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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| In patients older than 40 years with idiopathic Parkinson’s disease (P), is resisted gait training (I) or LSVT BIG (C) more effective in improving step length (O)? |

**AUTHOR**

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**CLINICAL SCENARIO**

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| In adult patients with Parkinson’s disease (PD), common clinical presentations include bradykinesia, tremor, rigidity and overall impaired balance and coordination. These impairments can ofterntimes affect ambulation and when ambulation is affected, patients often experience difficulties with push-off as well as forward swing due to a combination of the common symptoms. This frequently leads to decreased step length and subsequent short, festinating steps in more advanced stages of PD. To determine the most effective method to combat this phenomenon, I would like to find out whether forms of resisted gait training or a traditional LSVT BIG protocol is more effective in improving step length and subsequently reducing falls risk. |

**SUMMARY OF SEARCH**

[Best evidence appraised and key findings]

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| Eight studies met the inclusion and exclusion criteria including 2 RCTs, 1 case series, 2 quasi-experimental non-randomized studies, 1 nonrandomized pilot study, 1 randomized control pilot study, and 1 systematic review with meta-analysis.   * LSVT BIG is more effective than Nordic walking, home based exercise, and a shorter amplitude-oriented protocol in improving motor function seen through improved UPDRS-III scores and improved TUG and 10-m walk time.[1](https://sciwheel.com/work/citation?ids=5979851&pre=&suf=&sa=0&dbf=0) * LSVT BIG and other amplitude-oriented exercises are effective in significantly improving step length when performed at high intensity.[2](https://sciwheel.com/work/citation?ids=7522968&pre=&suf=&sa=0&dbf=0) * Treadmill training both with and without load saw significant improvements in ADL performance, motor function as well as spatiotemporal and angular variables of gait to include step length. [3](https://sciwheel.com/work/citation?ids=1507599&pre=&suf=&sa=0&dbf=0) * The amount of load provided during treadmill training does not influence degree of improvement in spatiotemporal and angular variables of gait.[3](https://sciwheel.com/work/citation?ids=1507599&pre=&suf=&sa=0&dbf=0) * Consistent and repetitive external cues during treatment for individuals with PD can influence variables of gait and locomotion. |

**CLINICAL BOTTOM LINE**

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| In individuals with PD, external cuing and frequent, intensive protocols have noted improvements in both objective and subjective outcome measures of function, gait and ADLs. There are elements to both LSVT BIG and resisted gait training that promote more effort or larger amplitude of movement and provide signals to the patient to combat bradykinesia and rigidity. However, due to training necessary and time it takes to complete protocol, resisted gait or treadmill training may be more feasible than LSVT BIG to improve step length and other aspects of motor function. |

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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) |
| * Parkinson’s\* * Neurologic * Gait disorders | * Resisted gait training * Swing resistance * Locomotor training * NOT resistance\* | * LSVT * LSVT BIG | * Step length * Limb propulsion * Gait mechanics |

**Final search strategy (history):**

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

Search number Query

26 (((#1) AND (#2)) AND (step length OR gait mechanics)) OR (((#8) AND (#12)) OR ((Parkinson's OR gait disorders) AND (LSVT BIG))) [Filter🡪 Middle Aged + Aged: 45+ years] (49 results)

25 (((#1) AND (#2)) AND (step length OR gait mechanics)) OR (((#8) AND (#12)) OR ((Parkinson's OR gait disorders) AND (LSVT BIG))) [Filter🡪 Middle Aged + Aged: 45+ years] (138)

24 ((resisted gait training OR swing resistance) AND (step length OR gait mechanics)) AND (Parkinson's OR gait disorders) [Filter🡪 Middle Aged + Aged: 45+ years] (39)

23 ((#8) AND (#12)) OR ((Parkinson's OR gait disorders) AND (LSVT BIG)) [Filter🡪 Middle Aged + Aged: 45+ years] (31)

22 ((#8) AND (#12)) OR ((Parkinson's OR gait disorders) AND (LSVT BIG)) (106)

21 ((#1) AND (#8) AND (#12)) OR ((Parkinson's OR gait disorders) AND (LSVT BIG)) (49)

20 ((#1) AND (#8) AND (#12)) OR (LSVT BIG) (52

19 (LSVT BIG) OR ((#8) AND (#12)) (109)

18 (LSVT BIG) AND ((#8) AND (#12)) (0)

17 (#8) AND (#12) (81)

16 (LSVT BIG) AND (step length OR gait mechanics) (0)

15 (LSVT BIG) AND (step length OR gait mechanics) - Schema: all (0)

14 (Parkinson's OR gait disorders) AND (LSVT BIG) (25)

13 (#1) AND (#8) AND (#12) (24)

12 step length OR gait mechanics (26,435)

11 (#1) AND (#8) AND (#4) (9)

10 (#1) AND (#8) (237)

9 (#1) AND (#2) (259)

8 resisted gait NOT resistance\* (501)

7 resisted gait AND locomotor training (45)

6 resisted gait\* AND locomotor training (45)

5 (#1) AND (#2) AND (#3) AND (#4) (0)

4 step length OR limb propulsion (21,262)

3 LSVT BIG (28)

2 resisted gait training OR swing resistance (1,379)

1 Parkinson's OR gait disorders (168,060)

*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**  **CINAHL**  **Embase** | **138**  **334**  **108** | **Middle aged+ Aged (45+) 🡪 49**  **Middle aged+ Aged (45+) 🡪 130 applied full text limiter 🡪 21**  **Middle aged+ Aged (45+) 🡪 33** |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| * Patients have undergone resisted gait training with elastic band or LSVT BIG * Outcomes influenced by step length or limb propulsion (10-m walk, TUG, 4 square step, etc) * RCT, systematic reviews, pilot studies, case studies * Studies in all languages and countries * Human studies |
| **Exclusion Criteria** |
| * Young adults, children * Atypical PD * Treadmill training without added resistance * Self-reported outcomes * Older than 1990 * Robotic-assisted treadmill training * Animals |

**RESULTS OF SEARCH**

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

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

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| **Author (Year)** | **Risk of bias (quality score)\*** | **Level of Evidence\*\*** | **Relevance** | **Study design** |
| **Ebersbach, G et al. (2014)**[2](https://sciwheel.com/work/citation?ids=7522968&pre=&suf=&sa=0&dbf=0) | **PEDro (7/11)**  **Subjects and therapists were not blinded due to nature of intervention, only 80% of measures taken for key outcome were obtained, and there was no intention to treat analysis. (PEDro website rated “NO” for concealed allocation however assessor was blinded to group allocation)** | **Level 2 downgraded; While results were statistically significant for LSVT BIG, there was a small effect size between groups as well as a large amount of variability in the 95% CI** | **High, discusses LSVT in comparison to a shorter amplitude focused training protocol in persons with PD (PwPD). Looks at their effects on outcomes such as step length, 6MWT, TUG, 10-m walk and UPDRS-III.** | **Randomized control trial** |
| **Janssens et al. (2014)**[4](https://sciwheel.com/work/citation?ids=3174700&pre=&suf=&sa=0&dbf=0) | **JBI Critical Appraisal Checklist for Case Series (6/10)**  **Study did not have consecutive or complete inclusion of participants due to only using 3 patients that were “selected from a neurologist’s practice and… rehab center.”**  **Additionally, there was no report of presenting site’s demographic information, leaving readers no way to determine what environmental aspects could have contributed. Lastly, there was no discussion of statistical analysis, although they did list MDC’s for outcome measures.** | **Level 4 downgraded; relatively high level of bias, small sample size with lack of generalizability, control group or randomization. However, could still be useful in clinical practice through providing validated outcome measures related to functional goals in PwPD.** | **Moderate, doesn’t compare LSVT BIG to another intervention or control. However, the three individuals fall within the population for my PICO and researchers utilized outcome measures that didn’t directly measure step length but could be inferred as a change in step length noted by improved TUG or 10m-walk scores with MDCs.** | **Case Series** |
| **Flood et al. (2020)**[5](https://sciwheel.com/work/citation?ids=9687722&pre=&suf=&sa=0&dbf=0) | **Downs and Black Checklist (23/31)**  **Received points off for no report of adverse events, no mention of source population, no blinding of subjects or assessors, no mention of time period for recruitment, randomization or concealed allocation, and no adjustments in statistical analysis for confounding variables (items 8, 11, 14, 15, 22, 23, 24, and 25).** | **Level 3 upgraded; although there was little control for bias due to nonrandomization and no blinding of participants or assessors due to nature of the study, researchers found and reported substantial treatment effect indicating clinical significance.** | **High, involves PwPD who receive intervention of LSVT BIG as well as those who do not. Measures outcome measures of interest (TUG and 10mWT) and provide information on gait parameters (step length, width, etc).** | **Quasi-experimental non-randomized study** |
| **McDonnell et al. (2018)**[1](https://sciwheel.com/work/citation?ids=5979851&pre=&suf=&sa=0&dbf=0) | **AMSTAR-2 (Moderate)**  **There is more than one weakness but no critical flaws. They could have provided a more comprehensive search strategy through searching reference lists of articles found or consulting with experts. Additionally, they could have provided more info on studies’ research designs, settings or timeframes for follow-up as well as additional info on studies that were excluded.** | **Level 1 upgraded; although there was a small number of studies included on the final analysis, they reported adequate statistical findings, meta-analyses and substantial treatment effect indicating clinical significance.** | **High, involves PwPD who participated in studies that compared LSVT BIG to other interventions and included motor function outcomes (UPDRS motor scale) that examined gait.** | **Systematic Review and Meta-Analysis** |
| **Mizrachi et al. (2020)**[6](https://sciwheel.com/work/citation?ids=11708397&pre=&suf=&sa=0&dbf=0) | **RoBANS**   1. **Low: no control group but variability present among pilot group (convenience sampling) indicating better representation of population sample** 2. **Low: mentioned and assessed possible confounding variables but did not include in statistical analysis** 3. **Low: all participants met inclusion criteria for pilot study; no control group** 4. **Low: no blinding, but not necessary for influence of bias in pilot study** 5. **Low: missing outcome data not necessary as it doesn’t affect results (3 participants dropped out due to fatigue)**   **Low: all protocols and outcome measures listed** | **Level 3 upgraded; reported extensive statistical findings with low bias** | **Moderate, involves a different population and no comparison group, but there is data on a version of resisted gait training and outcome measures analysed included gait mechanics such as step length.** | **Nonrandomized pilot study** |
| **Kim et al. (2020)**[7](https://sciwheel.com/work/citation?ids=11708494&pre=&suf=&sa=0&dbf=0) | **PEDro (9/11)**  **Subjects and therapists not blinded due to nature of intervention and there was no intention to treat analysis performed on one of the subjects that were part of the experimental group that dropped out due to discharge.** | **Level 2 upgraded; solid study design that controlled bias well and complete between group analysis** | **Moderate, utilized stroke patients and underwater gait training compared to regular PT. However, researchers measured step length as an outcome and underwater gait training could be seen as a method of resisted gait training.** | **Randomized Control pilot study** |
| **Savin et al. (2013)**[8](https://sciwheel.com/work/citation?ids=6489135&pre=&suf=&sa=0&dbf=0) | **RoBANS**   1. **Low- matched control’s speed on treadmill to that of a participant who had similar age and sex** 2. **High- no adjustment or discussion of confounding variables** 3. **Low- appropriate measure of outcomes in experimental and control group** 4. **Unclear- no mention of blinding in outcome assessment** 5. **Low- no missing data**   **Low- study protocol is available for viewing and outcomes are specified** | **Level 3 downgraded; small treatment effect size indicating lack of clinical significance** | **High, although the experimental population involved stoke patients, the intervention involved resisted gait training compared to a control group and measured step length directly as an outcome.** | **Quasi-experimental non-randomized study** |
| **Trigueiro et al. (2015)**[3](https://sciwheel.com/work/citation?ids=1507599&pre=&suf=&sa=0&dbf=0) | **PEDro (8/11)**  **No blinding of subjects or therapists due to nature of the study and no intention to treat analysis. (PEDro rated “NO” for blinded assessors however there were separate researchers tasked with random selection, training participants and statistical analysis.)** | **Level 2 upgraded; Although there is not strong treatment effect, there is strong study design and consistency with previous studies.** | **High, involved PwPD performing resisted gait training using different loads and comparing it to a control group without PD. Also, step length is an outcome that is directly measured.** | **Randomized control Trial** |

\*Indicate tool name and score

\*\*Use Portney Table 36-1: Summary of Levels of Evidence (2020). 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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| * McDonnell et al. (2018): Researchers performed both a systematic review and meta-analyses of evidence concerning LSVT BIG’s effectiveness in improving mobility in individuals with PD.[1](https://sciwheel.com/work/citation?ids=5979851&pre=&suf=&sa=0&dbf=0) Although an AMSTAR-2 appraisal yielded a moderate risk of bias, there were no critical flaws and only minor weaknesses that did not affect strength of findings. There were few studies that met their inclusion criteria however, it depicts the rigorous selection process in only yielding quality, relevant articles. Additionally, they described what variables they utilized to assess the quality of different articles to include meta-analysis, critical assessment of bias and confounding variables to treatment or results, and generalizability of findings to name a few. Furthermore, a systematic review with quality studies provides multiple studies and sources of evidence to review which allows clinicians to form a comprehensive assessment more efficiently. * Trigueiro et al. (2015): In this randomized control trial, researchers examined effects of treadmill training with a load in individuals with PD. This experimental design has been assessed in different neurological populations, but this study aimed to determine the appropriate amount of load needed to improve gait kinematics in those with PD (5% vs 10%).[3](https://sciwheel.com/work/citation?ids=1507599&pre=&suf=&sa=0&dbf=0) There was low risk of bias with points only taken off for lack of intention to treat analysis when a few participants dropped out before the intervention began and lack of blinding to therapists and subjects which was difficult due to nature of the study, but likely did not affect results. They also controlled for confounding variables by ensuring all patients performed intervention during their “on” time for medication and assuring patients in both the interventional and control groups did not exhibit drastically different characteristics at baseline which may have impacted results. Furthermore, researchers presented a strong study design with detailed methods and appropriate statistical analyses providing high relevance and clinical significance to the PICO topic. |

**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of (Lee Silverman Voice Treatment (LSVT)-BIG to improve motor function in people with Parkinson’s disease: a systematic review and meta-analysis) by (McDonnell et al., 2018)**

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| **Aim/Objective of the Study/Systematic Review:** |
| The objective of the systematic review and meta-analysis was to determine LSVT BIG’s effectiveness when compared to other interventions in improving motor function in individuals with PD. |
| **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. |
| **Search Strategy:** Utilizing combinations of the terms under the umbrellas of Parkinson’s Disease and LSVT BIG (such as Parkinson\*, Lee Silverman\*, big treatment\*, etc), they were able to yield 377 results after duplicates were removed.  **Selection Criteria**: Studies focused on atypical parkinsonian features, animal studies and studies focused only on speech impairment and LSVT LOUD treatment were excluded. Included was any study that utilized LSVT BIG as an intervention and measures any valid/reliable outcome related to “impairment, activity and/or participation,” (pg 609). In the final full-text review only RCTs were included. After applying selection criteria, 4 studies, with 3 being RCTs were included in final analysis.  **Methods**: Two researchers with the help of an academic librarian performed literature searches of Medline, Embase, CINAHL, AgeLine, Scopus and Cochrane Library. No date limits were applied, and search was conducted in September 2017. Of 377 records screened, 373 were excluded based on lack of relevance found in title or abstract, or lack of meeting inclusion/exclusion criteria. Quality of reviews were assessed by separate researchers utilizing Cochrane Risk of Bias Assessment. In cases of discrepancies, researchers utilized Cochrane Handbook to reach final consensus. Data from each of the studies were analyzed to determine “details related to participants, intervention, comparators, outcomes and key findings,” (pg 609). Meta-analysis was also performed to determine relationships among studies between primary outcome measure, Unified Parkinson’s Disease Rating Scale-III (UPDRS). |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| All 4 studies were performed in outpatient rehabilitation or movement disorders clinic settings. |
| **Participants**  [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]  Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article. |
| N= 163 total; Patients were primarily older adults (mean age 63-67) and were mild to moderately affected with Hoehn and Yahr stages of 1-3. All participants either volunteered or were referred by their physicians which could have “cause[d] selection bias, as they are not truly representative of wider population of people with Parkinson’s,” (pg 615). Studies included were all in English, but no information was provided on if groups were comparable at baseline. |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| Control groups utilized other common PT interventions to compare its effectiveness to LSVT BIG.   * In Dashtipour et al., control group (n=5) performed general exercise involving 30 minutes of treadmill walking and 30 minutes of seated UE exercises, 4x/ week for 4 weeks. No info provided on who delivered intervention. * In Ebersbach et al. (2010), there were two control groups. One of which performed small group Nordic walking (n=19) with certified Nordic walking instructors 2x/week for 8 weeks. The other performed home exercises (n=19) with “practical demonstration and training of stretching, active workouts for muscle power and posture, and high amplitude movements.” (pg 611) * In Ebersbach et al. (2015), there were identical control groups/design to Ebersbach et al. (2010) * In Ebersbach et al. (2014), control group performed a “shortened protocol (n=17) of identical amplitude-oriented exercises for 60 minutes, 5x/week for 2 weeks.” (pg 612) |
| *Experimental* |
| All experimental groups performed the standard LSVT BIG protocol which included 1:1 training of large-amplitude movements with certified-LSVT BIG clinician 4x/week for 4 weeks. Protocol includes focus on standard maximal daily exercises, simple one-step functional tasks, more complex hierarchy tasks and “BIG” walking with frequent, external cueing and feedback from therapist. |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| Three studies utilized the UPDRS-III as the primary outcome measure of motor function. The minimal clinically important difference (MCID) is estimated to be -2.5. Tests were administered by researcher and videotaped to be assessed by separate blind assessor. Higher scores were indicative of increased severity of disease. No specific details were provided on the test, but the motor portion of the UPDRS captures a multitude of information related to gait, balance, posture, coordination, and functional strength. Secondary outcomes included Timed Up and Go (TUG) and 10-meter walk to assess gait speed which both favour lower scores and are utilized as measures of falls risk as well as gait analysis. For the TUG, therapists measured how quickly the patient was able to stand up from a chair, walk 10 feet, turn around and sit down again without loss of balance. The 10-meter walk test therapists timed how quickly a participant is able to walk 10-meters to assess gait quality and speed. Focus for this paper’s results only included UPDRS, TUG and 10-m walk. Ebersbach et al. (2014) also explored UE functional outcomes from utilizing data from Ebersbach et al. (2010) to examine changes in “cued and non-cued reaction time” as well as the Box and Blocks Test which assess unilateral gross manual dexterity. Patients move as many blocks as they can from one compartment across a partition into another in one minute. No information was provided on cued and non-cued reaction outcomes and what that entailed. |
| **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. Primary Outcomes: UPDRS-III (pg 613)   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | LSVT-BIG | | | Other | | |  |  | | Study or Subgroup | Mean | SD | Total | Mean | SD | Total | Weight | Mean Difference, IV, Fixed, 95% CI | | Dashtipour 2015 | -8.3 | 11 | 6 | -5 | 11.5 | 5 | 2.2% | -3.3 [-16.68,10.08] | | Ebersbach 2010 | -5.05 | 3.9 | 20 | 1.68 | 5.95 | 19 | 38.6% | -6.73 [-9.9, -3.56] | | Ebersbach 2015 | -6.6 | 4.9 | 17 | -5.7 | 2.25 | 17 | 59.2% | -0.9 [-3.46, 1.66] | | Total (95% CI) |  |  | 43 |  |  | 41 | 100% | -3.2[5.18, -1.23] |   3 studies utilized UPDRS-III to determine motor function and meta-analysis of data was performed. When combined, n=43 in intervention group and n=41 in control group. A significant improvement in long-term motor function was found in the LSVT BIG group at follow-up assessment performed 16 weeks and 6 months post baseline measures. These significant results were also found in the Nordic walking program and home exercise groups. I2 test revealed substantial heterogeneity between groups (74%) indicating the other interventions were different from standard LSVT protocol. Effect size of -3.2 was also found for UPDRS.  Table 3. Secondary Outcomes: TUG (pg 613)   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | LSVT-BIG | | | Other | | |  |  | | Study or Subgroup | Mean | SD | Total | Mean | SD | Total | Weight | Mean Difference, IV, Fixed, 95% CI | | Ebersbach 2010 | -0.75 | 1.94 | 20 | 0.44 | 1.21 | 19 | 27% | -1.19[-2.2, -0.18] | | Ebersbach 2015 | -1.3 | 0.75 | 17 | -1.1 | 1.05 | 17 | 73% | -0.2 [-0.81, 0.41] | | Total (95% CI) |  |  | 37 |  |  | 36 | 100% | -0.47[-0.99, 0.06] |   Table 4. Secondary Outcomes: 10-m walk (pg 613)   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | LSVT-BIG | | | Other | | |  |  | | Study or Subgroup | Mean | SD | Total | Mean | SD | Total | Weight | Mean Difference, IV, Fixed, 95% CI | | Ebersbach 2010 | -1.12 | 0.84 | 20 | -0.45 | 1.08 | 19 | 78.6% | -0.67 [-1.28, -0.06] | | Ebersbach 2015 | -1.5 | 0.98 | 17 | -1.5 | 2.25 | 17 | 21.4% | 0.00 [-1.17, 1.17] | | Total (95% CI) |  |  | 37 |  |  | 36 | 100% | -0.53 [-1.07, 0.01] |   In both secondary outcome measures, the mean difference favoured the LSVT BIG protocol with the data supporting “a trend towards decreased time taken to complete the TUG and 10-m walk.” (pg 613)  As for the other secondary measures of UE function, Ebersbach et al. (2014) showed significant improvements in cued reaction time between LSVT-BIG and home exercise programs at 16-week follow-up, but no significant group x time interactions were found for Box and Blocks Test between shortened and original versions of LSVT BIG as seen in Ebersbach et al. (2015). |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| Meta-analysis of results from the different studies found LSVT BIG to be more effective than general exercise or a shortened protocol in improving UPDRS scores both immediately following exercise and with long-term effects sustained at 6 months post intervention. Additionally, considering the effect size of -3.2 for the UPDRS exceeded the MCID of -2.5 revealed some clinical significance of this finding. However, scores were assessed by a separate rater through video, and the test-retest reliability of video rating the UPDRS-III is currently unknown. Dashtipour et al. presented contradictory findings stating that LSVT-BIG was no more effective than a similar intensity exercise program consisting of treadmill training and seated UE exercises, however the effect size was only 0.5 with an “11% power to detect a difference between the groups.” (pg 615) Furthermore, the MCID was -6.8 in the LSVT BIG intervention group compared to -2.8 in the alternative exercise control group. |
| **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.] |
| An AMSTAR-2 quality assessment of the systematic review and meta-analysis revealed moderate confidence in the author’s findings. The authors could have conducted a more comprehensive search strategy through searching reference lists of articles. They could have provided more information on the different studies’ research designs and more specific time frames for follow-up. Limitations to the study included only 4 studies included in final analysis with all having moderate risks of bias due to lack of allocation concealment, blinding of participants, and incomplete outcome data. Furthermore, most of the data was collected prior to 2014 indicating a 7-year gap in the literature. In terms of external validity, it is difficulty to apply this information to the general PD population due to a low number of studies included as well as inclusion criteria of only involving PD patients with mild to moderate levels of disability. Nonetheless, meta-analysis did reveal strong effect and relationships between findings of the study in support of LSVT BIG. Additionally, the statistical analysis methods chosen were appropriate to determine aim of the study and included effect sizes, confidence intervals and Chi2 tests to support validity. |
| **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 systematic review and meta-analysis support the standard LSVT BIG being more effective than Nordic walking, home exercises as well as shorter amplitude-based protocols. In all studies, LSVT BIG showed more significant improvement in UPRDS as well as TUG and 10-m walk through effect sizes surpassing the MCID of measures. However, considering there were only 4 studies included in this review and 3 of them were led by the same author, this indicates results from this study should be taken with caution. Furthermore, the review did not explicitly state specific time periods of data collection and revealed that the different studies had different time periods in which they reported data which makes comparing specifics regarding follow-up difficult. There is very limited, recent research that assesses LSVT BIG comparatively amongst other interventions, and further research with larger sample sizes and more variability amongst subjects is needed for generalizability of results. |
| **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 is moderately relevant to the clinical scenario. Researchers selected studies that directly compared LSVT BIG to other interventions and performed a meta-analysis on results to determine differences in the effectiveness of LSVT compared to other interventions among the selected studies. But due to the limited number of studies and small sample size of only those mild to moderately affected with PD, it makes it difficult to generalize results to the entire PD population. Furthermore, because LSVT BIG is an intensive 60-minute protocol, it is difficult to apply this protocol to all PT settings, particularly inpatient. However, because the studies found significant effect and clinical differences in both primary and secondary outcome measures, it would be appropriate to consider that LSVT BIG would improve the clinical outcome of step length. With improved motor function and shorter TUG and 10-m walk time, one of the possible contributions could originate from improved step length. However, because this outcome was not discussed directly within the systematic review, it is difficult to confirm those assumptions without the correlating data. One of the studies included, Ebersbach (2015) measured step length directly and found that both LSVT BIG and a shortened amplitude-oriented protocol showed significant improvements in step length. |

**(2) Description and appraisal of (Effects of Treadmill Training with Load on Gait in Parkinson’s Disease: A Randomized Controlled Clinical Trial) by (Trigueiro et al., 2015)**

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| **Aim/Objective of the Study/Systematic Review:** |
| The aim of the study by Trigueiro et al. was to determine the effects of treadmill training with 0%, 5% and 10% body weight loads on gait in people with PD. Authors hypothesized that the higher percentage load (10%) would elicit greater improvements in motor function and gait kinematics in individuals with PD. |
| **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 study is a randomized controlled clinical trial that consisted of 35 individuals with PD. Participants were randomly divided into three groups, “treadmill alone (control group), treadmill with 5% load (experimental group 5%) and treadmill with 10% of load (experimental group 10%,” (pg 832). Participants were divided into groups through using a simple draw where their group allocation was concealed. Three separate researchers performed random selection, training of participants and statistical analysis to avoid bias. Participants completed Modified Hoehn and Yahr Scale, Mini Mental State Examination, the motor component of the UPDRS during pretraining and post training phases. Researchers also gathered information on age, anthropometric measures and duration of years subjects had been diagnosed with PD during pretraining phase to compare relationships among groups. Gait analysis data captured utilizing a 3D Qualisys Motion Capture System and gait training was performed on a GaitTraining System 2. Sessions occurred 3x/week for 4 weeks for a total of 12 sessions. Post training assessments were performed the day after last training session and included performing the UPDRS and analyzing gait kinematics (hip, knee and ankle angulation curves) from Qualisys data. |
| **Setting**  [e.g., locations such as hospital, community; rural; metropolitan; country] |
| No specific setting was mentioned however, considering researchers utilized high tech equipment, it was likely completed in a hospital, metropolitan or university 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. |
| N= 35, 8 subjects dropped out due to issues with transportation leaving the final sample to include n=27 (control=9, experimental 5% =9 and experimental 10% =9) who were analysed. The sample was made up of 18 men and 9 women aged 41 to 75 with a disease duration of 2 to 9 years. Participants were all diagnosed with idiopathic PD, men or women ages 40-75, Hoen and Yahr stages 2-3, on stabilized doses of PD medications, able to walk independently without aid. Participants were excluded if they had other neurologic or musculoskeletal issue, visual/auditory deficits, serious cognitive impairment, abnormal cardiac responses to exercise, unstable PD medications or pain/fatigue that would limit exercise.  No statistically significant intergroup differences were observed during pretraining assessment, and there was no intergroup differences between speed adopted during training periods. |
| **Intervention Investigated**  [Provide details of methods, who provided treatment, when and where, how many hours of treatment provided] |
| *Control* |
| All participants, including experimental groups completed 4 weeks of training that involved 30-minute sessions 3x/week during the “on” phase of their PD medications. During first training session, participants were allowed a 5-min warmup to adapt to equipment. Once adapted and every session thereafter, speed was gradually increased on the machine until participants were walking at their max tolerated speed. Verbal and manual cues were provided when necessary to maintain appropriate posture/alignment and patients were monitored for signs of fatigue and to ensure they remained under 75% of HRmax. |
| *Experimental* |
| There were two experimental groups (5% load and 10% load) who completed identical treadmill training but were fitted with a belt containing weight pockets that correlated to the percentage of their body weight depending on the group they were assigned to. Same verbal and manual feedback was provided to all groups. |
| **Outcome Measures**  [Give details of each measure, maximum possible score and range for each measure, administered by whom, where] |
| The Modified Hoehn and Yahr were utilized to assess motor function pretraining and post training. Specifics of measures were not provided, but information obtain from measures provided details on laterality of symptoms, need for assistive device, as well as balance, coordination, gait posture and functional strength. Higher scores on the Modified Hoehn and Yahr and UPDRS were indicative of more severe involvement. To determine most affected lower limb, researchers used info from motor portion of UPDRS when testing rigidity and leg agility.  Kinematic analysis of gait was obtained utilizing a Qualisys Motion Capture System. Cameras captured the movement of joints utilizing markers placed at iliac crest, greater trochanters, medial/lateral condyles of the femurs, medial/lateral malleoli, calcaneus and at the head of the 1st and 5th metatarsal. Rectangular clusters with specific markers to track pelvis, thigh and leg segments were also placed. Standing calibration was taken to obtain computerized image of positions of both anatomic markers and tracking markers. Utilizing data collected from system, researchers were able to obtain hip, knee and ankle angulation curves which provided spatial and temporal measures of gait to include speed (m/sec), stride length (m), step length on most affected side (m), double stance (%), total stance (%) and total swing (%) phases. Range of motion of hip, knee and ankle were also observed. This information was captured all 12 training sessions, but only training sessions 1, 6 and 12 were analyzed and reported. |
| **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.] |
| Functional Assessment of Effects of Treadmill Training with respect to Activities of Daily Living Domain of UPDRS   |  |  |  |  | | --- | --- | --- | --- | | Variable | Control Group | Treadmill + 5% | Treadmill + 10% | | Pre-Training | 18.22 ± 7.48 | 16.56 ± 7.05 | 15.78 ± 5.89 | | Post-Training | 17.00 ± 6.75 | 15.89 ± 7.46 | 15.67 ± 5.12 |   Functional assessment of participants showed significant improvement in intragroup differences regarding ADLs (P=0.03), however there were no intergroup differences showed in ADL performance (P=0.30).  Effects of Treadmill Training on UPDRS-III (Motor Exam portion)   |  |  |  |  | | --- | --- | --- | --- | | Variable | Control Group | Treadmill + 5% | Treadmill + 10% | | Pre-Training | 18.67 ± 12.66 | 25.89 ± 14.95 | 16.22 ± 12.62 | | Post-Training | 13.11 ± 8.99 | 21.00 ± 14.02 | 11.11 ± 6.29 |   Similarly to ADL performance, motor portions of the UPDRS-III reduced significantly and noted significant intragroup differences (P=0.003), however no intergroup differences were found (P=0.98).  Table 2. Analysis of Treadmill Speed between the first (S1), the sixth (S6) and the last (S12) sessions (pg 834)   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Variable | Treadmill (Control) | Treadmill +5% (Experimental 1) | Treadmill + 10% (Experimental 2) | P | | S1, m/sec | 0.37 ± 0.24 | 0.27 ± 0.12 | 0.31 ± 0.19 | 0.57 | | S6, m/sec | 0.58 ± 0.31 | 0.41 ± 0.22 | 0.57 ± 0.25 | 0.32 | | S12, m/sec | 0.71 ± 0.35 | 0.57 ± 0.24 | 0.82 ± 0.44 | 0.34 |   Average speed of treadmill increased improved over time among all groups. There were no significant intergroup differences in the initial, intermediate, or final stages of training in treadmill speed.  Table 3. Spatiotemporal Variables and Angular Variables in Pretraining and Post training Phases (pg 835)   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | |  | Treadmill (Control) | | Treadmill + 5% (Experimental 1) | | Treadmill + 10% (Experimental 2) | | 95% CI | | Variables | Pretraining | Posttraining | Pretraining | Posttraining | Pretraining | Posttraining | Lower-upper | | Speed (m/s) | 0.99 ± 0.13 | 1.05 ± 0.09 | 0.76 ± 0.17 | 0.85 ± 0.20 | 0.85 ± 0.2 | 1.04 ± 0.16 | 0.90-1.00 | | Stride length (m) | 1.11 ± 0.11 | 1.15 ± 0.09 | 0.93 ± 0.18 | 1.01 ± 0.17 | 1.19 ± 0.04 | 1.24 ± 0.12 | 1.06-1.15 | | MA step length (m) | 0.56 ± 0.04 | 0.57 ± 0.06 | 0.45 ± 0.09 | 0.51 ± 0.08 | 0.58 ± 0.03 | 0.61 ± 0.07 | 0.53-0.57 | | Double stance (%) | 15.99 ± 1.77 | 14.66 ± 1.73 | 17.62 ± 1.91 | 16.44 ± 2.04 | 15.62 ± 2.51 | 14.95 ± 1.86 | 15.21-16.54 | | Total stance (%) | 66.09 ± 1.53 | 64.91 ± 2.05 | 68.45 ± 1.71 | 66.27 ± 1.57 | 70.11 ± 11.13 | 65.08 ± 2.62 | 65.40-68.23 | | Total swing (%) | 33.91± 1.53 | 34.98 ± 1.98 | 31.55 ± 1.71 | 33.73 ± 1.57 | 30.89 ± 1.86 | 34.92 ± 2.62 | 31.96-34.70 | | ROM of hip (degrees) | 41.65 ± 4.47 | 42.20 ± 6.04 | 30.23 ± 5.54 | 31.74 ± 5.64 | 37.36 ± 3.55 | 39.82 ± 5.65 | 35.25-39.09 | | ROM of knee (degrees) | 58.06 ± 3.46 | 58.85 ± 4.05 | 51.72 ± 9.70 | 55.41 ± 12.91 | 59.49 ± 4.85 | 60.04 ± 2.10 | 54.48-60.05 | | ROM of ankle (degrees) | 22.27 ± 4.07 | 21.74 ± 5.14 | 18.56 ± 4.58 | 18.46 ± 3.46 | 20.75 ± 3.81 | 21.46 ± 1.77 | 19.11-21.97 |   Key: MA = most affected LE  Similar to other measures, there were significant intragroup changes amongst all three groups in regard to an increase in step length (P=0.001), speed (P= 0.04), stride length (P=0.002) and a decrease in double-stance (P=0.02) and total-stance (P= 0.04) phase. However, similar to the other measures, no intergroup pretraining and posttraining difference were noted in step length (P= 0.14), speed (P=0.78), stride length (P=0.57), double-stance (P=0.80) or total stance (P=0.46) phases. There were no significant intragroup or intergroup changes in total swing (P= 0.07 and 0.64 respectively). In terms of angular variables, only knee ROM displayed significant intragroup differences between pre and post training (P=0.03). Hip and ankle did not display significant intragroup differences (P=0.07 and 0.72 respectively), whereas none of the angular variables noted significant intergroup differences in the hip, knee or ankle (P= 0.59, 0.17, 0.72 respectively). |
| **Original Authors’ Conclusions**  [Paraphrase as required. If providing a direct quote, add page number] |
| All participants saw an improvement in performance of activities of daily living as well as motor function regardless of the amount of load provided during treadmill training. This finding supports the notion that treadmill training helps to increase cortical excitability and has the ability to stimulate neuroplasticity of the CNS. Treadmill training in general helps to “accentuate hip extension, thereby lengthening step… [additionally,] the treadmill facilitates the stretching of hip flexors and ankle dorsiflexors at the end of the stance phase, resulting in an increase in stride length, reduction in total stance time, and increase in swing time, thereby augmenting impulsion,” (pg 835). Treadmill training with load did not elicit a significantly better improvement in posttraining spatiotemporal or angular variables seen by the significant intragroup pre and posttraining differences in the control group as well as both experimental groups which contradicts study’s hypothesis. |
| **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.] |
| This level 2 upgraded randomized clinical control trial by Trigueiro et al. (2015) has a low-risk overall risk of bias noted by an 8/11 PEDro score. There was no blinding of subjects or therapist due to nature of the study with participants having to wear a load belt or not. Additionally, there was no intention to treat analysis performed on the 8 subjects that dropped out, nor was there mention on whether this would have affected results. Strengths of the study include the homogeneity of subjects during the pretraining stage which indicated similarities in levels of functions among subjects and between groups. Furthermore, researchers selected appropriate statistical measures to determine effect and intergroup interactions as a result of training. Additionally, randomization helps to strengthen the internal validity of the study. However, confounding variables such as limited information on how speed was selected for the participants could have influenced results considering that speed directly affects other spatiotemporal and joint angular variables of gait. In terms of external validity, the researchers included defined inclusion and exclusion criteria and outcomes selected applied to practical activities of daily living, functional activities, and ambulation. However, because of the smaller sample size and limited kinematic data on the less affected limb, it is difficult to generalize results to the larger PD population, especially those more severely affected or those who have bilateral involvement. |
| **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.] |
| With or without load, participants were able to improve walking speed and step length which demonstrate functional improvements in activities that were meaningful. Treadmill training alone is a repetitive task-specific form of gait training that improves the locomotive pattern and translates to improved ADL and motor performance which is more beneficial than a simple relief of bradykinesia or rigidity. This may be why the study showed no significant differences between groups regardless of amount of load, as the control and both experimental groups noted significant improvements between pretraining and posttraining. However, the results and variables from this study were highly influenced by gait speed. It does beg the question of how results may have been affected had participants walked at their comfortable gait speed with and without additional load as this would have provided a more accurate depiction of the benefits of treadmill training with load on typical ambulation. |
| **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.] |
| There was high relevance of the study to the clinical question and scenario. All participants were diagnosed with idiopathic PD with mild to moderate severity. There wasn’t a direct comparison to LSVT BIG training, but there was comparison of treadmill training with and without load which could be considered a form of resisted gait training. Additionally, researchers included a lot of outcomes one of which directly measured how resisted treadmill training compared to treadmill training without resistance would affect step length. Although there was high tech equipment utilized to measure variables within the study, the intervention itself was relatively simple to complete. The only equipment utilized to complete the actual intervention was a treadmill and weighted belt which is readily available at most outpatient clinics. Additionally, training sessions were only 30 minutes 3x a week which is feasible in a typical outpatient clinic or to be incorporated into a home exercise program. Furthermore, there doesn’t seem to be any extensive or expensive training involved making it more accessible for therapist considering incorporating this method into a patient’s plan of care. |

**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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| Overall, both studies included in this CAT indicate that intensive, repetitive large-amplitude and walking that provides constant feedback is capable of making significant changes in individuals with PD. The first study, a systematic review and meta-analysis by McDonnell et al., found LSVT BIG to be more effective than general exercise or a shortened protocol in improving UPDRS scores both immediately following exercise and with long-term effects sustained at 6 months post intervention. This study was moderately relevant to the clinical question as all participants were diagnosed idiopathic PD and it compares LSVT-BIG to Nordic walking, home based exercise programs and other shorter amplitude-oriented training protocols. However, although one study observed step length as a secondary outcome, the systematic review chose the motor portion of the UPDRS and other outcomes such as TUG and 10-m walk to compare amongst studies leaving only inferences on LSVT BIG’s influence on step length. With significant improvement in 10-m walk and TUG, one can predict that step length may have influenced outcome, but it would be difficult to concur without additional studies that directly measure step length. Overall, this study showed moderate risk of bias and can be applied to clinical practice with caution. Considering there were only 4 studies included in the review, additional studies with larger sample sizes and greater variability in patient severity (not just mild to moderate) are necessary to apply these findings to the general PD population. Future studies should also focus on comparison of LSVT BIG to other interventions in PD including more recent data. Furthermore, because LSVT BIG training is a very specific protocol that requires 60-minute sessions, 4x/week this may not be feasible in every setting and for every patient. Moreover, the cost of training and renewal is hundreds of dollars and usually requires multiple days of attendance and preparation that could be spent on patient care or documentation.  Trigueiro et al. examined the effects of load with treadmill training on gait in individuals with PD. They found that all participants saw an improvement in performance of activities of daily living as well as motor function regardless of the amount of load provided during treadmill training. This study was highly relevant to the clinical scenario as all participants were diagnosed with idiopathic PD, researchers compared a form of resisted gait training on a treadmill to regular treadmill training without resistance and step length was an outcome that was directly measured and reported. Overall, this study showed low risk of bias and can be applied with a few considerations. Naturally, treadmill walking accentuates angular variables of hip and ankle ROM which resultantly influences improvements in spatiotemporal variables. Furthermore, the external cuing of uniform walking provided by the treadmill belt moving at a certain speed and having to constantly adjust pace to match treadmill speed can influence variable regardless of it a load is present. Future studies should address this variable of treadmill speed as well as retention of gains noted by a prolonged follow-up period.  Based on the two studies described above it is difficult to determine if one intervention is better than the other in improving step length in individuals with PD as no studies directly compared the two interventions. However, these studies have revealed the benefits of each form of training on improving motor function. The systematic review revealed the LSVT BIG protocol elicited better improvements on the motor exam of the UPDRS compared to other interventions, although this was not a direct measure of step length. Yet, most of the studies included in the review were completed by the same author and yielded moderate risk of bias which could have influenced results. In terms of resisted gait training on the treadmill, there were benefits noted both with and without added resistance. The information from both studies provides readers with the notion that the focus should perhaps be shifted to specific principles that should applied to any treatment or rehabilitation plan in individuals with PD. First, frequent, high intensity sessions with constant feedback have noted improvements in motor function and ADL performance. Additionally, general external cuing with repetition have also shown to influence motor outcomes in PD. Because resisted gait training protocol is more feasible to the therapists, setting and patient (30 min sessions 3x/week, no additional training required vs. 60-min sessions 4x/week with extensive training that requires bi-annual renewal), it is a better option than LSVT BIG in improving step length. Even though it doesn’t improve outcomes to a greater degree than normal treadmill gait training, it is more task-specific in improving step length and applies similar ideology of more effort and larger amplitude movements which are the focal point of LSVT-BIG. |

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