

CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

In a 65 year old adult male with mobility deficits resulting from a stroke that occurred 3 months ago, are balance training exercises more effective than gait training for improving gait speed?

AUTHOR

Prepared by	Stacy Harris	Date	11/21/17
Email address	stacy_harris@med.unc.edu		

CLINICAL SCENARIO

The patient is a 65 year old male who presented to an outpatient physical therapy clinic 3 months post-stroke.

At evaluation, the patient had mild left-sided upper and lower extremity weakness. He was able to ambulate with supervision using a single point cane, but required contact guard to ambulate without an assistive device. He feels comfortable walking around at home, but expressed interest in improving his walking ability so that he can go out shopping and attend orchestra performances with his wife again. His time and gait speed during the 10 meter walk test without his cane were 23.4 sec and 0.43 m/s, respectively.

Gait speed in a clinic setting is often used to determine a patient's readiness for ambulation in the community. It is predictive of falls risk as well as safety risk with community participation (such as being able to cross a street before the crosswalk light ends). Individuals with stroke whose gait speed is <0.4 m/s are likely to be household ambulators, 0.4 m/s to 0.8 m/s are likely limited community ambulators, and >0.8 m/s are likely unrestricted with community ambulation.¹

Gaining evidence based knowledge regarding the effectiveness of balance training exercises vs. gait training in increasing gait speed would improve the efficiency and effectiveness of the instruction provided to patients similar to this man, improving their gait speed and resulting in increased patient safety in the community setting.

SUMMARY OF SEARCH

[Best evidence appraised and key findings]

- No literature was found that clearly and directly compared gait training with balance exercises for improving gait speed in a population similar to that of the clinical question. Studies with interventions focusing only on gait training were more common than studies focusing only on balance exercises.
- Body weight supported treadmill training in combination with overground gait training produced clinically significant improvements in gait speed by 1 year, regardless of whether the interventions began at 2 or 6 months post-stroke.
- A balance and strengthening exercise home program was just as effective as treadmill/overground gait training in improving gait speed.

CLINICAL BOTTOM LINE

In a 65 year old adult male with mobility deficits resulting from a stroke that occurred 3 months ago, either body weight supported treadmill training in combination with overground gait training, or a balance and strengthening program, will produce a clinically significant improvement in gait speed that is maintained at 1 year post stroke.

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

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

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	Intervention (or Assessment)	Comparison	Outcome(s)
stroke CVA cerebrovascular accident	balance training balance exercise* balance rehab*	gait training walk*	gait walk* ambulat* speed velocity

Final search strategy (history):

Show your final search strategy (full history) from PubMed.

#1 – stroke [MeSH term]

#2 – balance AND (training OR exercise* OR rehab*)

#3 – gait training OR walk*

#4 – (gait OR walk* OR ambulat*) AND (speed OR velocity)

#5 – #1 AND #2 AND #3 AND #4 (**More results desired**)

#6 – stroke OR CVA OR cerebrovascular accident (**Added to produce more results**)

#7 - #6 AND #2 AND #3 AND #4 (**Final Search + filters below**)

Filters: Randomized Controlled Trial; Publication date from 2000/01/01 to 2017/12/31; English; Aged: 65+ years

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	384	60 – Applied Filters: RCT, published after year 2000, English, Age 65+
CINAHL	215	78 – Limited to peer reviewed, published after year 2000, English, Male, 65+
PEDro	64	“balance training, gait training, gait speed, stroke”

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
Prioritization of RCTs Published after 2000 Studied a population of adults (65+) who had experienced a stroke Participants ambulate independently with or without AD Gait speed measured using short distance (e.g. 10 meter walk test) Published in English

Exclusion Criteria

Abstracts, conference proceedings, letters to the editor, dissertations, narrative review articles
Not published in English

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
Vahlberg (2017) ²	<u>PEDro Score: 9/11</u>	Level 1b	Mod	RCT
Ng (2008) ³	<u>PEDro Score: 7/11</u>	Level 1b	Mod	RCT
Dobkin (2014) ⁴	<u>QUIPS Tool:</u> Low Risk – 3/6 Mod. Risk – 1/6 High Risk – 2/6	Level 2b	Low	Retrospective, Cohort (Prognostic study)
Duncan (2011) ⁵	<u>PEDro Score: 8/11</u>	Level 1b	High	RCT
Tong (2006) ⁶	<u>PEDro Score: 8/11</u>	Level 1b	Mod	RCT
Laufer (2001) ⁷	<u>PEDro Score: 6/11</u>	Level 1b	High	RCT
Morone (2014) ⁸	<u>PEDro Score: 8/11</u>	Level 2b (only 60% follow up)	High	RCT
De Rooij (2016) ⁹	<u>AMSTAR Score: 6/11</u>	Level 1a	Low	Systematic Review and Meta-Analysis of RCTs

*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:

- **Duncan (2011)⁵**
 1. High Quality
 2. Good Level of Evidence
 3. Both interventions align with my clinical question, gait intervention aligns best – Body weight supported treadmill training and over ground walking vs. HEP (including well described static and dynamic balance exercises)
 4. Gait speed addressed as an outcome measure (10 meter walk test).
 5. Program is 12 weeks (3 months), follow up is at 1 year (12 months).
 6. Inclusion criteria included patients 45 days to 2 months s/p stroke.
 7. Large sample size – 408
- **Vahlberg (2017)²**
 1. High Quality
 2. Good Level of Evidence
 3. Well described balance exercise intervention vs. true control (allowing “regular activity”)

4. **Gait speed addressed as an outcome measure (10 meter walk test).**
5. **Program is 3 months, follow up is at 6 and 15 months.**
6. **Downside: Rated "Mod" relevance because inclusion criteria required patients be 1 year s/p stroke**

Final justification for choices:

Duncan et al.⁵ was an ideal choice because it is a high quality study, and was rated "high" relevance because interventions were entirely gait training compared with almost entirely balance/strength exercises, participants were the ideal time post-stroke (2 months), and gait speed was an outcome measure.

Laufer et al.⁷ was rated "high" relevance because of the time post stroke, gait speed as an outcome measure, and interventions included overground and treadmill walking. However, the intervention was regular therapy for the majority of the session and only 8 minutes of gait training, and the study was of fair quality.

The Vahlberg et al.² intervention was entirely balance exercises (aside from warm up) with incorporated strengthening components, had gait speed as an outcome measure, and was a high quality study. However, the time post stroke does not align with my clinical question so it was rated "mod" relevance.

Given the choice between Laufer and Vahlberg, I decided to choose Vahlberg et al. as the second article since the balance intervention aligned more with my intent behind the clinical question and it was a higher quality study, even though the time-post stroke did not match my patient population ideally.

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of "Body-Weight-Supported Treadmill Rehabilitation After Stroke" by Duncan et al., 2011.⁵ ("Protocol for the LEAPS Trial" by Duncan et al., 2007¹⁰ cited as needed.)

Aim/Objective of the Study/Systematic Review:

This study aimed to determine if usual care (traditional physical therapy and/or occupational therapy interventions) along with body weight supported treadmill training beginning at either 2 months or 6 months post-stroke is more effective than progressive strengthening and balance exercises provided by a physical therapist in-home 2 months post-stroke in increasing the number of participants with higher functional walking levels at follow up 1 year later (determined by gait speed). They also hypothesized that the earlier body weight supported treadmill training group would see greater increase in gait speed than the later group.

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 control trial
- 3 group design
- Participants randomized at 2 months post stroke into one of the three groups: Body weight treadmill training-2 months, Body weight treadmill training-6 months, strength/balance home therapy; 7:7:6 ratio, respectively.
- Randomization was done using a web based system with a stratified method so that each group would have a similar proportion of each severity of baseline impairment (<0.4 m/s and ≥0.4 to <0.8 m/s).¹⁰
- Single blinded study – assessors are blinded, but not participants or therapists.
- Allocation to group was not concealed
- Primary Outcome: Gait speed measured by 10 meter walk test at 2 months, 6 months, and 1 year post stroke.
- An a priori power analysis was conducted to determine sample size using a two-sided significance level of 0.05 to determine if "Locomotor training" (pg. 4) beginning at either 2 or 6 months is more effective than a home-based strengthening/balance program in improving gait function following stroke. The assumption was made that at least 30% of the participants allocated to the in-home program would increase their level of gait function. Based on this assumption, they calculated that they needed "400 participants to detect a clinically relevant effect size of 20%, with 85% power, adjusting for an estimated loss to follow up rate of 15%." (pg. 4)

Setting

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

The body-weight treadmill group interventions were located in several inpatient rehabilitation centers in Florida and California; although it was not explicitly stated, it seems that participants stayed at home as "travel to the treatment site" (pg. 3) was mentioned in the eligibility criteria.

The home based strength/balance intervention was located in participant's homes.

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.

- In this study, there were 408 participants with diagnosis of stroke: 139 in the 2 month group, 143 in the 6 month group, and 126 in the home therapy group.
- Participants were excluded if they had another major coexisting medical condition, no paresis in the leg on the side of the body affected by stroke, were not expected to be discharged home, and/or had a self-selected gait speed faster than 0.8 m/s.
- Participants were recruited by the 6 intervention sites in California and Florida if they were adults, the stroke had occurred within 45 days prior to entry into the study, they had the ability to walk at least 3 meters with one person assist or less, and had the ability to follow 3 step instructions.
- At 2 months post-stroke, all participants were required to pass an exercise tolerance test and baseline measures were taken prior to randomization into 1 of 3 groups.
- Mean age of participants was 62 ± 12.7 years. 54.9% participants were male. At the time of randomization, the mean number of days post-stroke was 63.8 ± 8.5 days. 53.4% had a gait speed of more than 0.4 m/s and 46.6% had a gait speed between 0.4 m/s and 0.8 m/s. 99.5% of participants scored between 2 and 4 on the modified Rankin scale. P values for between group demographic variables: male sex ($p=0.19$), age onset of stroke ($p=0.08$), time from stroke to randomization in days ($p=0.40$), side of hemiparesis ($p=0.42$), type of stroke ($p=0.94$), modified Rankin score ($p=0.19$), cognitive function ($p=0.87$), and gait speed ($p=0.96$), are all NOT statistically significant, indicating there is no significant variance between the groups, so the groups are comparable.
- Number lost to follow-up was not specifically reported, however, it was noted that the interventions were not completed by 13%, 17%, and 3%, of the 2 month, 6 month, and home therapy groups, respectively. This results in approximately 46 participants (11%) out of 408 lost to follow up.

Intervention Investigated

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

Control

- Active-control group utilizing home exercise program by physical therapist
- Training started 2 months post stroke.
- Three 90-minute sessions each week for 12 weeks (36 sessions total)¹⁰
- Exercises were divided into four categories: Upper/Lower extremity exercises, sitting balance exercises, static standing balance exercises, and dynamic standing balance exercises.¹⁰
- Participants were progressed through exercises by physical therapist individually as they were able to achieve certain exercises outlined in the treatment protocol.¹⁰
- Following each session, all home exercise participants were encouraged to walk on a daily basis.¹⁰
- All participants in this group were evaluated for need of an assistive device after the 12th, 24th, and 36th session.¹⁰
- Progression of each category of exercise in treatment protocol¹⁰ (pg. 15)
 - **Upper/Lower Extremity Exercises:** Gravity eliminated – active assisted, then active. Against gravity – no Theraband, then progression of Theraband in the following order: yellow, red, green, blue, black, silver.
 - **Sitting Balance Exercises:** Equal weight bearing, then weight shift by alternating lifting each leg. Same-side anterior (then posterior) diagonal reaching with non-paretic upper extremity. Opposite-side anterior (then posterior) diagonal reaching with paretic upper extremity. Opposite-side anterior (then posterior) diagonal reaching with non-paretic upper extremity. Same-side anterior (then posterior) diagonal reaching with paretic upper extremity.
 - **Static Standing Balance:** Feet shoulder width apart for 30 sec. – eyes open, then eyes closed. Feet together for 30 sec. – eyes open. Feet in semi-tandem stance with paretic leg in front – eyes open, then eyes closed. Feet together for 30 sec. – eyes closed. Feet in semi-

tandem stance with paretic leg behind – eyes open, then eyes closed. Feet in semi-tandem stance with paretic leg in front on a step – eyes open, then eyes closed. Feet in semi-tandem stance with non-paretic leg in front on a step – eyes open, then eyes closed.

- **Dynamic Standing Balance:** Catching a ball – first from front, then towards non-paretic side, then towards paretic side. Turning – first towards paretic side, then towards non-paretic side.
- Participants were permitted to receive usual care from an outside source, which was traditional physical therapy or occupational therapy, during the 1 year period of the study either during or outside of the intervention time period. All outside therapy time (in minutes) was recorded on monthly calendars and regularly submitted to the intervention therapists.¹⁰

Experimental (two groups)

- “Locomotor Training Program”¹⁰ (pg. 10) with body weight supported treadmill training and overground gait training.
- **Two groups:** one group started the below training at 2 months post stroke, the other group started the below training at 6 months post stroke.
- Three 90-minute sessions each week for 12 weeks (36 sessions total)¹⁰
- Step training for 20-30 minutes using body weight supported treadmill with verbal and manual assistance from physical therapists, as needed. Treadmill was followed with 15 minutes of overground gait training. Rests were given as needed so that entire session may last up to 90 minutes (including warmup up, stretching, and cool down).¹⁰
- Walking at home and/or in the community daily was encouraged.¹⁰
- All participants in this group were evaluated for need of an assistive device or brace after the 12th, 24th, and 36th session.¹⁰
- Training was broken into 3 Phases¹⁰
 - **Phase 1 – Sessions 1-12:** Treadmill – 1.6 mph minimum, 30-40% body weight support, goal of 4 x 5 min bouts to equal 20 minutes, and manual assistance with trunk and lower extremities. Overground – attempt new treadmill skills, education for home walking.
 - **Phase 2 – Sessions 13-24:** Treadmill – 2.0-2.8 mph, 20-35% body weight support, goal of less bouts of walking and greater duration of bouts to equal 20 minutes, and decreased manual assistance with trunk and lower extremities. Overground – attempt new treadmill skills, transfer learned skills and speed, introduce assistive device or orthotic, if needed.
 - **Phase 3 – Sessions 25-36:** Treadmill – 2.0-2.8 mph or higher, 0-20% body weight support, increase total time to 30 minutes, and no manual assistance with trunk or lower extremities. Overground – transfer learned skills and speed, work on adapting to environment including “stairs, curbs, terrain and change speed, stops, and turns.” (pg. 14)
- Participants were permitted to receive usual care from an outside source, which was traditional physical therapy or occupational therapy, during the 1 year period of the study either during or outside of the intervention time period. All outside therapy time (in minutes) was recorded on monthly calendars and regularly submitted to the intervention therapists.¹⁰

Outcome Measures

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

- All outcomes were measured by an assessor that was blinded to the intervention group at one of the clinic locations.
- The Primary Outcome measure in this study is also the outcome of relevance to the clinical question for this CAT.
 - Gait Speed at usual pace was measured using the 10 meter walk test, in m/s
- Secondary Outcome measures include:
 - 6 minute walk test, distance recorded in meters
 - Number of steps taken each day based on fitness tracker feedback
 - Stroke Impact Scale, 0-100 points possible (0 indicates complete dependence while a higher score indicates increased independence). Specific focus on ADL-IADL, Participation, and Mobility domains.
 - Fugl-Meyer Assessment of Motor Recovery in legs, 0-34 points possible (0 indicates absence of movement, 34 indicates full function)
 - Berg Balance Scale, 0-56 possible points (0 indicates unable to balance, 56 indicates ability to balance independently without difficulty)
 - Activities-Specific Balance Confidence Scale, 0-100 points possible (0 indicates no confidence in being able to maintain balance during described activities, 100 indicates complete confidence in being able to maintain balance during described activities)
 - Number of falls were recorded and reported by participants, including the extent of the fall.

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.]

The primary outcome measure of gait speed measured using the 10 meter walk test is also the outcome of relevance to the clinical question for this CAT. Findings are as follows:

Gait Speed (m/s)				
Variable (time post-stroke)	Treadmill 2 months N=139	Treadmill 6 months N=143	Home Exercise N=126	P-Value
Baseline (2 months)*	0.37±0.22	0.38±0.23	0.39±0.22	0.62
Change from baseline at 6 months*	0.25±0.21, (0.22, 0.28)	0.13±0.14, (0.11, 0.15)	0.23±0.20, (0.20, 0.26)	<0.001
Change from baseline at 12 months*	0.23±0.20, (0.20, 0.26)	0.24±0.23, (0.20, 0.28)	0.25±0.22, (0.21, 0.29)	0.67

*scores reported as mean±SD in m/s, (95% CI)

- At 6 months post-stroke, the earlier start (2 months) treadmill group and the home exercise group achieved a similar positive within-group effect size in mean gait speed. This increase was maintained at one year post-stroke.
- The later start (6 months) treadmill group had an increase in gait speed from study enrollment to program start, and achieved a within-group effect size from baseline to one year that was positive and similar to the other two study groups.

Absolute Effect Size of Mean Change in Gait Speed (m/s)		
Between-Group Comparison	6 months	12 Months
Treadmill-2 mo. vs Home Exercise*	0.02, (-0.03, 0.07); T2	0.02, (-0.07, 0.03); HE
Treadmill-6 mo. vs Home Exercise*	0.10, (-0.14, -0.06); HE	0.01, (-0.06, 0.04); HE
Treadmill-2 mo. vs Treadmill-6 mo.*	0.12, (0.08, 0.16); T2	0.01, (-0.06, 0.04); T6

*effect size in m/s, (95% CI); T2-favored Treadmill-2 mo., T6-favored Treadmill-6 mo., HE-favored Home Exercise

- At one year, the between-group effect sizes comparing the earlier (2 months) treadmill group and later (6 months) treadmill group with the home exercise group both favored the home exercise group.
- The between-group effect size between the two treadmill groups favored the groups that began at 6 months.

Finally,

- The authors reported that the primary study outcome of transitioning from one functional level to a higher functional level (based on gait speed: <0.4 m/s, ≥0.4 to <0.8 m/s, or >0.8 m/s) was met by 52.0% of all participants – separate group outcomes were not reported.
- They also reported the adjusted odds ratio comparing the earlier treadmill group with the home exercise group (0.83, 95% CI: 0.50, 1.39) and the adjusted odds ratio comparing the later treadmill group with the home exercise group (1.19, 95% CI: 0.72, 1.99).
- Additionally, the authors reported that for each 1 year increase in participant age, the adjusted odds ratio for the effect on the primary outcome of improving functional level was 0.95 (95% CI: 0.93, 0.97).

Original Authors' Conclusions

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

"Locomotor training" (pg. 2) beginning at either 2 months post stroke or 6 months post stroke does not result in greater improvements in gait speed than a progressive home exercise program delivered by a physical therapist. At 1 year post stroke, all study groups achieved a similar amount of increase in gait

speed, however, the 2 month treadmill training group and home exercise group achieved this increase around 6 months and were able to maintain their gait speed at the 1 year follow up. Regardless of intervention, beginning treatment sooner seems to indicate an earlier improvement in walking ability.

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: 8/11 based on-
 - Eligibility criteria specified: Yes; Random allocation: Yes; Allocation concealed: No; Comparable at baseline: Yes; Blinding of subjects: No; Blinding of therapists: No; Blinding of assessors: Yes; Adequate follow-up: Yes; Intention-to-treat analysis: Yes; Between-group comparisons: Yes; Point measures and variability: Yes.
- Allocation to group was not concealed; the study coordinator entered the baseline data into the computer and then received the group assignment. This process could have biased the outcomes as they were in control of entering information and group assignment. Additionally, participants and therapists were not blinded to group allocation and could have biased the outcomes in some way. However, the assessor was blinded to group allocation and additional measures were taken to avoid revealing group allocation (educating participants on not revealing group allocation during measurements, posters in evaluation lab as an additional reminder, assessor and participants were asked to complete an assessment to determine if allocation was indicated, and measurements were completed at locations and times when treatment was not occurring).
- The baseline demographics of each group were comparable due to the stratified randomization, which is a strength for this study. Follow up at 1 year was also good, as only 11% were lost.
- Limitation noted by authors: there was not a true control that did not receive any physical therapy intervention.
- Additional limitations: 1) There were 6 intervention sites in two states with multiple trained therapists, as well as multiple therapists administering the home exercise program. Even though training occurred for each intervention therapist, there is a risk of treatment evolving at different sites without regular face-to-face communication between therapists. 2) Due to the delayed start of one intervention group, all participants were permitted to attend "usual care" (pg. 2) outside the interventions of the study. There is no real way of knowing how that specifically affected the outcomes of each group (confounding variable). 3) The control group not only included interventions, it did not include interventions common to all intervention groups (e.g. only usual care). The effect of body weight supported treadmill training cannot completely be known without similar baseline interventions across all groups.
- This study was able to obtain 408 participants and had a loss to follow up of only 11%, which satisfied the sample size determined necessary for 85% power in their a priori power analysis. So there is an 85% probability that a Type II error was not made in this study.

Interpretation of Results

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

The authors reported that the within-group effect sizes for all groups at one year were statistically significant with a p-value of $p < 0.001$. This is in line with the 95% CI's that were calculated independently and included in the results above. At 6 months post-stroke, the within-group effect sizes for the earlier start (2 months) treadmill group and the home exercise group were also statistically significant based on interpretation of their CI's. In the Gait Speed outcome data table, the p-value of 0.62 indicates that the gait speed of the three groups were comparable at baseline, and the p-value of 0.67 indicates that the gait speed was similar (or lacking variance) at 1 year post stroke.

The within-group effect sizes for every study group were clinically significant,¹ with the mean change ranging from 0.23 m/s to 0.25 m/s. At one year post-stroke, although the between-group absolute effect sizes are both in favor of the home exercise group, neither effect size is statistically significant based on the CI's. The between-group effect size between the two treadmill groups is also not statistically significant. Regardless of statistical significance, the effect sizes are also so small (0.01 m/s to 0.02 m/s) that they also do not demonstrate a potential clinically significant difference.

The authors reported that, of the 52.0% of participants that transitioned from one functional level to a higher functional level, there was no significant difference between the groups who made this transition. They also did not determine there to be a significant interaction between the severity of impairment at baseline and when the participant began the treadmill training (2 or 6 months) on overall change in gait speed. Data on these conclusions was not provided in the study results.

The adjusted odds ratio comparing the earlier treadmill group with the home exercise group and the adjusted odds ratio comparing the later treadmill group with the home exercise group indicated no significant

difference between groups based on the CI's. For each 1 year increase in participant age, the adjusted odds ratio for improving functional level was statistically significant (0.95, CI: 0.93, 0.97), indicating decreased chance of improving functional level as age increases.

Even though all groups saw statistically significant and clinically significant improvement, based on the study design it is unknown whether the improvement was due to the study interventions, if the usual care that was received outside of the study had any confounding effect, if the lack of blinding of the participants and therapists caused any influence of bias, or if the different sites/therapists delivered the interventions exactly as described in the protocol. However, since the baseline measures and demographics of each group were comparable, that is a strength in terms of reducing the chance of bias. The lack of a true control group, or even a control group that only provided usual care, also makes it difficult to know if body weight supported treadmill training would be more effective on its own. However, since they were able to achieve 85% power, it is likely that the reported effects of the interventions are correct.

It is reasonable to conclude that the interventions each group received, including some usual care, are effective in creating a clinically significant change in gait speed that will be maintained 1 year post stroke, and that no intervention/group was any better, or more effective, than another.

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 included a patient population that was similar to the patient in my clinical scenario in the characteristics of age, time post stroke, 10 meter gait speed at baseline, and cognitive ability. The results suggest that any of the study group interventions would have been effective in creating a clinically significant and lasting change in my patient's gait speed. Given his increased age (near the mean age of 62 ± 12.7 for the study population of adults >18 years), his baseline functional level (gait speed of 0.43 m/s), the within-group effect size (~ 0.24 m/s), and the authors results indicating that 52% of participants moved up in functional level (with older participants having less chance than younger), it is unlikely that he would increase his functional level to >0.8 m/s with these interventions.

In deciding which intervention to utilize for his treatment, at a minimum, I would choose to implement the treadmill based training or the exercises from the home program that began 2 months post stroke. Even though the treadmill training group that began their intervention at 6 months was able to achieve a within-group effect size very similar to the other groups by 1 year, the other two groups improved their gait speed to this degree before the 6 month groups even began treatment. Since the effect size is essentially the same, I would prefer to improve his gait speed sooner rather than later. However, this does bode positively for a patient who may present to outpatient therapy much later following their incidence of stroke.

When deciding between the body weight supported treadmill training and the exercises (mostly static and dynamic balance exercises) from the home program, the decision would likely fall on the equipment available at the clinic. At the outpatient clinic where I saw the patient in my clinical scenario, they did not have a body weight supported treadmill to use and it is an expensive piece of equipment to purchase, so at that clinic the balance exercise program would have been the ideal choice. However, at another clinic that has access to a body weight supported treadmill, I think at that point the decision would fall on a discussion with the patient about their preferences. Would they enjoy walking on a treadmill and overground as their entire treatment? Would they prefer the variety that the balance/strength exercises provide? Would they feel comfortable in the harness while on the treadmill? Could they carry some of the balance exercises over into their home program, whereas the gait training could only occur at the clinic? Regardless of their choice, I would likely include a little of the intervention in their treatment that is not their main preference because all of the participants in the study were allowed to attend outside "usual care," and it is unclear exactly what treatments were provided outside of the study interventions. Therefore, I think that it would be reasonable to focus the treatment on mainly one of the interventions, with no preference to which, and incorporate aspects of the other as desired based on clinical judgement.

(2) Description and appraisal of "Short-term and long-term effects of a progressive resistance and balance exercise program in individuals with chronic stroke: a randomized control trial by Vahlberget al., 2017."²

Aim/Objective of the Study/Systematic Review:

This study aimed to determine if a balance program that included progressive strengthening exercises, "motivational group discussions" (pg. 1616), and a single home exercise would be effective in improving physical and psychological functioning along with physical activity participation in older adults 1 year post stroke who were living in the community.

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 control trial
- 2 group design
- Participants randomized into one of two groups: intervention group balance program with progressive strengthening exercises or control group; 1:1 ratio
- Randomization completed by a computer program with no restrictions
- Single blinded study – assessor was blinded, but not participants or therapists.
- Allocation to group was concealed by randomizing participants to group after baseline measures were taken. The principle investigator (not involved with assessments or interventions) directed the allocation process using a printed list.
- Primary Outcomes: Balance measured by Berg Balance Scale and Mobility measured by Short Physical Performance Battery at baseline, 3 months, 6 months, and 15 months
- Secondary Outcome (of relevance to clinical question): 10 meter walk test measured at baseline, 3 months, 6 months, and 15 months
- An a priori power analysis was conducted to determine sample size with a significance level of 0.05. They calculated that they needed 128 participants to “detect a 2-point difference on the Berg Balance Scale with a standard deviation of ± 4 points” (pg. 1618) with 80% power.

Setting

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

Setting was not explicitly stated, but based on the nature of the interventions, it is presumed to be at an outpatient clinic or similar location.

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.

- In this study, there were 67 participants at least 1 year post-stroke: 34 in the intervention group and 33 in the control group.
- Participants were excluded if they had cognitive deficits, severe issues with communication, or a systolic blood pressure >180 mmHg.
- Participants were recruited via the “Swedish national discharge register” (pg.1616) if they were between 65 and 85 years old, their most recent stroke was at least 1 year prior to inclusion in the study (but no more than 3 years), able to walk at least 10 meters, and no walking outside for 5 or more days each week (or balance deficits or low self-efficacy for falls).
- American Heart Association guidelines for the type of exercise utilized in the intervention group was used to evaluate the participants for contraindications to exercise.
- Intent to treat analysis was completed using the “hot-deck method” (pg. 1618)
- Range of participant ages was 65 to 85 years old, 76% of participants were male. P values for between group differences were not provided for comparison at baseline, however several variables are similar, with the exception of gender. At randomization, 79.4% of the intervention group and 72.7% of the control group were male, the mean age of the intervention group was 72.5 ± 5.5 years and the control group was 73.7 ± 5.3 years, the median (IQR) number of months post stroke was 13 (4) months for the intervention group and 13 (2) months for the control group, 82.3% and 17.6% of the intervention group and 81.8% and 18.1% of the control group had cerebral infarction and intracranial hemorrhage (respectively), and the Modified Motor Assessment scale median (IQR) score was 54.5 (5) for the intervention group and 54 (3) for the control group (out of 55).
- 10 participants were lost to follow up at 3 months (14.9%), 2 additional participants were lost at 6 months (12 total, 17.9%), and the total lost to follow up at 15 months was 14 (20.9%). In the intervention group alone, 8 participants (23.5%) were lost to follow up at the 3 month assessment, 9 participants (26.4%) at 6 months, and 10 total participants (29.4%) at the 15 month assessment.

Intervention Investigated

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

Control

- No intervention provided
- Participants were encouraged to maintain daily activities and were permitted to participate in physical activity as well as rehabilitation programs.
- Outcomes were measured at baseline, 3 months, 6 months, and 15 months from the start of the study

Experimental

- Two approx. 75 minutes sessions per week for 3 months
- Session structure:
 - **Warm up (10 minutes):** stationary bicycle or walking
 - **Circuit class (~45 minutes):** functional exercises focusing mainly on lower extremities, challenging both static and dynamic balance
 - In parallel or walking stance – squats, body weight transfer, standing from seated position
 - Lunge – sideways and forward
 - Step-up
 - Walking – forward in tandem, multiple directions, with turning, over obstacles, on soft surfaces
 - Stepping up onto boxes and over
 - Participants were each given one exercise to complete daily at home
 - **Motivational session (20 minutes):** discussion about personal goals and concerns surrounding physical activity – barriers to exercise, reasons for improving activity level, readiness for change, physical activity lifestyle
- Intensity during exercise was monitored using the Borg RPE scale. Participants exercised at their highest intensity for two minutes then rested for one.
- Low intensity resistance exercises utilized >15 repetitions and moderate intensity resistance exercises utilized 10-15 repetitions. The goal was to increase strength and endurance.
- To progress exercises, the load would be increased, the participants would be instructed to increase depth of squat or height of step etc., or balance would be challenged by narrowing the base of support.
- To increase load, participants wore a weight belt that held weights from 1 to 12 kg.
- There were 2 trainers (physical therapist and assistant) for every 7 participants.

Outcome Measures

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

- All outcomes were measured by a single assessor that was blinded to the group
- Primary Outcomes:
 - Berg Balance Scale, 0-56 possible points (0 indicates unable to balance, 56 indicates ability to balance independently without difficulty)
 - Short Physical Performance Battery, 0-12 points possible (higher score indicates better function)
- Secondary Outcomes:
 - Gait speed at a comfortable pace was measured using the 10 meter walk test, in m/s (**outcome of relevance to clinical question**)
 - 6 minute walk test, distance recorded in meters
 - PASE, 0 to more than 400 points possible (0 is less physically active in one week, higher score indicates more physically active – no max score defined)
 - Modified Motor Assessment Scale, Max score-55 (higher score indicates better motor function)
 - EQ-5D, 0-1 score (0 indicates low quality of life, 1 indicates high quality of life)
 - Geriatric Depressive Scale, ≥ 6 used to define the possibility of depression (higher score indicates increase possibility of depression)
 - FES(S), Max score-130 (higher score indicates better self-efficacy)
 - Charlson Comorbidity Index,¹¹ 27 points possible (higher score indicates increased risk in mortality)

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.]

The primary outcome measures were the Berg Balance Scale (BBS) and the Short Physical Performance Battery (SPPB).

Berg Balance Scale (0 – 56 points)				
Assessment	Intervention Group* N=34	Control Group* N=33	Between-Group Absolute Effect Size**	P-Value
Baseline	47.9±9.6	49.0±9.7	-----	-----
Change from baseline at 3 months	4.1±9.1, (1.04, 7.16)	-0.06±2.8, (-1.02, 0.90)	4.16, (0.92, 7.40)	0.001
Change from baseline at 6 months	2.3±9.5, (-0.89, 5.49)	0.8±7.9, (-1.90, 3.50)	1.5, (-2.69, 5.69)	0.24
Change from baseline at 15 months	1.3±5.4, (-0.52, 3.12)	-0.6±3.4, (-1.76, 0.56)	1.9, (-0.27, 4.07)	0.06

*scores reported as mean±SD, (95% CI); **mean difference, (95% CI)

- The within-group effect size for the Berg Balance Scale for the intervention group peaked at 3 months and then declined, but overall was a positive change. While the within-group effect size for the control group only showed a small positive change at the 6 month assessment.
- All between-group effect sizes for the BBS were in favor of the intervention group, with the largest at the 3 month assessment.

Short Physical Performance Battery (0 – 12 points)				
Assessment	Intervention Group* N=34	Control Group* N=33	Between-Group Absolute Effect Size**	P-Value
Baseline	8.2±3.0	8.5±2.5	-----	-----
Change from baseline at 3 months	1.0±2.8, (0.06, 1.94)	0.15±1.1, (-0.23, 0.53)	0.85, (-0.17, 1.87)	0.09
Change from baseline at 6 months	0.9±2.7, (-0.01, 1.81)	0.4±1.8, (-0.21, 1.01)	0.5, (-0.60, 1.60)	0.68
Change from baseline at 15 months	1.3±2.4, (0.49, 2.11)	0.7±2.4, (-0.12, 1.52)	0.6, (-0.55, 1.75)	0.3

*scores reported as mean±SD, (95% CI); **mean difference, (95% CI)

- The within-group effect size for the Short Physical Performance Battery for the intervention group was positive at each assessment, but had the largest change at 15 months. There was a small positive change in the within-group effect size for the control group at each assessment.
- All between-group effect sizes for the SPPB were in favor of the intervention group, with the largest at the 3 month assessment.

The secondary outcome measure of relevance to the clinical question for this CAT is the 10 meter walk test.

10 Meter Walk Test – Gait Speed (m/s)				
Assessment	Intervention Group* N=34	Control Group* N=33	Between-Group Absolute Effect Size**	P-Value
Baseline	1.0±0.35	1.08±0.30	-----	-----
Change from baseline at 3 months	0.10±0.23, (0.02, 0.22)	-0.02±0.16, (-0.07, 0.03)	0.12, (0.02, 0.22)	0.012
Change from baseline at 6 months	0.09±0.24, (0.01, 0.17)	-0.06±0.18, (0.00, 0.12)	0.15, (0.05, 0.25)	0.001
Change from baseline at 15 months	0.08±0.37, (-0.04, 0.20)	-0.0±0.25, (-0.08, 0.08)	0.08, (-0.07, 0.23)	0.034

*scores reported as mean±SD in m/s, (95% CI); **mean difference in m/s, (95% CI)

- The within-group effect size for the 10 meter walk test for the intervention group was positive at each assessment, but peaked at 3 months. None of the within-group effect sizes for the control group saw an increase from baseline.
- All between-group effect sizes for the 10 meter walk test were in favor of the intervention group, with the largest change in gait speed at the 6 month assessment.

Original Authors' Conclusions

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

A “progressive resistance and balance exercise program” (pg. 1615) along with discussions regarding motivation for exercise were effective in improving balance and gait speed in individuals with chronic stroke (1 year or more) following the 3 month program. Gait speed was still improved at the 6 month follow up.

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: 9/11 based on-
 - Eligibility criteria specified: Yes; Random allocation: Yes; Allocation concealed: Yes; Comparable at baseline: Yes; Blinding of subjects: No; Blinding of therapists: No; Blinding of assessors: Yes; Adequate follow-up: Yes; Intention-to-treat analysis: Yes; Between-group comparisons: Yes; Point measures and variability: Yes.
- Participants and therapists were not blinded to the intervention group. The authors do not indicate whether the participants were explicitly told which group they were allocated to, but they indicated that since the control group was given no exercise interventions and they were aware that the study was regarding exercise, they may have been more likely to search out additional exercise opportunities outside of the study on their own. This could have biased the results.
- Strengths: 1) Although it cannot be determined with certainty based on the data provided in the article, the baseline demographics of the two groups were somewhat similar. 2) There was only one therapist evaluating the participants at each assessment, which maintains the consistency of the measurements. 3) All interventions were performed at one clinic location. 4) The age range of participants was limited, which would have reduced the possibility of the variability between groups at baseline, 5) The intent to treat analysis helped to maintain some of the baseline group characteristics.
- Limitations noted by authors: 1) The large percentage of individuals lost to follow up in the intervention group may have resulted in some bias, 2) The number of participants presenting with depression was high and may have affected outcomes, 3) There was a large population of men and participants with mild to moderate stroke in the sample, which is uncharacteristic of the general population and may reduce the ability to generalize the results.
- Additional limitations: The sample size needed for this study to detect a significant difference was 128 individuals. Following screening procedures, they only enrolled 67 participants. They also lost 14.9% of participants to follow up at 3 months, and had lost 20.9% to follow up by 15 months. This would result in a lack of power for their study, meaning that some results may not have indicated statistical significance when they may actually be significant.

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.]

For the Berg Balance Scale, the only statistically significant within-group effect size was for the intervention group at 3 months, immediately following the conclusion of the exercise program. There is also a statistically significant between-group effect size at 3 months, in favor of the intervention group. Both the within-group and between group effect sizes are likely clinically significant changes, as the minimal detectable change for individuals with chronic stroke is 4.13 points for the BBS.¹² However, the confidence intervals for both effect sizes at 3 months are somewhat wide, indicating less precision with the point estimate.

Although there was a statistically significant within-group effect size at 3 months for the intervention group, the between-group effect size at 3 months was not statistically significant for the Short Physical Performance Battery. This is also the case at the 15 month assessment, and there are no other effect sizes that are statistically significant. The effect sizes are also small, so it is unlikely that they have clinical significance.

The outcome of relevance to this clinical question is gait speed, measured by the 10 meter walk test. There were statistically significant results for the intervention group at 3 and 6 months. The between-group effect size at 3 and 6 months was also statistically significant in favor of the intervention group. The minimal clinically important difference for gait speed in individuals with stroke is 0.06 m/s.¹ This difference was achieved at 3 months and maintained at 6 months for the intervention group, and the same occurred with the between group effect sizes for the same months. Again, however, the confidence intervals for these effect sizes are somewhat wide, indicating less precision with the reported point estimates.

The control group saw no statistically significant results for any of the outcome measures discussed here. Results overall may have been affected by the lack of blinding of participants and therapists, and biased the outcomes of the study. However, with only one blinded therapist taking measurements, there is a reduced possibility of assessor bias. Baseline characteristics of the groups were somewhat similar, leading me to feel comfortable concluding they did not significantly affect the results.

Of great concern: Because of the lack of power in this study, it is more likely that a type II error occurred: which would lead to conclusions that results were due to chance when there was actually an unidentified real effect. With regard to gait speed, there was a positive within-group effect size at 15 months, but the confidence interval suggests the results are not statistically significant. Since 0.08 m/s is still a clinically significant change, it is possible that with a larger sample size, we would have seen a statistically significant result.

It is reasonable to conclude that the progressive balance exercises, along with motivational discussions, were effective in creating a clinically significant change in gait speed that persisted at the 6 month follow up assessment, but perhaps had a longer lasting effect than was evident from the results.

Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]

The patient population in this study was not as similar to the patient in my clinical scenario as that of the previous article. Similarities do include gender, cognitive ability, and ability to walk 10 meters. Differences include mean age of participants and time post stroke. Although the study included participants from age 65-85 years, the patient in my clinical scenario is 65 years and the mean ages of the study groups were older, at 72.5+5.5 years and 73.7+5.3 years. Also, the median time post stroke for both groups was approx. 13 months. Literature has reported that individuals who are younger at the time of stroke⁴ or who receive therapy closer to the incidence of stroke¹⁰ are more likely to see improvement of function than individuals who are older or have a greater time post-stroke. For these reasons, I am less concerned about the differences between my patient and the study population, since he is already advantaged in comparison due to his age and time post stroke. My only concern would be whether or not his stroke was mild enough that he would be able to complete the exercises from the intervention in a way that would be effective. Based on his function at the evaluation and my clinical judgement, I believe this patient would be able to complete the intervention exercises.

Although the results of the study did not conclusively determine that the progressive resistance balance exercises were effective in increasing gait speed beyond the 6 month follow up, there was a clinically significant change from baseline to the 3 month assessment that was maintained at 6 months. With these results, it is reasonable to conclude that this treatment protocol may be effective in improving gait speed for my patient. In implementing this treatment plan, additional supplies may be needed. The progression of the intervention requires adding weights to a waist belt to increase resistance for the strengthening components of the balance exercises. If the clinic did not already have a reasonable substitute, these would be affordable and easily obtained. Within a typical physical therapy session, there would not be 20 minutes to set aside for only motivational discussion, however, I believe that this could be accomplished throughout the treatment

sessions while other exercises were being completed. Many of the exercises would also be appropriate for incorporating into a home program.

In general, this treatment plan utilizes exercises commonly used in physical therapy interventions currently. It would be important to discern the patient's level of comfortability with each individual exercise and its progression, but that would be no different than any other physical therapy treatment plan. Unlike the previous article where there is another treatment option entirely, in this case I think implementation would be based mostly on clinical judgement with instances of patient input and feedback.

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.]

The study by Duncan et al.⁵ compared two types of interventions for improving gait speed, a body weight supported treadmill and overground gait intervention and a balance and strengthening program delivered at the participants' homes. Both interventions resulted in a similar within-group effect size of mean gait speed at 1 year post stroke that was statistically significant and clinically important. When deciding which intervention to use with the patient in my clinical scenario, several factors were considered. Access to a body weight supported treadmill is a key factor in whether that intervention can be implemented easily and affordably. If the clinic has access to that type of treadmill, then the choice of intervention can be a joint decision taking into account patient preferences and clinical judgement, however, the balance exercises would be more easily incorporated into a home exercise program. Since all intervention groups were permitted to partake in outside "usual care," introducing components of either intervention to the other's treatment plan may still be effective and appropriate.

The study by Vahlberg et al.² compared an intervention of progressive resistive balance exercises and motivational discussion, to a control group with no treatment that was permitted to participate in outside care; gait speed was also measured as an outcome. The balance/strengthening intervention produced a statistically significant and clinically important within-group effect size in mean gait speed that was maintained at the 3 and 6 month follow up assessments. Long-term effects at 15 months were not statistically significant, but the sample size of the study was insufficient in achieving the necessary power to detect a significant difference. So it is possible that with a larger sample size, a statistically significant effect size would be seen in a similar population. Their balance/strengthening intervention would be easy and cost-effective to implement in an outpatient setting, and the progressive nature of the exercises allow for modifying the challenge and the possibility of completing the exercises at home.

Both studies were similar in quality and risk of bias. However, the within-group effect sizes for mean gait speed with both intervention groups in the study by Duncan et al. were twice as large as those seen with the balance/strengthening intervention in the study by Vahlberg et al., and the confidence intervals were also narrower, indicating more precise results. This could be the result of a more effective set of interventions, and/or differences in population demographics and time post stroke, as well as the previously mentioned issue regarding sample size/power of the Vahlberg et al. study.

Regardless of the reason behind the difference in effect, the treadmill and overground gait training or the balance exercises from the home program outlined in the study by Duncan et al. would be an ideal choice for treating the patient in my clinical scenario as the population is well matched, the within-group effect sizes are clinically significant and much larger than those in the other study, and since they were directly compared within the same study it provides additional confidence that either choice will likely be effective, which allows for increased flexibility with the patient and their preferences.

The study by Duncan et al. was well-done with some exceptions that I would like to see modified and implemented in a future project. Part of the difficulty with determining the more effective intervention in their study was the lack of a true control, in part due to understandably not wanting to negatively affect a participant's outcomes by randomly allocating them to a control group without an intervention. Since their version of a control (the home balance/strengthening program) was so effective, an ideal study design would have 3 groups. All groups would get a structured set of interventions delivered by the researchers that could be deemed "usual physical therapy care." In addition to the usual care interventions, one group would receive the balance/strengthening interventions beginning at 2 months post-stroke, and the other would receive the treadmill and overground gait training beginning at 2 months. Hopefully having more control over the other interventions received by the control group would be less likely to be a confounding factor within the results. With this new structure, the potential of bias could also be reduced by the ability to blind the participants to their allocation since all groups would receive interventions. Additionally, delivering the interventions from one location with a set number of therapists instructing the interventions would also help to reduce bias. Finally, none of the reviewed studies did follow up assessments beyond 15 months. It would be useful for this new study design to include a follow up assessment at 1, 2, and 5 years post stroke to determine if the improvements in gait speed can be maintained long term.

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