SF-36 physical and mental component scores changed from 35.4 (8.50) to 37.4 (9.65) and 42.9 (11.2) to 44.6 (11.5), respectively.6  Between-Group Changes:  From baseline to 6 weeks, participants in the experimental group demonstrated significantly greater improvements in DHI, MFIS, PDQ, and SF-36, but not in the Gaze Stabilization Test, Dynamic Visual Acuity Test, or Timed 25-Foot Walk compared to the control group. After 14 weeks, participants in the experimental group demonstrated significantly greater improvements in the DHI, MFIS, PDQ and SF-36, but not in the Gaze Stability Test, Dynamic Visual Acuity Test, or Timed 25-Foot Walk.6  Summary Table of Results for changes over time from baseline at 6 and 14 weeks and between groups at 6 and 14 weeks. Significant improvements have bolded p-values:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | BEEMS Group  (vestibular rehab) | | Control Group  (no intervention) | | Δ Group, (95% CI),  p-value | | | 6-wk Δ\* Time (SD) | 14-wk Δ\*\* Time (SD) | 6-wk Δ\* Time (SD) | 14-wk Δ\*\* Time (SD) | 6-wk | 14-wk | | CDP-SOT Composite Score (/100 points) | 9.1 (2.1) | 11.8 (2.1) | 4.3 (2.1) | 3.6 (2.2) | 4.89, (1.39-8.38), **p=0.006** | 8.32, (4.73-11.9), **p<.0001** | | CDP-SOT 1 + 2 Score (/200 points) | 5.6 (2.0) | 6.1 (2.0) | -2.1🏳 (2.0) | -1.5 (2.0) | 7.64, (3.87-11.4),  **p<.0001** | 7.54 (3.66-11.4), **p=.0002** | | CDP-SOT 3-6 Score (/400 points) | 40.4 (9.5) | 53.3 (9.5) | 20.2 (9.5) | 16.4 (9.6) | 20.3, (4.53-36.0), **p=0.01** | 36.9, (20.7-53.1), **p<.0001** | | DHI Total Score | 13.1 (2.3) | 17.9 (3.8) | 0.6 (3.4) | 3.9 (3.4) | 13.5 (7.25-17.7), **p<.0001** | 13.9, (8.62-19.3), **p<.0001** | | MFIS Total Score | 14.1 (2.3) | 17.4 (2.4) | 2.7 (2.3) | 5.1 (2.3) | 11.4, (7-15.7), **p<.0001** | 12.3, (7.79-16.7), **p<.0001** | | PDQ Total Score | 8.3 (2.3) | 8.8 (2.3) | 0.8 (2.2) | 2.3 (2.2) | 7.43 (3.77-11.1), **p<.0001** | 6.48 (2.72-10.2), **p=.0008** | | SF-36 Physical Component | 4 (1.4) | 5.2 (1.4) | 0.4 (1.4) | 1.9 (1.4) | 3.47, (1.12-5.81), **p=.004** | 3.2 (0.79-5.62), **p=.01** | | SF-36 Mental Component | 5.4 (1.7) | 5.6 (1.7) | -0.1 (1.7) | 1.7 (1.8) | 5.57, (2.43-8.71), **p=.0006** | 3.93, (0.7-7.16), **p=.02** | | Gaze Stability Test (deg./sec) | 15.8 (5.5) | 12.4 (5.5) | 14 (5.5) | 11.5 (5.7) | 1.88  (-11.5-15.2), p=0.78 | 0.94,  (-12.7-14.6), p=0.89 | | Timed 25 FWT (sec) | 0.2 (0.3) | 0.48 (0.32) | 0.092 (0.3) | 0.14 (0.31) | 0.15,  (-0.31-0.02), p=0.08 | 0.34,  (-0.73-0.04), p=0.08 |   \*Δ’s in points from baseline to 6-wks  \*\*Δ’s in points from baseline to 14-wks  🏳(-) point changes in scores indicate worsening score compared to baseline *(Δ’s do not reflect increases or decreases in scores since several outcomes lower in total points with improvements in function; rather, Δ’s indicate improvement when positive and worsening when negative)* |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| The authors concluded that vestibular rehabilitation following their protocol was able to improve balance, fatigue, and dizziness in participants with MS with lesions in the brainstem and/or cerebellum. While the group with brainstem and/or cerebellar lesions had improved to a greater extent after 6 weeks, the non-lesion group had similar results at the 14-week marker, which the authors hypothesize could be due to “refining integration of sensory inputs with motor outputs no matter where deficits occur within the postural control system”6 (p. e806). They conclude that incorporating this protocol of vestibular rehabilitation into a “functional training program could further enhance improvements of walking and safe participation in daily physical activity”6 (p. e806). |
| **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.] |
| Internal validity:  This study has high internal validity based on its random group allocation of participants and the blinding and concealment of all assessors and statisticians as to participants group assignments. In addition, the study compared demographic variables and characteristics including outcome measure scores between the two groups at baseline, identifying no significant differences, except for poorer CDP-SOT scores in the group with cerebellar and/or brainstem lesions than those without, which was expected. The baseline homogeneity reduces the risk of group assignment interfering with the effects of the study.6  External validity:  Participants were recruited through the Rocky Mountain MS Center and through the University of Colorado in addition to community advertisement. The type of sampling used by this study is convenience sampling, which indicates a geographic bias and a potential educational bias, since participants sent from the university and MS center may have greater medical knowledge and/or awareness.6  Strengths:  This study was a randomized controlled trial, indicating level 1b evidence, which is very high. Blinding the assessors and using a consistent assessor for the outcome measures improves consistency and helps eliminate inter-rater error. Use of stratified randomization also helps prevent group differences in demographics or clinical measures at baseline. This study also used minimal clinically meaningful differences to support the statistical significance identified in the results.6  Weaknesses:  This study had a relatively small sample size, which is a weakness affecting the power of the study. It also disallowed the authors from making statistical comparisons between the treatment effects between the lesion and non-lesion groups. There was also no measure of dynamic gait, which the authors recognize as a weakness, especially since strict gait speed as measured by the Timed 25-Foot Walk did not identify significant change. Additionally, the measures of VOR function included (gaze stabilization and dynamic visual acuity) do not directly measure VOR as well as a measure such as the video head impulse test. While standard deviations and confidence intervals were provided for each effect of time and between-group comparison with p-values indicating significance, there were no effect size calculations performed. Another weakness of the study was the inability to blind the participants, which is always difficult with physical or exercise-based interventions. This study compared the vestibular balance protocol to a control groups without treatment, while a control group with conventional balance training or non-balance functional training would better demonstrate the specific efficacy and efficiency of vestibular rehabilitation in the MS population. Lastly, the use of both visual and somatosensory integration in the BEEEMS intervention weakens the ability to detect the results solely elicited by vestibular rehabilitation; however, this can also be considered a strength in terms of clinical relevance since clinical treatment almost always consists of a combination of interventions to treat patients.6 |
| **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.] |
| The results from this study demonstrate significant improvements after a relatively short period of time in fatigue, dizziness, and balance following a vestibular rehabilitation protocol two times weekly. While the differences between the lesion and non-lesion groups found at 6 weeks did not carry over to 14 weeks, vestibular rehabilitation proved helpful across groups with MS. One of the limitations of this study is the absence of effect size of the various outcome measures. However, the inclusion of minimal clinically important differences compared to the changes seen in the study helps determine that the effects of the study were significant and worthwhile for participants. Based on the authors’ findings, inclusion of vestibular rehabilitation into a comprehensive plan of care for a patient with MS who reports dizziness and/or balance dysfunction can not only improve these complaints, but also expedite clinically significant changes.6 |
| **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 also yields highly applicable results and has high relevance to my PICO question; however, it is not as relevant as the study by Afrasiabafar et al. While it has a very multifaceted vestibular rehabilitation intervention group, the control group does not have any standard balance or strength intervention. In addition, this study relied upon the SMART Balance Master and the CDP-SOT test, which are both excellent measures of somatosensory, visual, and vestibular balance, but the SMART Balance Master is an incredibly expensive piece of equipment, not commonly found at regular outpatient physical therapy clinics. The performance of balance and eye-movement exercises twice weekly and progressing to once weekly with daily home-based exercise is very relevant to physical therapy and mirrors typical therapy schedules and assignment expectations. However, these findings demonstrate significant improvements in dizziness, fatigue, and balance after only 6 weeks, which speaks to the efficiency of this type of training in the MS population. Similar vestibular rehabilitation exercises could be implemented with low cost and time requirements to supplement a comprehensive physical therapy plan of care for a patient with MS who complains of dizziness or has evidence of brainstem/cerebellar involvement. Lastly, there was no treatment provided to the control group, which disallows the comparison of conventional balance training or functional strength training versus vestibular rehabilitation in terms of efficacy and efficiency.6 |

**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 and Clinical Implications**  Both studies enrolled high functioning participants with MS who were able to ambulate and presented with dizziness and other balance difficulties at baseline. While each study had a vestibular rehabilitation experimental group, only one of the studies (the Afrasiabifar study) included a comparison balance and strength group. The outcome measures differed between studies, but both studies saw significant balance improvements at the final assessment. The mean improvement in Berg Balance Score in the Afrasiabifar study of 8.9 points is greater than both the standard error of measurement and minimal detectable change of 1.75 and 4.78 points, respectively, as identified in older adults by Shirley Ryan’s Ability Lab.11 In addition, the improvement seen in the vestibular training experimental group (via Cawthorne Cooksey exercises) could not be matched after 12 weeks by the standard balance and exercise group (via Frenkel exercises), which saw a mean improvement of only 2.3 points on the Berg Balance Scale, which is below the MDC for older adults. Of note, vestibular rehabilitation may evoke more efficient results in comparison to standard strength and balance training. The Hebert study included many more outcome measures, but did not have a comparison balance or exercise group. However, significant improvements were seen by all participants in the vestibular rehabilitation (BEEMS) group on the SOT as well as on the Dizziness Handicap Inventory, Modified Fatigue Impact Scale, Perceived Deficits Questionnaire, and Short Form-36. However, significant changes were not identified on the Gaze Stability Test, Dynamic Acuity Test, or Timed 25-Foot Walk. Similarly, the average improvement of 13.5 points over the course of the intervention is greater than the MDC of 8 points on the Sensory Organization Test as identified by Shirley Ryan’s Ability Lab for persons with vestibular disorders.12 The improvements in reports of dizziness, fatigue, and quality of life are also important to note since these are several other areas of health commonly affected in people with MS that various physical therapy interventions target. Location of lesions was taken into account by the Hebert study, which is important to note since people with MS who have lesions in the cerebellum and brainstem will likely benefit more from vestibular rehabilitation than their counterparts lacking lesions in those specific areas of the brain.5,6 However, persons without lesions in those areas still saw significant improvements in numerous areas, which demonstrates generalizability of the BEEMS intervention to people with MS regardless of MRI findings and potentially related vestibular dysfunction. The BEEMS intervention is an effective protocol for people with MS; however, it targets visual and somatosensory function in addition to vestibular rehabilitation, indicating the use of multiple interventions as most effective rather than simply isolated vestibular or conventional balance training.6  Both studies identified significant improvements over time and between groups at the end of the interventions. The period of time for each study, 12 weeks and 16 weeks, are also relatively short periods of time that could be performed in a clinical setting, where insurance, time management, and other health concerns are taken into account.5,6  Limitations of these studies included relatively small sample sizes, which reduces the power and increases the risk of type II error. In addition, neither study was able to blind their participants due to the physical interventions unique to each group. There is also a lack of standardization of vestibular rehabilitation protocols, which may have an effect on the efficacy and efficiency of vestibular training. The use of different outcome measures and pieces of equipment also affects the reliability of results for vestibular rehabilitation. The CDP-SOT requires an expensive Balance Manager, which is not commonly owned in many physical therapy clinics because of its expense. Standardizing measures of vestibular function and general balance would further ease the comparison of the two studies’ findings. Additionally, frequency of falls was not reported by either study, but both the SOT and the BBS have been correlated to risk of falls in various populations.5,6 While specific scores on the BBS and SOT correlate with increased risk of falls (for the Berg: <51 points in those who have a history of falls and <42 points in those without incidence of previous falls; for the SOT: a score of 38 points or less indicates increased likelihood ratio of repeated falls), the BBS is a measure of non-vestibular balance function; therefore, it does not relay improvements in vestibular function.11,12  **Implications for Future Research**  Ideally, physical therapy interventions are meant to be maintained independently upon discharge, therefore, identifying independent means of effective home-based vestibular training will further enhance the evidence behind utilizing vestibular rehabilitation in people with MS who present with centrally-caused vestibular dysfunction. Research into long-term treatment and effects, maintenance of vestibular benefits achieved through the interventions, and larger sample sizes are needed to further investigate the long-term efficacy and feasibility of vestibular rehabilitation in the MS population. While there is a great deal of research on general balance regimens and exercise in people with MS, specialized therapies such as vestibular rehabilitation still lack depth in evidence. |

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