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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| In female older adults (70 or older) with Parkinson’s Disease, is the LSVT BIG program or the use of external visual cueing more effective in improving gait?  |

**AUTHOR**

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**CLINICAL SCENARIO**

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| On my previous clinical experience at an outpatient neuro facility in Greenville, NC, my CI and I treated an older lady with Parkinson’s Disease using the LSVT BIG program. This particular patient had been seen by my CI before utilizing more traditional therapeutic interventions, but she experienced a decline in function following the death of her husband in December of 2016. This patient demonstrated good improvements in her TUG, Berg Balance Score, and 5X STS. However, her 10m walk test was essentially unchanged, though she did demonstrate improvements in step length and arm swing with gait. I want to explore if the LSVT BIG program is any more effective than the use of external visual cueing for improving gait. Both of these interventions are targeted at larger amplitude movements (increased step length), but LSVT BIG utilizes verbal cueing so it will be interesting to see which form of cueing is more effective in this patient population. This topic is important for clinicians because shuffling of gait and decreased amplitude of movement can largely impact patient mobility, independence, and safety. It is necessary to be able to implement an intervention that can specifically target gait. Additionally, this topic is relevant to clinical practice because it takes additional training to become LSVT BIG certified, so it is helpful as a clinician to know if the evidence supports this program and demonstrates that it is as or more effective than other interventions.  |

**SUMMARY OF SEARCH**

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| * There is currently no published research comparing the effectiveness of LSVT BIG and external visual cueing in improving gait in patients with Parkinson’s Disease. Therefore, a two-part literature search was conducted to synthesize the best available evidence for each intervention. This yielded 4 relevant articles about LSVT BIG and 4 articles that explored external visual cueing
* These studies varied in quality and risk of bias, with there being fewer high-quality studies for LSVT BIG
* Overall, the evidence about LSVT BIG demonstrates that it effective in improving motor performance, and it has some effect on gait measures, though the findings are not clinically significant.
* The literature also demonstrates that external cueing is effective in improving gait parameters and motor performance, but that a distinction cannot be made about which type of cueing is superior at this point in time.
* There is evidence that visual cueing results in significant improvements in step length, gait speed and cadence, and those improvements are clinically relevant.
* Key areas for future research include more randomized controlled trials comparing the effectiveness of LSVT BIG with other interventions, more research on which type of cueing produces superior results, and further research on the frequency, duration and intensity of cueing that leads to the best improvements in gait.
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**CLINICAL BOTTOM LINE**

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| The evidence presented suggests that visual cueing is superior to LSVT BIG for clinically improving gait speed in older adults with Parkinson’s Disease, but this conclusion is weak and thus needs further exploration. Additionally, conclusions cannot be made in regards to other parameters and measures of gait due limited availability of research. Lastly, there can be no conclusions made about whether visual cueing is superior to other types of external cueing in improving gait secondary to the high variability of methodologies of available studies. Overall, the evidence is weak and lacking for this specific clinical question, and future research is needed to fully understand the use of these treatments in patients with Parkinson’s Disease with gait impairments.  |

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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*** |

**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\* diseasePD | LSVT BIG | Visual cue\*Visual feedback | GaitWalk\*Ambulat\* |

**Final search strategy (history):** Due to the limited research available regarding the LSVT BIG program, a two-step search strategy was utilized. First, the best available literature about LSVT BIG was found. Then, the best available literature about the use of visual cueing was found.

1. Parkinson\* Disease OR PD

2. LSVT BIG

3. visual AND (cue\* OR feedback)

4. gait OR walk\* OR ambulat\*

5. speed OR velocity

6. #1 AND #2 AND #3 AND #4 **(no results found based on PICO question)**

7. #1 AND #2 AND #4

8. #1 AND #3 AND #4 AND 5

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| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| **PubMed (search #7)****CINAHL (search #7)** **PubMed (search #8)****CINAHL (search #8)****Embase (search #8)** | **5****3****68****29****117** | **N/A****N/A (same papers found in PubMed)****52- Apply filter “publication date 2005-2017****22- Apply filter “publication date 2005-2017”****14- Apply filter “Cochrane Review, Systematic Review, Meta Analysis, RCT” and apply filter “publication year 2005-2017** |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| * Studies published in 2005 or later
* Participants over the age of 60 diagnosed with Parkinson’s Disease
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| **Exclusion Criteria** |
| * Abstracts, conference proceedings, review articles
* Not published in English
* Studies that included patients with other conditions/disorders that could impact gait independent of the Parkinson’s Disease (for example; history of CVS, concomitant orthopaedic injuries, etc)
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**RESULTS OF SEARCH**

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

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| **Author (Year)** | **Risk of bias (quality score)\*** | **Level of Evidence\*\*** | **Relevance** | **Study design** |
| **Millage et al. (2017)1** | **Downs and Black Checklist 14/29** | **2b** | **Low: study participants were Hoehn and Yahr Stage I, and had unilateral involvement. My population of interest had more advanced PD** | **Quasi-experimental: single group pretest-posttest** |
| **Janssens et al. (2014)2** | **Downs and Black Checklist 9/29** | **4** | **Low: study participants were all male, 2 out of 3 were younger than my patient of interest, the UPDRS III scores were reported on but varied greatly between three participants, assessed gait but in combination with balance, also assessed multiple other primary outcomes**  | **Case Series** |
| **Ebersbach et al. (2010)3** | **PEDro: 7/11** | **1b** | **High** | **Randomized Controlled Trial** |
| **Farley et al. (2005)4** | **Downs and Black Checklist 15/29** | **2b** | **High** | **Quasi-experimental: single group pretest-posttest** |
| **Spaulding et al. (2013)5** | **AMSTAR 5/11**  | **2a-studies included were not strictly RCTs** | **High** | **Meta-analysis** |
| **Rocha et al. (2014)6** | **AMSTAR 9/11** | **2a- downgraded from 1a because quasi-experimental RCTs were included too** | **High** | **Systematic Review** |
| **Lim et al. (2005)7** | **AMSTAR 8/11** | **2a- downgraded from 1a because non-controlled studies were also included** | **Moderate: compares visual cues to other types of cueing, gait as primary outcome measure, but no inclusion of UPDRS scores (only Hoehn and Yahr stage)** | **Systematic Review** |
| **De Icco et al. (2015)8** | **PEDro 5/11** | **1b** | **High** | **Randomized Controlled Trial** |

\*Indicate tool name and score

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

**BEST EVIDENCE**

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

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| * **Ebersbach et al. (2010)3:** This study is a randomized controlled trial (level of evidence 1b), that compared LSVT BIG with Nordic walking and a control home exercise program in patients with Parkinson’s disease, Hoehn and Yahr stages 1-3. The outcome measures of interest were UPDRS motor subscale score, the PDG-39 (a quality of life outcome measure), TUG score, and 10m walk time, and they were measured initially and at the completion of the 16-week intervention. This study is the highest quality evidence currently published about the LSVT BIG protocol, and it is the only study that is randomized and has a control group for comparison. The risk of bias was assessed as 7/11 on the PEDro scale, which demonstrates moderate to high quality and lower risk of bias than the other studies included. Lastly, this study had the largest sample size, 60 participants, of all of the LSVT BIG studies and was the only study that looked at the sustained effects of the interventions.
* **Rocha et al. (2014)6:** This study was a systematic review (level of evidence 2a), that synthesized both randomized and non-randomized studies. The review included 7 studies, 6 of which were randomized controlled trials and one that was a quasi-experimental study. The quality of the studies included in this systematic review was higher than the meta-analysis found by Spaulding et al., thus justifying its use as best evidence. Additionally, this systematic review is more recent than the meta-analysis and the other systematic review included. The risk of bias was assessed as 9/11 on the AMSTAR tool, which is the highest quality study found on the use of visual cueing. This indicates that it is strong methodologically and has a low risk of bias. This study looked at different types of external cueing, including visual, auditory, sensorial, and combined cueing. The primary outcomes of interest were: step/stride length, gait speed, and cadence.
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**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of “Comparing Exercise in Parkinson’s Disease—The Berlin LSVT® BIG Study” by Ebersbach et al., 20103**

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| **Aim/Objective of the Study/Systematic Review:** |
| The primary objective of this randomized controlled trial was to evaluate and compare the effectiveness of the LSVT BIG program, a Nordic walking program, and an independent home exercise program in improving motor performance in patients with Parkinson’s disease. Secondary objectives included evaluating the effectiveness of these programs in improving quality of life and gait in patients with Parkinson’s Disease. |
| **Study Design** |
| * Prospective randomized controlled trial

**Blinding*** The outcome assessor was blinded but the physical therapist delivering all treatments and the participants were not blinded.
* The outcome assessor was blinded to group allocation, as well as at what time point in the study the participants were at on examination

**Group Allocation and Concealment*** The participants were randomly allocated to a group by drawing lots, which therefore means that there was no allocation concealment.

**Outcomes Measures and Assessment*** The primary outcome of interest was motor performance as measured by the UPDRS-III motor section
* Secondary outcomes were quality of life as measured by the PDQ-39, and gait as measured by the TUG and 10m walk test
* The blinded outcome assessor assessed all outcomes of interest
* Outcomes were measured at baseline and then 16 weeks after that point

**Data Analysis*** Mean difference, with standard deviation, was reported from baseline to follow-up for all outcome measures
* Intergroup differences in change in outcome measure scores was assessed using an analysis of covariance (ANCOVA)
* If there was a significant intergroup difference, then pairwise comparisons were performed for the three groups.
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| **Setting** |
| * The LSVT BIG and Nordic walking interventions were completed in an outpatient physical therapy clinic
* The home exercise program group completed independent exercises in the home environment
* No geographical information given
 |
| **Participants** |
| **Number of Participants and Dropouts** * 60 participants enrolled in the study (20 LSVT BIG, 20 Nordic walking, 20 home)
* Only 58 participants completed the study and thus were available for assessment at the 16-week follow-up (20 LSVT BIG, 19 Nordic walking, 19 home). The Nordic walking dropout withdrew consent at 2 weeks with no further explanation, and the home group dropout was before week 4 secondary to psychosis.

**Sampling** * Convenience sampling was utilized as participants were recruited via referral from outpatient clinics and physicians’ offices

**Eligibility Criteria** * Important aspects of eligibility criteria were that participants could only be Hoehn and Yahr stages 1-3 and participants with dementia (as defined by MMSE score of <25) were excluded.

**Participant Characteristics** * There were no significant differences between the three groups for age, disease duration, time spent exercising weekly in addition to intervention, and L-dopa equivalence dose at baseline
* There were 36 female participants and 22 male participants, divided essentially evenly amongst the groups
* The average age of the participants in each group was 67.1 for the LSVT BIG group, 65.5 for the Nordic walking group, and 69.3 for the home exercise group.
* The average Hoehn & Yahr stage was 2.8 for the LSVT BIG group, 2.6 for the Nordic walking group, and 2.5 for the home exercise group
* The average disease duration in years was 6.1 for the LSVT BIG group, 7.8 for the Nordic walking group, and 7.4 for the home exercise group.
* The L-dopa equivalence dose reported in mg per day was 486 for the LSVT BIG group, 530 for the Nordic walking group, and 463 for the home exercise group
* Average time spent exercising weekly outside of the intervention was 2.53 for LSVT BIG group, 2.10 for the Nordic walking group, and 2.6 for the home exercise group
 |
| **Intervention Investigated** |
| *Control* |
| * The control group in this study was the home exercise group
* This group received a one-hour educational and training session in the home about a home exercise program that included stretching exercises, exercises that utilized high-amplitude movement, postural exercises, and exercises targeted at increasing muscular power.
* No further specifics were reported in the study about the exercises, the frequency at which the exercises should be performed, or the intensity at which exercises should be performed
* The same physical therapist that delivered the LSVT BIG and Nordic walking provided the education and training for the home exercise group
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| *Experimental* |
| * The two experimental groups for this study were the LSVT BIG group and the Nordic walking group
* Both groups were provided treatment by the same un-blinded physical therapist that also provided intervention for the control group

**LSVT BIG Group*** Participants in this group received intervention according to the LSVT BIG protocol
* The sessions were 1 hour in duration, 4 times per week for 4 weeks.
* The sessions were one-on-one
* It is important to note that the LSVT BIG program is pillared on intensive motivation and perceptual feedback, as participants are encouraged to work at 80% of their maximal effort level for every repetition of every exercise.
* The exercises can be divided into two groups: standard maximal daily exercises and functional component tasks.

Standard Maximal Daily Exercises * The standard maximal daily exercises are multidirectional, repetitive, full body movements that target maximal amplitude. Additionally, some of the exercises require a sustained hold, and thus address stretching as well4.
* The 7 exercise that comprise the maximal daily exercises are: floor to ceiling (8 repetitions, 10 second hold each), side to side (8 repetitions, 10 second hold each), forward step (8 repetitions each side), sideways step (8 repetitions each side), backward step (8 repetitions each side), rock and reach forward (8 repetitions each side), reach and twist sideways (8 repetitions each side)1

Functional Component Tasks* The functional component tasks of the LSVT BIG program work on specific, participant-defined activities of daily living that need to be improved.
* These ADL tasks are broken down into components practiced and performed utilizing high-amplitude movement1
* These tasks are strung together and made more complex as the program progresses1

**Nordic Walking Group*** Participants in this group received intervention according to a standardized Nordic walking protocol for beginners.
* The sessions were 1 hour in duration, 2 times per week for 8 weeks
* The sessions were performed in groups of 4-6 participants
* The sessions included a warm up, the Nordic walking intervention, and a cool down
* No additional details about the Nordic walking standardized protocol was provided, and a reference was not provided.
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| **Outcome Measures** |
| * The primary outcome measure of interest in this study was the UPDRS-III score, which is the motor section of the UPDRS with a maximum score of 56 representing greater disability. This section includes an analysis of gait, and thus is applicable to the clinical question posed above.
* Of the secondary outcome measures assessed, the TUG (reported in seconds) and the 10m walk test (reported in meters/second) are applicable to the clinical question posed.
* The UPDRS-III score was determined by the blinded outcome assessor who watched a video-tape of the participant performing the items on the UPDRS-III
* The TUG and 10m walk test were also assessed by the blinded outcome assessor
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| **Main Findings** |
| * Only data for UPDRS-III, TUG, and 10m walk test will be reported for the purposes of this review
* The alpha value was set at p<0.05 to determine statistical significance
* There was a statistically significant difference between the groups for change UPDRS-III scores from baseline to follow up (F-statistic=11.9, p<0.001)
* Pairwise comparison demonstrated a significant difference between the LSVT BIG group and Nordic walk group in favour of LSVT BIG (F-statistic= 21.2, p<0.001, 95% CI (-7.87, -3.39)), and the LSVT BIG group and the home exercise group in favour of LSVT BIG (F-statistic=16.7, p<0.001, 95% CI (-9.87, -3.59))
* There was a statistically significant difference between the groups for change in TUG time (F-statistics= 3.64, p=0.033)
* Pairwise comparison demonstrated a significant difference between LSVT BIG group and the Nordic walking group in favour of LSVT BIG (F-statistic= 4.77, p=0.036, 95% CI (-2.48, -0.18)), and the LSVT BIG group and the home exercise group in favour of LSVT BIG (F-statistic=5.58, p=0.024, 95% CI

(-2.21, -0.17)).* There was not a statistically significant difference between the groups for change in 10m walk test (F-statistic= 2.97, p=0.059)
* However, pairwise comparison demonstrated a significant difference between the LSVT BIG group and the home exercise group in favour of the LSVT BIG group (F-statistic= 3.08, p=0.015, 95% CI (-1.28, -0.06)
* Of note, I calculated the 95% CI based on difference between means and SD, as this information was not provided in the study.
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| **Original Authors’ Conclusions** |
| The authors of this study concluded that LSVT BIG training resulted in improved motor performance, and that the degree of change was superior to a Nordic walking training program and a home exercise program. They also concluded that LSVT BIG training was superior in improving gait as compared to a Nordic walking training program or a home exercise program. Thus, overall it was concluded that LSVT BIG is an effective treatment strategy for patients with Parkinson’s Disease.  |
| **Critical Appraisal** |
| **Validity** |
| The PEDRO score for this systematic review was 7/11, with the study not having allocation concealment, blinding of all subjects, blinding of administering therapist, or intention to treat analysis. As such, the risk of bias in this study was moderate. However, it is important to note the difficulty of blinding administering therapists and participants in clinical intervention studies such as this one. This study was of moderate to high quality, and it also represents the highest quality study published using the LSVT BIG protocol thus far. The strengths of this study included its design, the sample size, and the time-frame in which the researchers assessed outcome measures. The design of this study contributes to its high quality because not only were participants randomized, but the study compared LSVT BIG to a program (Nordic walking) that has already been demonstrated to be successful in Parkinson’s Disease, as well as an active control group of home exercises that targeted similar outcomes (increased amplitude of movement, etc). The second point at which the outcome measures were taken is also a strength of this study, as they were taken at 16-weeks which is 12-weeks post-completion of the LSVT BIG program and 8-weeks post-completion of the Nordic walking program. It was specifically noted that this time lag was sufficient to detect sustained effects of the interventions, which is a benefit as a clinician because you want to employ treatments whose effects remain past the point of completion. The weaknesses of the study were the inability to control medication changes throughout the study, the inclusion of Hoehn and Yahr stages 1-3 only, and the lack of methodologic detail. As noted in the study, there were changes in L-dopa equivalence dose in all three groups, and while those changes were similar in all groups, this dosage change could potentially represent a confounding factor. Only including Hoehn & Yahr stages 1-3 limits the generalizability of these treatments to patients with more severe Parkinson’s disease. Lastly, the lack of methodologic detail hinders reproducibility. Additionally, with a protocol such as LSVT BIG, where a large component of the treatment is based on patient-identified functional limitations, it is important to at least note what they were, as some functional tasks could have inadvertently work on gait as well (stepping over objects, walking with changes in speed, etc). With all of this in mind the quality of the evidence provided by this study was high, and this study represents the best available literature surrounding the use of LSVT BIG in patients with Parkinson’s Disease. |
| **Interpretation of Results** |
| The results of this study support the use of LSVT BIG in patients with Parkinson’s Disease to improve motor performance and gait. The LSVT BIG program was superior at improving UPDRS- III scores, and TUG scores as compared to Nordic walking or a home exercise program, and it was also superior at improving 10 m walk times as compared to the home exercise program group. In considering clinical significance and effect size of the improvements seen post-LSVT BIG, absolute effect size can be calculated based on the mean at baseline and at follow-up. For UPDRS-III scores there was an effect size of 5.05 points, which is clinically significant based on the established MCID of 2.5 points1. For the TUG scores, there was an absolute effect size of 0.75 seconds, which is not clinically significant based on the established MDC of 3.5 seconds in patients with Parkinson’s Disease9. Lastly, the timed 10m walk test showed an absolute effect size of 1.12 seconds, which translates to a decrease in 0.112 m/s for gait speed. This is not clinically significant based on the established MCID of 0.16 m/s for gait speed in patients with Parkinson’s disease1. With all of this in mind, while the results for gait measures were statistically significant, they are likely not clinically significant. However, improved motor performance as measured by UPDRS-III scores was both statistically and clinically significant. |
| **Applicability of Study Results** |
| This study was highly applicable to the clinical question of interest, as the patient population in this study was older and at a similar stage of Parkinson’s Disease as the patient described in the clinical scenario. Of note, though not specifically mentioned, the patient described in the clinical scenario presented with some signs of cognitive impairment, but there was no formal diagnosis of any dementia related disorders. Seeing as dementia was one of the exclusion criteria for this study, that has to be kept in mind when considering the implementation of LSVT BIG for a patient such as the one described. This study is also applicable to the clinical question at hand because Nordic walking is thought to be effective in patients with Parkinson’s Disease because it provides rhythmic external cues10, thus this study in particular is also comparing the effectiveness of types of cueing on gait (though that is not the primary objective). Even though the type of cueing is not visual cueing as explicitly stated in the clinical question, this still add clinical value to this study. Lastly, it is important to consider the practicality and feasibility of these interventions. Both LSVT BIG and Nordic walking require special training, and thus are not as easy to implement in a clinical setting as other interventions. The intensity of the LSVT BIG protocol also needs to be considered, as it requires a one-hour treatment session, 4 days a week for 4 weeks. This might not be feasible in certain clinics and settings, and thus must be considered before implementation.  |

**(2) Description and appraisal of “Effects of external cues on gait parameters of Parkinson’s disease patients: A systematic review” by Rocha et al., 20146**

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| **Aim/Objective of the Study/Systematic Review:** |
| The objective of this study was to evaluate and compare the effectiveness of different types of external cues on gait in people with Parkinson’s Disease, and to explore the effects of such cues on quality of life, freezing of gait, and psychomotor performance.  |
| **Study Design** |
| * Systematic review with that pooled data from randomized controlled trials and quasi-randomized controlled trials

**Search Strategy*** A search literature search was conducted from March to August 2013 and included the following databases: Cochrane Library, PubMed, Lilacs, CINAHL, Pedro, and Sumsearch
* In addition, a manual search was completed of the journals Movement Disorders, Physical Therapy, and annals of the Movement Disorders Society
* The search strategy was dependent on the database, but the same key words were used in each database.
* Key words included: Parkinson’s disease, feedback, biofeedback, neurofeedback, psychology biofeedback, cue, cues, cueing, rehabilitation, physical therapy, physiotherapy, exercise, locomotion, gait, neurologic gait disorders, optical flow field, visual, auditory, sensory, and tactile

**Selection Criteria*** The search and evaluation of the literature was completed by two independent evaluators
* The inclusion criteria for the studies selected were: older adults diagnosed with Parkinson’s Disease, participants had to be on medication, the studies had to evaluate gait, and the studies had to compare either two types of external cues or an external cue with another physical therapy intervention
* Studies were excluded if they included analysis of any other diseases/disorders, if they included forms of Parkinsonism (as opposed to a diagnosis of PD), if they compared healthy controls with patients with Parkinson’s Disease, or if they had a different study design than what was desired.

**Methods*** The two evaluators also analysed the risk of bias for all of the studies included using a standardized table in which included items could be rated as adequate, inadequate, or unclear. Adequate was associated with low risk of bias and inadequate/unclear were high risk of bias.
* The 7 items assessed in the standardized table included: randomization of participants, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting, and other potential biases.
* Heterogeneity was assessed using an I2 statistical test in which 30-60% was moderate heterogeneity, 50-90% was substantial heterogeneity, and 75-100% was considerable heterogeneity
* The mean difference with standard deviation was pooled for the variables of the studies that were comparable
* Additionally, sub-group analyses were performed for both type of cueing and the outcomes of interest
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| **Setting** |
| Though not specifically stated, the interventions of the studies appear to have been community-based in outpatient therapy clinics for the studies included. |
| **Participants** |
| **Characteristics of Included Studies*** Seven total studies were included in this systematic review: 6 randomized controlled trials and one quasi-randomized controlled trial
* Two studies analysed the use of visual cues, two studies analysed the use of auditory cues, one study examined the use of verbal instruction during gait training, one study analysed the use of a combination of visual and auditory cues, and one study looked at the use of sensory/proprioceptive cues

**Quality of Studies/Risk of Bias*** Two of the included studies were rated as low risk of bias on all 7 items of the standardized table
* The other 5 studies had a mixture of low risk of bias, unclear risk, and high risk of bias.
* The items rated as unclear in said studies were randomization of participants, allocation concealment, and blinding of outcome assessors.
* The items rated as high risk of bias included allocation concealment, blinding of outcome assessors, and selective reporting.

**Characteristics of the Pooled Participants*** Overall, 204 patients with Parkinson’s Disease were included
* The ratio of male to female was 114 to 60
* The average age was 68.8 years’ old
* The average Hoehn and Yahr Stage was 2.4
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| **Intervention Investigated** |
| *Control* |
| The control group varied depending on the study. The control groups utilized included groups that received no intervention, groups that received gait training with no cueing, and groups that received conventional therapy. Additionally, one study compared overground gait training with cueing versus treadmill gait training with cueing, in which case the control group was the overground group. |
| *Experimental* |
| * The experimental group also varied depending on the study, but included some combination of overground versus treadmill training, and varying types of external cues. The specific experimental groups included treadmill training with visual cues, overground training with visual cues, overground training with visual cues and conventional therapy, treadmill training with auditory cues, overground training with auditory cues, overground training with verbal instruction, treadmill training with visual and auditory cues, overground training with visual and auditory cues, and treadmill training with perceptual cueing.
* The average number of sessions was 19.1, and the range was from 10 sessions to 28 sessions
* The duration of the sessions ranged from 20 minutes to an hour, with 30 minutes being the most common duration.
* The duration of intervention ranged from 2 weeks to 8 weeks, with a frequency range from 3 times per week to 7 times per week
* No information was given on the specifics of who provided treatment in each study
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| **Outcome Measures** |
| The outcome measures of interest that were included in this systematic review were gait speed (in centimetres/second), step length (in centimetres), cadence (in steps/min), and stride length (in centimetres). Secondary outcome measures were the UPDRS-III motor score, and frequency of freezing of gait. It is important to note that no studies included looked at quality of life, which was an objective of the study that was not met, |
| **Main Findings** |
| * The alpha value was set at p<0.05 to determine statistical significance
* For the purposes of this clinical question, data on the type of training (overground vs. treadmill) will not be included

**Step Length**Visual Cues* An overall mean difference was 10.53 cm with a 95% CI of (4.74, 16.33) in favour of the intervention group (p=0.0004)
* The heterogeneity analysis found an I2 value of 82%

Auditory Cues* An overall mean difference of 7.4 cm with a 95% CI of (0.65,14.15) in favour of the intervention group (p=0.03)
* No test for heterogeneity because there was only one study for this subgroup
* Verbal Instruction
* An overall mean difference of 12.25 cm with a 95% CI of (-4.89, 29.39) in favour of the intervention group (p=0.16)
* Total Pooled Data
* The pooled mean difference was 9.39 cm with a 95% CI of (5.13,13.65) in favour of the intervention group (p<0.0001)
* The heterogeneity analysis found an I2 value of 51%

**Gait Speed**Visual Cues* An overall mean difference of 30.32 cm/s with a 95% CI (19.86, 40.79) was found in favour of the intervention group (p<0.00001)
* The I2 value was 94%

Auditory Cues* An overall mean difference of 23.46 cm/s with a 95% CI (14.97, 31.95) was found in favour of the intervention group (p<0.00001)
* The I2 value was 82%

Sensorial Cues* An overall mean difference of 8.90 cm/s with a 95% CI (2.09, 15.71) was found in favour of the intervention group (p=0.01)
* No test for heterogeneity because there was only one study for this subgroup

Visual and Auditory Cues* An overall mean difference of 20 cm/s with a 95% CI (4.20, 35.80) was found in favour of the intervention group (p=0.01)
* No test for heterogeneity because there was only one study for this subgroup

Total Pooled Data* The pooled mean difference was 18 cm/s with a 95% CI of (13.46,22.54) in favour of the intervention group (p<0.000001)
* The heterogeneity analysis found an I2 value of 78.3%

**Cadence**Visual Cues* An overall mean difference of 29.72 steps/min with a 95% CI (17.83, 41.61) was found in favour of the intervention group (p<0.00001)
* No test for heterogeneity because there was only one study for this subgroup

Auditory Cues* An overall mean difference of 5.35 steps/min with a 95% CI (-0.43, 11.14) was found in favour of the intervention group (p=0.07)
* The I2 value was 40%

Sensorial Cues* An overall mean difference of 8.4 steps/min with a 95% CI (5.55, 11.25) was found in favour of the intervention group (p<0.00001)
* No test for heterogeneity because there was only one study for this subgroup

Total Pooled Data* The pooled mean difference was 8.77 steps/min with a 95% CI of (6.27,11.27) in favour of the intervention group (p<0.00001)
* The heterogeneity analysis found an I2 value of 80%

**Stride Length**Auditory Cues* An overall mean difference of 10.90 cm with a 95% CI (-0.50, 22.29) was found in favour of the intervention group (p=0.06)
* The I2 value was 9%

Sensorial Cues* An overall mean difference of 14 cm with a 95% CI (9.92, 18.08) was found in favour of the intervention group (p<0.00001)
* No test for heterogeneity because there was only one study for this subgroup

Total Pooled Data* The pooled mean difference was 13.65 cm with a 95% CI of (9.81, 17.49) in favour of the intervention group (p<0.00001)
* The heterogeneity analysis found an I2 value of 0%
* **UPDRS-III Score**
* Combined visual and auditory cues led to a statistically significant improvement in UPDRS-III scores (p=0.009)
* The specific mean differences were not reported

In summary, the use of external cues in general resulted in significant improvements in step length, gait speed, cadence, and stride length. The use of visual cues resulted in statistically significant improvements in step length, gait speed and cadence. The use of auditory cues resulted in statistically significant improvements in step length and gait speed. The use of sensorial/perceptive cueing resulted in statistically significant improvements in gait speed, cadence, and stride length. It was also found that using a combination of visual and auditory cueing resulted in statistically significant improvements in gait speed.  |
| **Original Authors’ Conclusions** |
| The authors’ concluded that external cueing, including visual, auditory, and sensory cues, can lead to significant improvements in gait parameters in patients with Parkinson’s Disease. They also concluded that a combination of visual and auditory cueing can result in significant improvements in psychomotor functioning. Lastly, the authors’ concluded that it is not possible with the current literature to determine what types of cueing are superior in improving the gait parameters explored secondary to the variability in the methodology of the studies. As such, it is up to clinical reasoning to determine which parameter is impacted in patients with Parkinson’s Disease, and thus which type of cueing might be beneficial to utilize in intervention. |
| **Critical Appraisal** |
| **Validity** |
| The AMSTAR score for this systematic review was 9/11, with the study not having status of publication as an inclusion criteria and not having assessed the likelihood of publication bias. Thus, the overall risk of bias of this systematic review is low. Additionally, the quality of the studies included in this systematic review was high, with primarily randomized controlled trials included. Another important consideration in the validity of this study is the risk of bias of the included studies. Overall, the studies had low to moderate risk of bias based on the standardized chart utilized in the paper, therefore further contributing to the validity and strength of this study. The greatest strengths of this study were the high methodologic quality of the included studies as mentioned above, and the inclusion of multiple types of external cueing (as opposed to just auditory and visual). The exploration of sensorial cueing and combined cueing adds gives a more holistic picture of the factors that can improve gait in patients with Parkinson’s Disease. The biggest weaknesses of this systematic review was the heterogeneity of the included studies, which of course is of no fault of the researchers. Because of the large heterogeneity, further statistical analysis including effect size could not be completed, and thus it was not able to be determined which type of cueing is superior for improving each of the gait outcomes of interest. Another weakness of this systematic review was not providing the specific search strategies used within the databases to find the included studies. This makes reproducibility of this study difficult. With all of this in mind, this study provides a well- synthesized systematic review of high quality, and is the best evidence to date on this particular topic. |
| **Interpretation of Results** |
| The overall analysis of pooled data that demonstrated that external cueing resulted in significant improvements in the gait parameters of step length, gait speed, cadence, and stride length is valuable in that it validates the effectiveness of cueing on gait in this population. However, it must be considered that some of the control groups were no treatment, and thus bring into question the strength of this conclusion. Additionally, the analyses of pooled data on the effects of cueing type on specific gait parameters demonstrated that visual cueing can improve step length, gait speed, and cadence; auditory cueing can improve step length and gait speed; and sensorial/perceptual cueing can improve gait speed, cadence and stride length. However, though these analyses demonstrated that some types of cueing resulted in significant improvements in specific gait parameters whereas others do not, it cannot be assumed that it is because those cues are superior due to the large heterogeneity between all of the studies. In considering clinical significance of effect size, it is important to note that the authors reported effect size in terms of absolute effect size, or mean difference. Keeping this in mind, the type of cueing with the greatest absolute effect size for step length was visual cueing with a pooled mean difference of 10.53 cm. The type of cueing with the greatest absolute effect size for gait speed was also visual cueing, with a mean difference of 30.32 cm/sec. The greatest effect size for cadence was also seen with visual cueing, with a mean difference of 29.72 steps/min. Lastly, the greatest effect size for stride length was seen with sensorial cueing, with a mean difference of 14 cm. The challenge, then, is determining whether these are clinically meaningful. Gait speed is the only parameter included that has published literature regarding the MCID in patients with Parkinson’s Disease, and it has been found to be 0.16 m/s1. As such, the effect size of 0.3032 m/s (converted) seen in this study demonstrates that visual cueing is clinically significant and thus applicable to practice. Using clinical judgement alone, I would fare to say that a decrease in cadence of almost 30 steps per minute is clinically relevant, as is an increase in step length of approximately 11 cm and stride length of 14 cm. In a patient with Parkinson’s Disease who presents with shuffling of gait, and thus increased cadence and decreased step length, changes such as these would be marked in changing overall gait mechanics.  |
| **Applicability of Study Results** |
| This study is very applicable to my clinical scenario, as the population of the study is older adults with Parkinson’s Disease and it does explore, in-depth, the effects of various types of cueing on different aspects of gait. Even though the study was unable to determine which type of cues are superior to improving different aspects of gait mechanics, the evidence is useful in numerous clinical scenarios. Based on the assessment of gait deficits, clinicians can utilize different types of cueing alone or in combination that have been demonstrated to be effective in order to find the treatment strategy most effective for the patient at hand. Lastly, in considering practicality and feasibility, the interventions described in this systematic review are both. Though the specific intervention protocols were not described for each study, it can be assumed that providing the same (or similar) visual, auditory, and sensory cues is cost friendly, requires little equipment or manpower, and is easily implementable in all clinical settings. |

**SYNTHESIS AND CLINICAL IMPLICATIONS**

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| Throughout the process of answering the clinical question posed at the beginning of this critically appraised topic report, it became evident that the research on both LSVT BIG and the effectiveness of external visual cueing is significantly lacking. Most of the studies found about LSVT BIG were either of poor methodological quality, were unrelated to the clinical question, or were at a high risk of bias. Most had small sample sizes, were not randomized, had no control groups, and were lacking long-term measures. Though the literature about visual cueing was less limited, the levels of evidence were higher, and the search yielded a meta-analysis, two systematic reviews, and a randomized controlled trial, many of these studies demonstrated limitations and highly variable intervention protocols. As such, the two studies identified as the best available evidence were a randomized controlled trial about LSVT BIG by Ebersbach et al.3 and a systematic review about the use of various external cues by Rocha et al6. These studies were both of high methodologic quality, had low to moderate risk of bias, and were highly relevant to the clinical question at hand. The findings from the Ebersbach et al. study demonstrated that LSVT BIG is an effective, superior treatment in improving motor performance in patients with Parkinson’s Disease, and that it is also effective in improving gait3. However, upon further analysis of the findings and effect sizes, the changes seen in gait outcomes were not clinically significant, and thus must be interpreted with caution. The findings from the Rocha et al. paper demonstrated that external cueing resulted in improved gait parameters as compared to controls in patients with Parkinson’s Disease4. The improvements seen with visual cueing were in step length, gait speed and cadence, and the improvements seen with auditory cueing were in step length and gait speed, all of which were statistically and clinically significant4. However, there could be no conclusions made about which cues were superior secondary to the heterogeneity of the intervention protocols4. Synthesizing the evidence about these two interventions to answer the clinical question posed is difficult, as there is no literature that compares these specific interventions. Based on the data presented about the Ebersbach and Rocha studies, a conclusion can only be drawn in regards to treatment effect on gait speed, as both studies assessed this. The data leads to the conclusion that external visual cueing is better in producing improvements in gait speed as compared to LSVT BIG as the effect sizes are 0.3032 m/s and 0.112 m/s, respectively. This conclusion must also be taken with a grain of salt, as the length time before follow-up was not explicitly stated in the Rocha study, and thus could be a reason for the difference. Additional studies that were not included in this review can contribute to the ability to answer the clinical question at hand. A study by Millage et al. that was a quasi-experimental, single group, pretest-posttest design found that 5 of the 9 participants met the MCID value necessary for gait speed 3 months post-LSVT BIG intervention1. However, this study only included patients who were at Hoehn and Yahr stage I, and even though the stage is unknown of the patient described in the clinical scenario, she could qualitatively be placed in a more advanced stage1. A study by Farley et al. helps in synthesizing the evidence surrounding the clinical question at hand because it assessed similar gait parameters to the Rocha et al. study4. This study found that LSVT BIG resulted in increased gait velocity and stride length, but did not result in cadence improvements4. Interestingly, the study found that gait velocity changes were greatest for participants at Hoehn and Yahr stages 1 and 2, and that those at stage 3 had a reduction in gait velocity with intervention4. Though the specific gait velocity change values are not reported, it can be extrapolated from figure 2b that the Hoehn and Yahr stage 1 group had a change of approximately 0.25 m/s and the stage 2 group had a change of approximately 0.1 m/s4. The participants in the Ebersbach study had a mean Hoehn and Yahr stage of 2.8, and a similar finding for change in gait speed3. Thus, synthesizing all of these additional findings, it could be possible that LSVT BIG is effective in improving gait velocity, but that the changes are more pronounced in earlier stages as these additional two studies had improved results with patients in earlier stages. Future implications for research are numerous for a clinical question such as this. First, there needs to be more randomized controlled trials comparing the effectiveness of LSVT BIG with other active interventions that have been supported in the literature as effective for patients with Parkinson’s Disease. Another area of future research includes comparative studies on which types of cueing produces superior gait results. In order for this to be accomplished, however, there need to enough studies that are homogenous in methodology to perform a high quality meta-analysis. Therefore, future studies are also needed to determine the optimal frequency, duration, and intensity of cueing and intervention for gait effects.  |

**REFERENCES**

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| 1. Millage B, Vesey E, Finkelstein M, Anheluk M. Effect on Gait Speed, Balance, Motor Symptom Rating, and Quality of Life in Those with Stage I Parkinson’s Disease Utilizing LSVT BIG®. *Rehabil Res Pract*. 2017;2017:1-8. 2. Janssens J, Malfroid K, Nyffeler T, Bohlhalter S, Vanbellingen T. Application of LSVT BIG Intervention to Address Gait, Balance, Bed Mobility, and Dexterity in People with Parkinson Disease: A Case Series. *Phys Ther*. 2014;94(7):1014-1023. 3. Ebersbach G, Ebersbach A, Edler D, et al. Comparing Exercise in Parkinson’s Disease-the Berlin BIG Study. *Mov Disord*. 2010;25(12):1902-1908. 4. Farley BG, Koshland GF. Training BIG to Move Faster: The Application of the Speed–Amplitude Relation as a Rehabilitation Strategy for People with Parkinson’s Disease. *Exp Brain Res*. 2005;167(3):462-467. 5. Spaulding SJ, Barber B, Colby M, Cormack B, Mick T, Jenkins ME. Cueing and Gait Improvement Among People with Parkinson’s Disease: A Meta-Analysis. *Arch Phys Med Rehabil*. 2013;94(3):562-570. 6. Rocha PA, Porfírio GM, Ferraz HB, Trevisani VFM. Effects of External Cues on Gait Parameters of Parkinson’s Disease Patients: A Systematic Review. *Clin Neurol Neurosurg*. 2014;124:127-134. 7. Lim I, van Wegen E, de Goede C, et al. Effects of External Rhythmical Cueing on Gait in Patients with Parkinson’s Disease: A Systematic Review. *Clin Rehabil*. 2005;19(7):695-713. 8. De Icco R, Tassorelli C, Berra E, Bolla M, Pacchetti C, Sandrini G. Acute and Chronic Effect of Acoustic and Visual Cues on Gait Training in Parkinson’s Disease: A Randomized, Controlled Study. *Parkinsons Dis*. 2015;2015:1-9.9. Huang S-L, Hsieh C-L, Wu R-M, Tai C-H, Lin C-H, Lu W-S. Minimal Detectable Change of the Timed Up Go Test and the Dynamic Gait Index in People With Parkinson Disease. *Phys Ther*. 2011;91(1):114-121. 10. van Eijkeren FJM, Reijmers RSJ, Kleinveld MJ, Minten A, Bruggen JP ter, Bloem BR. Nordic Walking Improves Mobility in Parkinson’s Disease. *Mov Disord*. 2008;23(15):2239-2243.  |