CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

For a 68-year-old male with Hoehn-Yahr Stage 2 Parkinson's Disease, does Rhythmic Auditory Stimulation (RAS) and gait training compared to gait training without RAS, produce greater improvements in standing balance?

AUTHOR

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CLINICAL SCENARIO

A patient who has Hoehn-Yahr stage 2 Parkinson's Disease (PD) is recommended to physical therapy by his doctor. The patient has decreased balance, as well as Parkinsonian gait with decreased step length and shuffled steps. The patient would benefit from gait training to encourage larger, quicker steps. The use of Rhythmic Auditory Stimulation (RAS) has been used to improve gait in patients with PD to time their steps and encourage these improvements in gait characteristics. Increasing step length increases the time on one leg, which represents single limb stance. Single limb stance requires balance and often patients with decreased balance take shorter steps to reduce their time on a single limb. Based on the changes in gait associated with RAS and gait training, this PICO question was developed to see if there were any benefits to a patient's balance from this intervention. If there is a change in the patient's balance from gait training with RAS, that could help clinicians improve a patient's balance and gait in a more effective manner, targeting two problems with one intervention.

SUMMARY OF SEARCH

[Best evidence appraised and key findings]

- 8 studies were found that met the inclusion and exclusion criteria. They consisted of 3 randomized controlled trials, 1 randomized study with matched pairs for disease stage, 3 cross-sectional studies, and 1 single group pre-test post-test intervention study. 2 studies were reviewed in detail
- Rhythmic auditory stimulation produced statistically significant improvements for balance in patients with Parkinson's Disease, however there was no clinical significance
- The literature is limited for evidence about gait training with RAS and the effects it has on balance in patients with PD; future research is needed
- Future research would benefit from high quality randomized controlled trials analyzing the differences between conventional gait training and gait training with RAS

CLINICAL BOTTOM LINE

There was a lack of evidence comparing the results of gait training with RAS to conventional gait training. Statistically significant results were shown for improvements in balance, however the results were not clinically significant. The studies analyzed were poor to fair in quality but there was a lack of literature using balance as an outcome measure with this intervention. There may be benefits of using RAS for gait training to improve balance in patients with Parkinson's Disease, however more research is needed to confirm this. From the current evidence, using RAS to improve balance in patients with Parkinson's Disease will not produce clinically significant results. If a patient has severe balance impairments, other balance interventions should be used to improve their balance. If a patient has mild balance problems and RAS is used alongside gait training, there may be improvements in balance, however more research is needed to confirm this.

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

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

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Parkinson Parkinson* disease PD	Rhythmic Auditory Stimulation RAS Metronome Auditory cue* Gait train* Walk*	Gait train* Walk*	Static balance Stand* balance Balance

Final search strategy (history):

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

1. Parkinson's Disease [MeSH Terms]
2. Parkinson*
3. Rhythmic auditory stimulation OR auditory cue* OR metronome
4. (gait OR walk*) AND (train)
5. Static balance OR stand* balance OR balance
6. #1 AND #3 AND #4 AND #5
7. #2 AND #3 AND #4 AND #5
8. #1 AND #3 AND #4
9. #1 AND #3 AND #5
10. Balance
11. (gait OR walk*)
12. #1 AND #3 AND #10 AND #11
13. #1 AND #3 AND #10
14. **#1 AND #3 AND #11**

Line 14 was used for the final search strategy

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

Databases and Sites Searched	**Number of results**	**Limits applied, revised number of results (if applicable)**
PubMed	**101**	**Limits: English, published since 2000; this led to 91 results**
Cinahl	**61**	**Limits: English; led to 53 results**
Cochrane	**61**	**No limits applied**
Web of Science	**38**	**I was able to search this database with #1 AND #3 AND #10 AND #11 and did not apply any limits**

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
Published in English Published after 2000 Subjects had Hoehn-Yahr Stage 2 Parkinson's Disease or later
Exclusion Criteria
Not published in English Abstracts Conference proceedings Letters to the editor Dissertations Narrative review articles

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

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

Author (Year)	Risk of bias (quality score)*	Level of Evidence**	Relevance	Study design
Kadivar (2011)[1]	**PEDro Scale 5/11**	**2b**	**Moderate**	**Randomized with Matched Pairs for Disease Stage**
Song (2015)[2]	**PEDro Scale 4/11**	**2b**	**High**	**Randomized Controlled Trial**
Hove (2012)[3]	**Downs and Black^ 13/29**	**3b**	**Moderate**	**Cross-sectional**
Harro (2014)[4]	**PEDro Scale 7/11**	**1b**	**High**	**Randomized Controlled Trial**
Freedland (2002)[5]	**Downs and Black^ 15/29**	**3b**	**Low**	**Cross-sectional**
Suteerawattananon (2003)[6]	**Downs and Black^ 13/29**	**3b**	**Low**	**Cross-Sectional**
Ginis (2016)[7]	**PEDro Scale 7/11**	**1b**	**Moderate**	**Randomized Controlled Trial**
Ford (2010)[8]	**Downs and Black^ 15/29**	**3b**	**Low**	**Single Group Pre-test Post-test Intervention Study**

*Indicate tool name and score

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

^Modified Downs and Black was used, with a maximum of total score of 29. For number 27, 2 points were awarded if a power analysis was performed, 0 if not.

BEST EVIDENCE

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

- **Harro (2014)[4]- This study was a randomized controlled trial, with one of the highest levels of evidence and one of the lowest risks of bias from the selected studies. This study was of high relevance to my PICO question as it included balance measures directly. The study also used a gait training protocol with rhythmic auditory stimulation, relating it directly to the PICO. The subjects included in the study ranged from Hoehn-Yahr stages 1-3, which was part of the inclusion criteria, along with being published after 2000 and in English.**
- **Song (2015)[2]- Even though this study was high in risk of bias and a poorer quality study, it was more relevant to my PICO question than the other studies. This study is a randomized controlled trial that examined patients with Parkinson's disease including Hoehn-Yahr stage 2. They looked at rhythmic auditory stimulation with these patients and then examined balance afterwards using outcome measures, which is the intervention in the PICO question.**

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of The effects of speed-dependent treadmill training and rhythmic auditory-cued overground walking on balance function, fall incidence, and quality of life in individuals with idiopathic Parkinson's disease: A randomized controlled trail by CC Harro, MJ Shoemaker, O Frey, AC Gamble, KB Harring, KL Karl, JD McDonald, CJ Murray, JM VanDyke, EM Tomassi, and RJ Van Haitsma, 2014[4]

Aim/Objective of the Study/Systematic Review:

The goal of this study was to see the effects that speed dependent treadmill training (SDTT) and rhythmic auditory cues (RAC) with gait training had on balance, fall incidence, and quality of life in patients with Parkinson's disease. The study also wanted to see how the effects of these interventions changed from baseline and how the two training methods compared to each other. The study also addressed gait function with these two interventions but those results are included in another report.[9]

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.

- Randomized controlled trial
- Subjects were classified as freezers or non-freezers (based on the Freezing of Gait Questionnaire) and by age (those <70 years and those>70 years). Then the subjects were randomly assigned a group using a computer generated number to assign them to speed-dependent treadmill training or rhythmic auditory cueing.
- Single blinded study- the assessors were blinded but not the patients or therapists
- Allocation was not concealed
- Outcomes were measured at baseline, post-training, and three months post-training
- P value of <0.05 was considered statistically significant, however values in the main findings table are rounded to the nearest hundredth, so p values that equal 0.05 may be significant (denoted by *)

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

The authors were associated with Grand Valley State University in Grand Rapids, Michigan. This is likely where the interventions were performed, although it is not clearly stated.

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.

- 20 subjects with Parkinson's Disease (Hoehn-Yahr Stages 1-3). 10 in the SDTT group and 10 in the RAC group
- 4 subjects were Hoehn-Yahr Stage 1; 13 subjects were Hoehn-Yahr Stage 2; 3 subjects were Hoehn-Yahr Stage 3
- Eligibility Criteria: aged 18-89, having a diagnosis of idiopathic Parkinson's Disease (Hoehn-Yahr Stages 1-3), able to walk without physical assistances for five minutes without resting and with or without the use of an assistive device, on a stable medication schedule for Parkinson's Disease for the past month (reported by the subject's neurologist), and has functional vision and hearing (with or without aides) to understand cues.
- Excluded if they: scored less than 20 on the Saint Louis Mental Status Examination, had a history of other neurological disorders or vestibular disorders, had orthopaedic injuries that affected the ability to walk, had a history of Parkinson's Disease related deep brain stimulation, unable to speak and read English, or had an unstable medical status or unable to participate in moderate exercise.

- The subjects were recruited from the community and local clinical organizations with a convenience sample
- Mean age: 66.1 ± 10.21 years
- Gender Distribution: 13 males and 7 females
- Average time since onset of PD: 4.12±2.26 years
- RAC group: 8 males and 2 females, Stage 1: 1, Stage 2: 7, Stage 3: 1, average age 67.3
- SDTT group: 5 males and 5 females, Stage 1: 2, Stage 2: 6, Stage 3: 2, average age 64.9
- 2 participants used a standard cane for community ambulation
- The groups were all similar at baseline for characteristics and outcome measures.
- 22 subjects were randomized into groups however only 20 received the interventions as one declined to participate and one was omitted due to screening failure. There were no drop-outs during the intervention
- 1 subject was not included in a 3 month post-training follow up because they developed vertigo and the researchers did not want it to confound the data

Intervention Investigated

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

Control

The Speed Dependent Treadmill Training (SDTT) group participated in 30 minute training sessions three days a week for six weeks. The participants had a total of nine hours of training. The training was provided by three trained researchers. Each session provided one on one treatment and supervision. The participants completed a five minute warm-up at the beginning of each session at the subject's own comfortable gait speed. All training was performed on a treadmill with a safety harness for the patient. The participant then walked for five minutes at their subjective maximum "fast" walking speed (V1) followed by 2.5 minutes of recovery at their comfortable gait speed. They then walked again at their V1 speed followed by 2.5 minutes of recovery at their comfortable gait speed. If the participant was able to maintain the V1 speed without a decline in gait pattern, balance, or excessive cardiovascular fatigue, they walked for 5 more minutes at V2, a 5% increase from V1. If they were unable to maintain V1 in the previous 2 trials, they continued at the V1 speed for five minutes. They concluded each session with 5 minutes of walking at their comfortable gait speed for a cool-down.

The subjects were allowed to use the treadmill railings for the first minute of each speed change, to allow them to regain balance from the change in speed. Participants were encouraged to use a reciprocal arm swing. Researchers monitored the subjects' blood pressure, heart rate, and perceived exertion throughout the sessions.

Each week the training protocol was reviewed and the patient's comfortable gait speed was reassessed and their fastest gait speed from the previous session was then utilized as V1.

Participants received verbal cues intermittently for posture, stride length, and arm swing corrections. The participants were required to not attend any outside therapy that involved gait training or treadmill walking during the intervention time.

It is not specifically stated where these training sessions took place, but it was likely at Grand Valley State University.

Experimental

The Rhythmic Auditory Cued (RAC) group participated in 30 minute training sessions three times a week for six weeks. The participants had a total of nine hours of training. Three trained physical therapists provided the treatment in a small group setting, with 5 participants to one therapist. The training consisted of the participants walking around a track with individual iPods that played patient selected music. The patient was given music options from songs at a needed beat per minute (bpm) rhythm. The patients were instructed to walk on the beat, matching each step to the beat. The music selection came from PitchSwich which provides song options based on needed bpm and patients' preference in music genre.

The participants walked for 5 minutes as a warm up at their comfortable gait speed, based on a 10-meter walk test they performed. After the warm up, the patients walked for 10 minutes at a cadence 5-10 bpm faster than their comfortable gait speed. After the first ten minutes, the patients' cadence increased by 5-10 beats per minute for another ten minutes if they were able to maintain their gait pattern, balance, and without having excessive cardiovascular fatigue. If they were unable to maintain their gait pattern, balance, or experienced excessive cardiovascular fatigue, then they continued to walk for ten minutes at the same cadence. Each session ended with a five minute cool down at the patients' comfortable gait speed.

The comfortable gait speeds were reassessed each week, and the music playlists were altered accordingly. Cardiovascular responses were monitored throughout the sessions and patients were progressed when they

were able to meet the cadence changes. If participants had difficulty finding the desired beat in the music, the researchers assisted by clapping at the targeted bpm or using a metronome.

Participants received verbal cues intermittently for posture, stride length, and arm swing corrections. The participants were required to not attend any outside therapy that involved gait training or treadmill walking during the intervention time.

It is not specifically stated where these training sessions took place, but it was likely at Grand Valley State University.

Outcome Measures

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

All outcome measures were taken during the patient's on-phase of their Parkinson's Disease medication. Measures were taken at baseline, after the final intervention, and three months post-training. Three researchers conducted the measures and they were blinded to group assignment and did not participate in the intervention sessions.

Balance measures include:

- Rapid Step-Up Test (RST): This is a repeated step-up test to assess functional balance, strength, and lower extremity coordination. The participant repeatedly steps onto and off of an 8 inch step stool as quickly and safely as possible for ten repetitions and the researcher records their time in seconds.
- Berg Balance Scale (BBS): This measure assesses functional balance and standing balance, along with anticipatory and voluntary postural control. The maximum score is a 56 (0-56 range) with a 56 indicating excellent balance. The Minimum Detectable Change (MDC) for the BBS was found to be 5 points in patients with Parkinson's Disease.[10]
- Limits of Stability (LOS): This test is performed on the SMART EquiTest System. This test examines the effect the vestibular, visual, and somatosensory systems have on balance.[11] The measure is reported as a percentage for the end point excursion and composite end point excursion. The test requires patients to move their center of gravity to eight targets without losing balance.[11] The MDC for average end point excursion is 13.8%.[11]
- Motor Control Test (MCT): This test is performed on the SMART EquiTest System. This test examines postural responses to different size perturbations anteriorly and posteriorly.[11] Scores are reported for composite response latency, composite amplitude, large amplitude scaling, and medium amplitude scaling. The response latency time is reported in milliseconds (ms) and the amplitude scores are reported in degrees per second (°/s).[11] The MDC for latency time is reported to be 7.4 ms and the average amplitude is 2.7 °/s.[11]
- Sensory Organization Test (SOT): This test was performed on the SMART EquiTest System. This test measures postural stability under six different postural conditions.[11] Scores report the number of falls that occurr and the composite equilibrium score. Equilibrium scores could have been from 0 to 100, with 100 being the best score.[11] The MDC for the number of falls is 2.7 falls and the MDC for composite equilibrium is 11.6.[11]
- Activities-specific Balance Confidence Scale-16 (ABC-16): This is a self-reported measure that rates the participant's balance confidence on mobility tasks. The MDC was found to be 13%.[10]

Fall incidence and the Parkinson's Disease Questionnaire-39 were the other outcome measures used in this study, however the PICO question is looking for specific balance measures, so these were not included in this analysis.

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.]

SDTT n=10

Outcome Measure	Baseline	Post-training	3 months post-training	Within group comparison from baseline to post-training	Within group comparison from baseline to 3 months post-training
BBS (0-56)	50.9±5.4	52.5±3.8	54±2.7	p=0.12	p=0.08
RST (s)	21.4±7.8	19.86±7.1	18.23±5.26	P=0.05*	P=0.02*

LOS Composite (%)	65±11.6	59.6±13	65±9.2	P=0.05*	P=0.24
LOS (%)	59.5±16.8	55.5±15.8	63.9±14	P=0.35	P=0.83
MCT Composite Latency (ms)	133.8±11.1	134.2±8.8	131.3±9	P=0.89	P=0.47
MCT Composite Amplitude (°/s)	9±3.4	9.2±3.3	8.8±3.7	P=0.52	P=0.80
MCT large amplitude Scaling (°/s)	11.3±4.3	12.3±4.5	11.2±4.2	P=0.23	P=0.89
MCT medium amplitude scaling (°/s)	9.7±4.1	9.4±3.7	9.2±4.5	P=0.66	P=0.47
SOT Composite (0-100)	65.7±14.6	70.6±12.7	71±13.2	P=0.02*	P=0.18
SOT Falls (#)	1.9±1.8	1.2±1.7	1.3±1.9	P=0.05*	P=0.47
ABC-16 (%)	88.1±12.8	91.7±8.4	95.1±5.4	P=0.23	P=0.26

*denotes statistically significant improvement

RAC n=10

Outcome Measure	Baseline	Post-training	3 months post-training	Within group comparison of baseline and post-training	Within group comparison of baseline and 3 months post-training
BBS (0-56)	51±3.3	53.1±2.9	53.8±2.2	P=0.02*	P=0.01*
RST (s)	23.29±4.18	21.48±4.1	18.74±2.51	P=0.04*	P=0.002*
LOS Composite (%)	57.8±12	58.4±11.2	58.2±12.3	P=0.86	P=0.86
LOS (%)	52.1±16.1	56.2±13.9	53.2±17	P=0.29	P=0.78
MCT Composite Latency (ms)	137.2±6.9	137.4±7.4	136.9±6.5	P=0.91	P=0.85
MCT Composite Amplitude (°/s)	9.9±3.1	9.7±3	10.1±3.5	P=0.8	P=0.53
MCT large amplitude (°/s)	13±3.6	13±3.8	13±3.8	P=1	P=0.92
MCT medium amplitude (°/s)	10.5±3.6	10.3±3.3	11.2±4.1	P=0.8	P=0.15
SOT Composite (0-100)	68.4±10.7	73.1±7.5	72.7±10.5	P=0.05*	P=0.03*
SOT falls (#)	1±1.4	0.3±0.7	0.7±1.3	P=0.22	P=0.12
ABC-16 (%)	90.4±6.3	92.3±5	92.1±7.3	P=0.24	P=0.41

*denotes statistically significant improvement

For both interventions, there was a significant reduction in time for RST, which was maintained at the 3-month post-training follow up. The RAC group had a significant improvement in the BBS both at the post-training and follow-up testing. The SOT composite scores were significantly improved for both groups at post-training, but was only retained in the RAC group at the follow-up. The SDTT showed significant improvements in SOT falls and LOS composite at post-training, but retention was not shown at the 3-month follow up. There were no statistically significant improvements in the MCT group or the ABC-16, however the ABC-16 does have a high baseline score for both groups, so there may have been a ceiling-effect.

The study reports there was only one statistically significant difference between groups. The RST from baseline to 3 month post-training with a faster score retained for RAC group compared to the SDTT group, with a p value=0.018. However, the authors report that the study was underpowered to examine between group differences.

Original Authors' Conclusions

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

The authors concluded that externally cueing training for locomotion in patients with Parkinson's Disease works for either treatment method, SDTT or RAC. Both of these methods produced improvements in balance. The RAC group had better retention at the 3-month follow-up compared to the SDTT group for balance improvements. Neither intervention showed a significant reduction in fall incidence. "Addressing balance and gait-related fall risk factors is one important component of a comprehensive fall prevention program in persons with PD; therefore, externally-cued locomotor training paradigm should be incorporated in a multi-factorial approach to fall risk reduction." (page 554)[4]

Critical Appraisal

Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

PEDro Scale Score: 7/11- eligibility criteria: yes; random allocation: yes; concealed allocation: no; baseline comparability: yes; blinded subjects: no; blinded therapists: no; blinded assessors: yes; adequate follow-up: yes; intention-to-treat analysis: no; between-group comparisons: yes; point estimates and variability: yes

Strengths: This study randomly allocated subjects and blinded the assessors who performed the outcome measures. The subjects were similar at baseline across the two groups and they had adequate follow-up and reported between group comparisons with data.

Weaknesses: The allocation was not concealed for the randomized allotment and the patients and therapists were not blinded. While there was a between group comparison, the authors report the "study was under-powered to examine between group differences given our primary balance outcome measures." (page 549)[4] They gave one statistic between groups but no other data was reported. One outcome measure was reported to likely have had a ceiling effect (the ABC-16) so another outcome measure could have provided better data.

This study targeted multiple factors of Parkinson's Disease, including balance, falls risk, and gait changes, however the gait changes, and subsequently other outcome measures, were reported in another study. Having all of the results and data in one paper and report would make it more clear the full results of the study.

The participants were recruited through a convenience sample and the patients were community ambulators, so the results of the study may not be generalizable to more impaired patients, reducing the external validity. It was also reported that one patient developed vertigo so his 3-month follow up data was not reported. However, he was a frequent faller, high fall risk, and had freezing of gait episodes, so exclusion of his data may have skewed the results.

There was no "true" control group, but rather two different externally cued interventions. A group that performed conventional overground gait training as a control would be beneficial for a better comparison of the interventions. Having more subjects in the study would increase the power to allow for a comparison between groups to see if one intervention was superior.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

This study has some risk of bias, as evident by its PEDro score of 7/11 and the lack of blinding and concealment of allocation. However, of the available studies, this is one of the best available. It is a randomized controlled trial and a higher level of evidence study. Despite this, the study was unable to provide a good comparison between the two intervention groups due to a small sample size used.

The study found statistically significant improvements in balance and fall risk for multiple measures, however the MDC for these measures (BBS, SOT composite, and SOT falls) were higher than the change actually seen. This means that the results were statistically significant, but not clinically significant as the change needed to be higher to guarantee that the changes seen are not due to measurement error.

The one outcome measure that showed statistically significant improvements for both groups, the RST, did not have a MDC or MCID available in the literature. The RST's main research has been done on elderly and patients post-stroke. The test is considered "reasonable to recommend" across all Hoehn-Yahr stages by the Parkinson's Disease Evidence Database to Guide Effectiveness (PDEDGE) but they do note the lack of data for this patient population.[12] With a lack of MDC or MCID, it makes it hard to tell if the results would be clinically significant as well.

Despite the lack of clinical significance, this study does show that there is a potential for improvement in balance after interventions of RAC and SDTT. More research should be performed with a larger sample size and with a true control group. It would also be interesting for patients who are more impaired to participate in the study, so the potential for a ceiling effect is lessened and there would be more room for evident improvement. As the study stands, there is no negative harm of using these interventions, but there is not enough data to support a clinically important outcome.

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 targeted the patient in my PICO question as his age, diagnosis, and stage of diagnosis were all included in the subject sample. This study analyzed balance outcomes after intervention with RAS, however the data was only statistically significant. There was also not a comparison to conventional gait training and there was a lack of between group comparisons which would have told which intervention was superior.

Due to the lack of clinical significance, if a patient needs to improve their balance, then other interventions should be recommended.

The patient from the PICO was working on improvements in gait with RAS. There could be some benefits from that intervention for their balance, but if balance is the direct goal, then other interventions should be utilized as well to give the patient the best results.

(2) Description and appraisal of Rhythmic auditory stimulation with visual stimuli on motor and balance function of patients with Parkinson's disease by JH Song, PY Zhou, ZH Cao, ZG Ding, HX Chen, GB Zhang, 2015[2]

Aim/Objective of the Study/Systematic Review:

The objective of this study was to see if gait training with rhythmic auditory stimulation (RAS) and visual stimuli caused motor or balance changes in patients with Parkinson's Disease.

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.

- Randomized Controlled Trial
- The patients were randomly divided into the control and experimental groups using a random digits table
- The study did not report any information about blinding of any of the subjects, therapists, or assessors and it did not mention concealing allocation.
- Outcome measures were performed at baseline, at the end of training at 4 weeks, and at 8 weeks

- P-value of <0.05 was considered statistically significant

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

Xiangyang Hospital in China at the neurology department of internal medicine.

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.

- 116 patients with Parkinson's Disease
- Patients were selected from January 2011 to December 2014 for the treatment
- Eligibility Criteria: Parkinson's Disease diagnosis according to the Queen Square Brain Bank standard, no cognitive impairment according to the mini mental state exam, able to cooperate with the study requirements, and able to walk independently after taking their PD medications
- Excluded if: they had another neurological disease affecting gait, cardiopulmonary or bone and joint disease, or vision or hearing impairments
- Mean age was 66.1±7.9 in the control group and 65.7±8.1 in the experimental group
- Gender: 29 males and 27 females in the control group and 30 males and 26 females in the experimental group
- The average Hoehn-Yahr stage for subjects was 2.8±0.4 with an average of 6.7±3.1 years of the disease in the control group. The experimental group had subjects with an average Hoehn-Yahr stage of 2.9±0.5 and 6.9±2.9 years of disease.
- Both groups were comparable at baseline for their gender, age, course of the disease, mini mental state exam, and Hoehn-Yahr classification. The p-value being greater than 0.05 meaning there is no statistical significance between the groups.
- It was reported that 4 patients dropped out in each of the groups. The study reports there were 116 subjects but only gave background data for 112, so they may have been excluded from the results, however it is unclear as to when and why they dropped out.
- There was no information reported on the amount of subjects analyzed for follow-up

Intervention Investigated

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

Control

The control group was given anti-PD medications: Madopar, Piribedil sustained-release tablets, Pramipexole, and/or Entacapone. Each patient was evaluated and their medication regime was adjusted based on their course of condition. The regime was adjusted to be taken over four weeks depending on the patient's needs.

No information was given on who provided the medication, but the study was performed in the neurology department, so it was likely someone in that department. It seems that each patient had their medication dosage tailored to their specific disease stage and course of the disease, so the control subjects took their medication as they were instructed.

Experimental

The experimental group received the same medication regimen for four weeks as the control group did. They also participated in RAS and visual auditory stimulation with gait training. The participants had their normal walking speed calculated which was used to determine the rhythm for the treatment. For the RAS part, the patient was asked to step on the beat produced by a beat box software. While they were doing that, they were also asked to step on a ribbon (20 cm long and 3 cm wide) that was spaced according to the patients' step length. The rhythm and step length of each treatment was adjusted each day as needed.

There is no information given on who led the interventions. All treatment was provided at the neurology department at the Xiangyang Hospital in the China.

The participants trained for 30 minutes a day, 5 days a week for 4 weeks. A total of 20 sessions were held.

Outcome Measures

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

Step frequency, step length, gait speed, Unified Parkinson's Disease Rating Scale (UPDRS) part II, UPDRS part III, 6-minute walk test, and the Berg Balance Scale (BBS) were the outcome measures used in this study, however the BBS is the only one that addresses balance specifically.

The BBS tests both static and dynamic balance with a score ranging from 0 to 56, with a 56 representing the best balance.[10] The MDC for the BBS is 5 points.[10] It was not reported who administered the test, but testing took place at the neurology department in the hospital.

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.]

	Cadence	Step Length	Gait speed	UPDRS part II	UPDRS part III	6-minute walk test	BBS	P-value
F value	821.080	501.991	171.580	22.147	94.989	3242.764	542.646	0.000
F value of time	407.172	186.826	95.689	61.444	59.375	941.582	137.708	0.000
Time x F value	405.777	340.622	110.457	20.689	40.866	1081.266	103.178	0.000

This is the only statistics and data that the study reported. The study provided a graph displaying each outcome measure at baseline, 4-weeks, and 8-weeks for both the control and experimental groups, however, there was no data provided, just a graph (page 2004).[2] The p-values all represent that there was statistical significance of the results, however there is no other data to base these values on.

From the graph provided on page 2004, the groups seem to be similar at baseline across all conditions. Note, all of this information is assumptions from the graph provided and cannot be based on numbers but rather estimates of the values. There seems to be improvements in stride length, cadence, gait speed, UPDRS part II scores, UPDRS part III scores, the 6-minute walk test, and the BBS by the eight week mark, and these seem to all be statistically significant as well.

The data in the above graph shows there is statistically significant improvements between the groups, favouring the experimental group. There is also an improvement seen within the experimental group from baseline.

Unfortunately, the lack of data makes it hard to determine any other conclusions from the study.

Original Authors' Conclusions

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

The authors concluded that rhythmic auditory stimulation along with visual stimulation and gait training improves gait and balance in patients with Parkinson's Disease.

Critical Appraisal

Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

- PEDro Scale Score: 4/11- eligibility criteria: yes; random allocation: yes; allocation concealed: no; comparable at baseline: yes; blinding of subjects: no; blinding of therapists: no; blinding of

assessors: no; adequate follow-up: no; intention-to-treat: no; between-group comparisons: yes; point measures and variability: no

- Many aspects in the study were not reported, so they were assumed not there. According to this information, there was no blinding of any of the subjects, therapists, or assessors. There was no concealed allocation, there were no point measures and variability data provided, and the follow-up was not provided. All of these aspects are weaknesses of the study.
- The strengths of the study are that they did randomize the subjects, had similar baseline results for the groups, and they did report values for comparing the groups at the end.
- While this study does provide statistically significant results, there is a high risk of bias because of lack of information and data. The results of the outcome measures are only reported graphically with no values, making it difficult to interpret the data.
- There was no data for the amount of patients that were included in the data at each testing, which is important to know if there was significant follow-up
- It would have also been beneficial if the control group participated in conventional gait training instead of only receiving medication. The experimental group walked for 30 minutes every session, which likely helped to improve their results compared to a group that did not participate in any functional activity
- The p-values are all reported as 0.000, but the lack of data provided implies caution should be taken with interpreting these results

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.]

From the data provided and the graph, there seems to be a statistically significant improvement on balance and gait for the experimental group, however it is hard to tell from the graph provided. The p-values represent statistically significant improvements so it seems that it was effective, however any treatment may be effective compared to a control group who did not participate in any form of gait training. The MDC for the BBS is 5 points, and while the data is not provided, if you assume the graph on page 2004 is accurate, there seems to be a 5 point difference from baseline to the 8 week mark for the BBS, which would show a clinically significant improvement for the within group comparison. However, compared to the control group at 8 weeks, the five points do not seem to be reached. The f-values reported and their p-values show that there was a statistically significant difference between groups, within groups at the time points, and between groups at times after baseline.

The authors concluded that the intervention improved balance, but the poor quality of the study and the lack of data provided makes it hard to trust the results. This intervention may be effective, and it likely was compared to a control group who participated in no functional activities, however more research and evidence is needed to confidently say RAS improves balance in patients with PD.

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.]

The study included RAS for gait training along with visual stimuli. The visual aspect was not included in the PICO question; however, it could be added if it was effective. The patients included in the study include the patient demographics from the PICO question for his age, gender, and Hoehn-Yahr stage. From the data provided, it seems that gait training works to improve balance for patients with Parkinson's Disease, however the clinical significance cannot be determined. The poor quality would make it hard to use this study as evidence-based support for use of the treatment with a patient. The PICO question did address a comparison with conventional gait training, which was not used in this study. Having a comparison of the intervention to a conventional gait training intervention would be useful to see if the results were significant. The study also required 5 days per week training for 30 minutes, which would be difficult to perform in a clinic given visit limitations.

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.]

Evidence Synthesis:

The results from the two articles has poor backing for the use of RAS with gait training to improve balance for patients with Parkinson's Disease. Both studies showed statistically significant improvements from baseline to post-training in their balance with the BBS, however the clinical significance could not be determined for one study due to the lack of data provided and the data was not clinically significant for the other. The Harro study did not have enough power to compare the two interventions introduced, and while the p value shows significant improvement for the Song study, there was not data provided to individually interpret. The RST in the Harro article was the only measure that was compared between groups and was found to be statistically significant with improvements found in the RAC group, however there is a lack of evidence on the RST in patients with Parkinson's Disease, and Harro et al reported the study was underpowered to examine between group differences.

There is a need for higher quality studies, especially comparing the effects of RAS with gait training on balance and comparing it to conventional gait training measures to see if there are benefits. To answer the PICO question, it does not seem that there is enough evidence to support using RAS with gait training to improve balance in patients with Parkinson's Disease. There may be benefits of the use of this method, however if a patient has balance impairments, other balance interventions would likely need to be implemented to get clinically significant improvements. If a patient has a mild balance impairment and gait training is needed, then using RAS to improve gait may also improve the balance, the current research is just unable to fully support it. For the patient in the PICO question, it would be better to utilize separate balance interventions along with his gait training to get the best results.

Implications for clinical practice:

The current data does not support clinical use of RAS with gait training in patients with Parkinson's Disease to improve balance. The clinical scenario that sparked the PICO question and article analysis was asking if RAS with gait training also had benefits for balance along with gait changes. The statistical significance of the articles and the authors conclusions all support improvements in balance, however there were no clinically significant changes seen. The quality of the studies could be improved and there could be actual changes occurring that are not represented in the study, which is where future research is needed. From the current evidence, if the patient has decreased balance, other balance interventions will likely need to be implemented to help improve balance overall. If a patient has a small balance impairment then RAS with gait training may make the needed improvement, but other balance interventions would need to be used until further evidence is able to ensure the improvement.

Implications for future research:

Future research is still needed for this topic. Future research should include a larger sample size to be able to better compare the experimental and control groups. The studies should also be of better quality, ensuring blinding and methods of reducing bias to allow for true results. A control group that performs conventional gait training should also be used in future research to see if this intervention is able to improve balance.

The two studies analyzed in this report had a higher risk of bias, however these were the only studies that truly analyzed the effects of RAS on balance using balance outcome measures. There are higher quality studies that incorporate RAS and gait training with this patient population, however their outcome measures looked at differences in stride length, which implies improvements in balance, however it does not use a true balance outcome measure. More studies that incorporate a balance outcome measure, such as the BBS, would be beneficial to see if there are actually balance improvements when gait training with RAS.

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