CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

In a 65 yo female chronic stroke patient with RLE hemiparesis are greater improvements in gait speed observed when using HIT treadmill training compared to conventional physical therapy?

AUTHOR

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CLINICAL SCENARIO

The patient is a 65 yo female who suffered a L MCA CVA ~3 months prior to initiating outpatient physical therapy. She still demonstrates R-sided hemiparesis that affects her gait and reduces her walking speed.

Many stroke patients have slow self-selected walking speeds, but it is perhaps of even greater concern that these patients do not have the capacity to increase gait speed much past their self-selected speeds[1]. In order to functionally ambulate in a safe manner individuals must have the ability to increase their walking speed in response to environmental demands, and gait speed is a common measure used to assess stroke patient's progress[1,2]. Gait speed has robust psychometric properties in this population, having excellent test-retest reliability and strong construct validity[2]. It can be used to classify stroke patients into different functional categories, and in stroke it is associated with LE strength, balance, endurance, falls risk, functional mobility, and level of disability[2]. In addition to impaired motor control, stroke patients often have decreased conditioning and aerobic capacity. Supervised moderate intensity continuous exercise at 40-70% of peak O_2 uptake or HR is the most commonly prescribed intervention to improve aerobic fitness in stoke patients, and it also represents the most common mode of repetition of practice for gait in many stroke patients[3].

High-intensity interval training (HIT) is a mode of aerobic and anaerobic conditioning that is gaining increased attention in a variety of patient populations, including cardiac rehabilitation and stroke[3,5,7]. As Boyne et al described, "it maximizes exercise intensity through bursts of concentrated effort.[3]" In short, HIT involves consecutive rounds of a specified high intensity burst duration of activity followed by a predetermined recovery interval that mitigates fatigue[3,5,7]. The burst activity is performed at or very near maximal effort. Because HIT protocols demand high intensity, sessions are often of much shorter duration than standard interventions.

HIT has the potential to provide greater improvements in both aerobic conditioning and gait speed than does conventional aerobic conditioning and physical therapy.

SUMMARY OF SEARCH

[Best evidence appraised and key findings]

- To date there is limited evidence that specifically examines the effects of HIT on gait speed in chronic stroke patients. Upon searching 4 databases a total of 20 articles were recovered and 8 of those 20 were selected for further consideration based upon descriptions from the abstracts. 2 of those 20 articles were selected for inclusion of this CAT based on relevance.
- Various HIT protocols increase gait speed in chronic stroke patients who are currently not participating in a rehabilitation program.
- Optimal HIT parameters have yet to be determined, but parameters that include 30 s treadmill bursts followed by some combination of 30-60 s recovery will likely have the greatest improvement effect on both aerobic capacity and gait speed.
- Future research should include a greater number of participants in an RCT to enhance the power of these studies' conclusions. Future investigation should also further explore optimal HIT parameters, MCID for gait speed in chronic stroke, and define safety guidelines for use of HIT in clinical practice.

CLINICAL BOTTOM LINE

While there is limited evidence, current findings suggest that HIT treadmill training is more effective than conventional steady-state, low-intensity treadmill walking for enhancing gait speed capacity in chronic stroke patients who demonstrate LE hemiparesis.

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

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Stroke CVA Cerebrovascular accident Hemiparesis	High intensity interval training High intensity exercis*	Conventional physical therapy	Gait speed Walking speed

Final search strategy (history):

1. Stroke [MeSH Terms]
2. Stroke OR CVA OR cerebrovascular accident
3. High intensity interval training OR High intensity exercis*
4. Physical therapy OR physiotherapy
5. (Gait OR walk*) AND speed
6. #1 AND #3 AND #4 AND #5
7. #2 AND #3 AND #4 AND #5
8. #1 AND #3 AND #5

Databases and Sites Searched	Number of results	Limits applied, revised number of results (if applicable)
PubMed	**17**	**For the first three databases the search results were very few in number but the revised search strategy in line 8 above yielded sufficient results**
CINAHL	**12**	
EMBASE	**13**	**For WoS utilizing the basic search strategy turned up 63 articles but when applying the search limit to the past 2 years, 20 results appeared.**
Web of Science (WoS)	**20**	

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
• Studies patients >40 years old with chronic stroke • Subjects have LE hemiparesis • Intervention includes HIT • Measured gait speed at baseline and conclusion of study
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
Holleran et al (2015)[4]	**PEDro Scale 4/10**	**2b**	**Moderate**	**RCT (crossover design)**
Boyne et al (2015)[5]	**Downs and Black Checklist 17/31**	**2b**	**High**	**Repeated measures design**
Jørgensen et al (2010)[6]	**Downs and Black Checklist 16/31**	**2b**	**Low**	**Quasi-experimental design: single group**
Boyne et al (2016)[7]	**PEDro Scale 8/10**	**1b**	**High**	**RCT**
Hornby et al (2016)[8]	**PEDro Scale 7/10**	**2b**	**Moderate**	**RCT**
Outermans et al (2010)[9]	**PEDro Scale 6/10**	**2b**	**Moderate**	**RCT**
Mahtani et al (2016)[10]	**PEDro Scale 5/10**	**2a**	**Moderate**	**Retrospective analysis of 2 RCTs**
Boyne et al (2017)[11]	**AMSTAR 7/11**	**1a**	**Low**	**Systematic review/meta-analysis**

*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:

- **Boyne et al (2015)[5]**
- **Boyne et al (2016)[7]**

The PICO question is rather specific, and the search has revealed that the topic of high intensity interval training effects on gait speed in chronic stroke patients has not been thoroughly studied. Upon appraising the articles it becomes evident that, generally speaking, the articles were overall a less relevant than how the abstracts suggested. Many of the articles examined high intensity vs low intensity OR standard PT but few truly examined high intensity interval training. Furthermore, some of the studies were more concerned with subacute rather than chronic stroke patients. The distinction is relevant since one would expect large functional gains in the subacute phase but measures in the chronic phase are likely to be different, slower gains. While it may be preferable to select articles with differing primary authors, Boyne most directly answers the PICO question that is put forth in 2 of the 8 selected articles, easily making them the most highly relevant. These two articles are the only ones that include true HIT on a treadmill + gait speed outcome measure + chronic stroke. Inferences can certainly be drawn from the other articles, but an inference is not a direct answer. Hence relevance is the number one driving factor for final selection. Fortunately, one of the two articles (2016) is of good evidence (1b) and low bias (8/10). While the other article has greater risk of bias (17/31) it is still at a good level of evidence (2b) and directly answers my question.

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of "Within-session responses to high-intensity interval training in chronic stroke" by Boyne et al, 2015.[5]

Aim/Objective of the Study/Systematic Review:
The aims and objectives of this study are to describe HIT, to compare the within-session effects of HIT among three different sets of parameters of HIT treadmill exercise, and to determine the optimal recovery period during HIT in chronic stroke subjects.
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.
• The study used a within-session repeated measures design. • Initially, each prospective subject was screened for eligibility by clinical examination and maximal effort, graded treadmill exercise testing (GXT) with ECG stress testing. Next, peak oxygen consumption (VO_{2peak}) and HR_{peak} was determined during a second GXT with gas exchange analysis. • Three single session HIT treadmill tests were conducted with each subject with a one week washout period between sessions. Each session featured one of three HIT protocols, each week featuring a different protocol. The authors report that the order of the three HIT protocols was randomized and "counterbalanced" across all subjects.
Setting [e.g., locations such as hospital, community; rural; metropolitan; country]
The study screening, examination, and testing was conducted in a cardiovascular stress laboratory within an unspecified university hospital.
Participants [N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up] Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.
N=18. A total of 22 subjects were "recruited from the community and signed an informed consent form before participation", but three of them did not meet the inclusion/exclusion criteria. One subject was lost to follow up, leaving 18 subjects with complete data for analysis. Subjects were not blinded but order of HIT protocol was randomized. Inclusion criteria: • 40–85 years of age • unilateral stroke >6 months prior to enrolment • gait speed ≤1.0 m/s, measured by 10-m walk test • ability to walk 10 m with assistive devices as needed but no physical assistance • ability to walk for 3 min on the treadmill at ≥0.13 m/s (0.3 mph) without development of aerobic exercise contraindications • stable cardiovascular condition (AHA class B, permitting aerobic capacity >6 METs) • not currently participating in rehabilitation Exclusion criteria: • "significant resting ECG abnormalities" • evidence of myocardial ischemia or significant arrhythmia on treadmill ECG stress test • hospitalization for cardiac or pulmonary disease within 3 months • pacemaker or implanted defibrillator • lower extremity claudication • Mini-Mental State Examination result <23/30 • severe lower extremity spasticity (Ashworth ≥3) • lower extremity weight-bearing pain >4/10 on VAS

Key participant demographics: 10 male, 8 female; mean age in years = 61.9 (8.3); age range = 48.9–82.2; BMI = 28.5 (6.1) kg/m^2; stroke type: 16 ischemic, 2 hemorrhagic; 8 L side affected strokes; years since stroke = 5.8 (4.2) (range = 0.5–13.9); LEFM motor score (0–34) 24.2 (5.6); comfortable overground gait speed = 0.60 m/s (0.29) (range = 0.19–0.96); fastest overground gait speed = 0.76 m/s (0.40) (range = 0.19–1.34);

Intervention Investigated

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

Each subject participated in all three HIT protocols with a one week washout period between sessions. Each session lasted approximately 30 minutes.

As a safety precaution, during all treadmill activity the participants wore an overhead supported harness system (Biodex Offset Unweighting System; Biodex Medical Systems, Inc., Shirley, NY). The harness was used as a falls protection and not for supporting bodyweight. The participants used the treadmill's handrail for balance and wore their habitual orthotic devices. Starting HIT speed was determined before the first session by having participants walk on the treadmill at their fastest comfortable walking speed and then increasing the speed by 0.1 mph every 5 s until the subject demonstrated a mechanical fault (such as drifting backward or marked gait instability) or if the participant requested to stop. HIT protocols were initiated at 0.1 mph below the speed at failure.

All three HIT protocols entailed a 5 minute treadmill warm up at 30-50% VO_{2peak}, up to 20 minutes of HIT (if tolerated), and a 5 minute cooldown also at 30-50% VO_{2peak}. The HIT treadmill bursts involved 30 seconds of treadmill walking at maximum or near maximum tolerated speeds. Once the participant successfully completes a burst, the speed is increased by 0.1 mph for the next burst following the rest period. On the other hand, if the subject demonstrated mechanical fault, then the speed was decreased by 0.1 mph on the subsequent burst. The variable being manipulated in the experiment was the rest break between bursts. Each session featured one of three protocols (P30, P60, and P120) using either a 30 s, 60 s, or 120 s recovery period between bursts. Hence, the total duration of high intensity varied among the groups. For example, after 20 minutes, P30 would require 10 total minutes of high intensity treadmill walking and 10 minutes of recovery period; whereas, P60 would require 6.5 minutes of activity and 13.5 minutes of recovery within a 20 minute timeframe. The recovery activity between bursts was at the discretionary preference of the participant; he/she was permitted to stand still, march in place, or sit.

Outcome Measures

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

The article does not specify who administered the HIT protocols. As previously mentioned, the treadmill activity and measures took place at a university hospital. All the measures for this study are described by continuous data that have no pre-determined maximum score or range. The four measures for this study were as follows:

- **Exercise tolerance** was measured in two ways: 1) number of subjects able to complete 20 consecutive minutes of HIT, and 2) the total HIT time tolerated until exhaustion.

- **Aerobic intensity** was measured by assessment of O_2 consumption and HR. Mean VO_2 and duration of time above different threshold percentages of VO_{2peak} were used as measures of O2 consumption. The VO_{2peak} threshold percentages represented exercise tolerance and the percentages selected were 40% (moderate intensity), 60% (vigorous intensity), and 85% (very hard intensity). The instrument used to collect data pertaining to O_2 consumption was the TrueOne 2400 metabolic system (TrueOne 2400; Parvo Medics, Sandy, UT). HR reserve (HRR) threshold percentages (also at 40%, 60%, and 85%) were calculated with the following formula:
  $$HR\ (bpm) = HRR\ threshold\ \% \times (HR_{peak} - HR_{resting}) + HR_{resting}.$$
  Mean HR during HIT was also measured.

- **Treadmill speed** was defined as the fastest speed achieved during HIT and recorded as m/s.

- Step count measured the **repetition of practice**. The Step Watch Activity Monitor (Orthocare Innovations, LLC, Oklahoma City, OK) was placed around the each participant's non-paretic ankle and captured both the total step count. The number of participants completing at least 1000 steps during the HIT protocol was also recorded.

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.]

Time until exhaustion and number of participants able to complete 20 minutes of HIT varied among the three protocols. For P30 completion n=11, and the median time to exhaustion was 14.0 min (range, 2.8–19.2). For P60 completion n=15, and the median time to exhaustion was 11.9 min (range, 11.1–13.4). All 18 participants completed P120.

Time spent above 40% and 60% VO_{2peak} threshold was significantly greater ($p<0.05$) in P30 and P60 compared to P120 with no significance difference between P30 and P60. However, time spent above 85% VO_{2peak} threshold was significantly greater in the P30 group compared to both P60 and P120. Mean aerobic intensity was significantly different among all three protocols (P30 > P60 > P120) for both PO_{2peak} and HRR.

The greatest increase in gait speed was observed in P60: ↑178%±84% of fastest overground walking speed, ↑140%±20% of starting HIT treadmill speed, and ↑193%±48% of the VO_{2peak} baseline GXT speed. The P60 mean gait speed was 1.13 m/s (CI 95% 0.95–1.31). P120 represented the second fastest overground walking speed, 1.10 m/s (CI 95% 0.92–1.28). There was no statistical significance in gait speeds between P60 and P120 but both were significantly faster ($p<0.05$) than the top speed achieved in P30, 1.03 m/s (CI 95% 0.85–1.21).

The number of steps taken during testing was significantly different ($p<0.05$) among all three protocols, P30>P60>P120. Mean number of steps taken were as follows: P30, 2027 (CI 95% 1836–2218); P60, 1600 (CI 95% 1409–1792); P120 1268 (CI 95% 1007–1460).

Original Authors' Conclusions

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

- With appropriate screening, monitoring, and precautions, HIT treadmill training in chronic stroke is a safe and effective modality for improving aerobic capacity and dimensions of gait.
- Maximal HIT that uses 30 s bursts improves aerobic capacity. The maximal effort requires that the participant increase his/her step count and walking speed.
- A combination of P30 and P60 may be optimal for improving gait performance in chronic stroke patients. P60 appears to be the best parameter for improving gait speed and could be used for early sessions. After some initial adaptation, P30 parameters could then be introduced to further increase step count and increase aerobic capacity.
- HIT has potential for generalizability for improvements in aerobic capacity and gait dimensions in chronic stroke patients but longitudinal RCTs are needed to support this claim.

Critical Appraisal

Validity

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

This study is of level 2b evidence but only of moderate quality given a score of 17/31 on the Downs and Black Checklist. With regard to internal validity, the investigators made no attempt to blind the participants or the raters, but much of this is a consequence of the repeated measures design. On the other hand, intervention order was randomized, and each of the participants received the same treatment and length of time for follow up. Each of the subjects was recruited in the same time period which reduces selection bias[13]. The study appears to be free of selection bias given the random allocation order and participation of each subject in all three intervention protocols. One subject was lost to follow up, and investigators performed an intention to treat analysis, using a restricted maximum likelihood approach. The remaining 18 complied with follow up and the treatment protocols; however, 7 participants were unable to complete P30 and 3 of those 7 were also unable to complete P60 due to self-reported fatigue/exhaustion. The outcome measures used in this study were reliable, valid, and reasonable. Power appears to be sufficient in this study considering *a prior* estimates indicated that at least 17 participants would be needed for a power >85%.

The external validity of this study is feasible considering the wide ranging features of these chronic stroke subjects, including age, co-morbidities, and baseline performances. It is also likely that the community from which the subjects were recruited is representative of larger chronic stroke populations given the subjects' demographic data. Furthermore, the study was conducted within a university hospital which is a reasonable setting for receiving chronic stroke patients.

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.]

HIT treadmill training is a feasible means for increasing gait speed in within-session treatments in chronic stroke patients. It is interesting that within a few rounds the subject can significantly increase his/her treadmill walking speed beyond what was determined at the start of a session. In the P60 group mean fastest treadmill speed nearly doubled (193%±48%) compared to the initial GXT speed. There was no statistically significant difference between P60 and P120 in terms of increasing peak treadmill speeds, but both were significantly faster than P30. It appears as though 60 s is sufficient time between bursts to restore the energy needed to walk on a treadmill at maximal effort for 30 s.

It is understandable that 39% of the participants were unable to complete the P30 protocols considering that the shortened recovery periods across 10 HIT rounds are likely insufficient for the restoration of anaerobic metabolic pathways. Furthermore, subjects in this study sample were untrained and had reduced baseline VO_{2peak} capacity and many had a history of cardiac events and/or other comorbidities that are associated with decreased performance such as hypertension, hypercholesterolemia, smoking, and diabetes mellitus. The benefit of P30 is that it allows for greater repetition of practice; however, 30 s recovery periods are unlikely to be the optimal initial parameter for chronic stoke patients given the trade-off of excessive fatigue and increased mechanical fault, thereby, increasing the likelihood of orthopaedic injury. Shortened recovery intervals could be used as a means of progression with HIT training, but further investigation is needed to determine if that is the case.

In terms of effect size, all three groups significantly (p=0.002) increased their fastest treadmill walking speed in absolute terms. Baseline mean fastest treadmill speed was 0.84±0.32 m/s. Fastest mean treadmill speeds for P30 were 1.03 m/s (0.85–1.21), for P60 were 1.13 m/s (0.95–1.31), and for P120 were 1.10 m/s (0.92–1.28). While these figures do not specially relate overground walking speed, treadmill walking is very similar to overground walking. While it was specifically measured it is likely that increases in fastest treadmill speed will correlate with faster overground walking velocity.

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 is relevant to the clinical scenario because the investigators demonstrate that all three HIT protocols increase fastest treadmill walking speed in patients with chronic stroke. The results would be even more compelling had the investigators measured fastest overground walking speed to see if there is immediate translation into functional ambulation. On the other hand, it is possible that post intervention fatigue would likely impair fastest possible walking speed, and so such results may not be as meaningful.

It is likely meaningful to both the clinician and the chronic stroke patient that a significant difference in walking speed can be demonstrated within one 30-minute session. It is encouraging and exciting that such short-term improvements are observed, but the goal of increasing gait speed in chronic stroke patients is a long-term outcome goal. This study demonstrates that increases in treadmill speed are possible within a short time frame, but further investigation is needed to see if HIT protocols translate into long-term gait velocity improvements.

(2) Description and appraisal of "High-Intensity Interval Training and Moderate-Intensity Continuous Training in Ambulatory Chronic Stroke: Feasibility Study" by Boyne et al, 2016.[7]

Aim/Objective of the Study/Systematic Review:

The major objective of this small RCT is to assess the feasibility of conducting a large scale RCT that compares/contrasts the training effects of HIT and moderate-intensity, continuous aerobic training (MCT). The authors are interested in protocol efficacy, safety, and data pertaining to aerobic capacity and dimensions of gait.

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.

- The study is a preliminary RCT for a prospective, larger RCT.
- Participants were screened for eligibility by medical record review, clinical examination, and GXT with ECG for stress testing.

- Eligible participants were randomly allocated to either HIT or MCT groups by a person with no other role in the study who randomly drew assignments from opaque, sealed envelopes. The group allotment was designed such that there would be a 2:1 ratio of HIT to MCT participants. The authors claim that this was to maximize information about the much less studied HIT.

- Study participation occurred 3 days/week for 4 weeks for a total of 12 sessions.

- At baseline and one week after intervention a blinded rater executed the outcome measures.

Setting

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

The study was conducted at two sites: a cardiovascular stress laboratory and a rehabilitation research laboratory.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

N=16. After screening, 18 of 26 subjects were eligible for study participation. 13 were randomized to the HIT group, and 5 were randomized to the MCT group. Two participants withdrew from the HIT group, discontinuing intervention.

Inclusion criteria:

- Inclusion criteria were:
- aged 35 to 90 years
- unilateral stroke experienced >6 months before to enrolment,
- ability to walk 10 m overground. assistive devices permitted but with no physical assistance
- ability to walk 3 minutes on the treadmill at ≥0.13 m/s without aerobic exercise contraindications
- stable cardiovascular condition (AHA class B, allowing for aerobic capacity >6 METs)
- currently not participating in rehabilitation.

Exclusion criteria:

- "significant resting ECG abnormalities"
- evidence of myocardial ischemia or significant arrhythmia on treadmill ECG stress test
- hospitalization for cardiac or pulmonary disease within 3 months
- pacemaker or implanted defibrillator
- LE claudication
- inability to communicate with researchers or correctly answer consent comprehension questions
- severe LE spasticity (Ashworth scale score >2)
- LE weight-bearing pain >4/10 on a VAS

There was a significant difference in baseline VO_{2peak} (p=0.02) and fractional utilization (p=0.15) between the two groups, but otherwise the two groups were equivalent.

Salient baseline demographics for the participants include:

- HIT group (n=11): gender = 7 male; mean years of age = 59±9 (40–71); BMI = 28.5±5.2 kg/m^2 (22.4–38.2); years post-stroke = 3.8±2.9 (1.0–10.3); ischemic stroke = 9; L side affected = 3; Fugul-Meyer leg motor score = 24.2±4.8 (16.0–31.0); comfortable 10-m walk speed = 0.63±0.48 m/s (0.06–1.45); VO_{2peak} = 16.0±4.0 mL/kg/min (9.0–21.7); % VO_{2peak} predicted = 64.4±26.2 (27.3–100.5)

- MCT group (n=5): gender = 2 male; mean years of age = 57 (12) [41–73]; BMI = 26.4±4.8 kg/m^2 (21.4–32.6); years post-stroke = 6.3±2.0 (4.5–9.1); ischemic stroke = 2; L side affected = 4; Fugul-Meyer leg motor score = 23.2±7.3 (11.0–30.0); comfortable 10-m walk speed = 0.76±0.36 m/s (0.18–1.10); VO_{2peak} = 21.6±4.0 mL/kg/min (17.3–26.0); % VO_{2peak} predicted = 83.4±11.5 (69.9–96.5)

Intervention Investigated

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

All participants were outfitted with an overhead support harness (Offset Unweighting System, Biodex Medical Systems Inc, Shirley, New York) that was used as falls protection but not to support bodyweight. Furthermore, a horizontally placed elastic band was secured at waist to the rear of the treadmill that served as a cue to the supervising therapist to discontinue treadmill activity in the event that the participant was drifting excessively, incapable of keeping pace with the treadmill. Participants were permitted to hold the treadmill handrail or harness straps for balance support. If participants ordinarily wore orthoses, they were permitted to do so during all treadmill activity.

Both groups followed the same 25 minute structure: 3 minute treadmill warm up at 30-50% HRR, 20 minutes of treadmill intervention protocol, and a 2 minute cooldown also at 30-50% HRR.

Control

The authors claim to base the MCT intervention on previously established protocols: continuous treadmill walking with speed adjusted as needed to maintain 45%±5% HRR. In the final two weeks of intervention target HR was adjusted to 50%±5% HRR.

Experimental

The HIT protocol entailed maximal effort safe walking speed in 30 s bursts punctuated by 30-60 s recovery periods. For the first 3 sessions the recovery period lasted 60 s, but for the remaining 9 sessions the recovery period was set at 30 s. Treadmill speed was increased by 0.1 mph after successful completion of each burst. However, if the participant was unable to complete the burst without mechanical fault, marked gait instability, or without drifting backwards against the horizontal band, then the treadmill speed was decreased by 0.1 mph for the subsequent burst. Initial treadmill speed was determined each session after warm up with a steep ramp test that involved increasing the treadmill speed by 0.1 mph every 5 s until mechanical fault, marked gait instability, or without drifting backwards against the horizontal band was observed. The initial treadmill speed was set at 0.1 mph below this speed that elicited failure.

Outcome Measures

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

- **Recruitment feasibility** (for larger future study) was assessed by counting the number of consenting participants; whereas, **training feasibility** was measured by counting the number sessions actually attended by participants and the total number of participation minutes. Eight of the HIT participants were also interviewed qualitatively to provide feedback and further determine feasibility.
- **Aerobic intensity** was measured by HR with an ECG chest strap and HR computer (RCX5, Polar Electro Inc, Lake Success, New York). **Neuromuscular intensity** was interpreted from recording maximal treadmill speed. An activity monitor was fastened to each participant's non-paretic leg (StepWatch, Orthocare Innovations LLC, Oklahoma City, Oklahoma) recorded step count which was used to capture **repetition of practice**. **RPE** on 6-12 Borg was used halfway through each intervention to assess participant perceived intensity.
- Patient Safety was assessed via ECG and blood pressure monitoring and observation for s/s of cardiorespiratory distress, new neurologic deficits, or orthopedic injury.

Trained and blinded raters assessed the following outcomes at baseline and at 1 week post intervention:

- Maximal effort GXT measured **aerobic capacity** markers: VO2peak and ventilator aerobic threshold. The GXT protocol has been validated in stroke and entails treadmill walking at 85% of fastest comfortable walking speed and increasing the incline 2-4% every two minutes until the subject reports excessive fatigue, demonstrates severe gait instability, or exhibits a cardiovascular safety limit. Gas exchange was measured with TrueOne 2400 (Parvo Medics, Sandy, Utah).
- Reliable and valid measure of **metabolic cost of gait** in stroke patients entails recording VO2peak in the final 2 minutes of a 5 minute walk at a self-selected walking speed on a treadmill. The investigators used the same speed at baseline testing and post-intervention. Physiologic demands of gait are determined by fractional utilization calculation which entails metabolic cost of gait ÷ aerobic capacity.
- The 10-m Walk Test was standardized using the Locomotor Experience Applied Post-Stroke (LEAPS) guidelines. The investigators recorded gait speed over the middle 10 m of a 14-m course.
- The 6-MWT measures the distance a subject can walk in six minutes and was standardized using the American Thoracic Society guidelines.

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.]

There were no statistically significant outcome changes in the MCT group. The HIT group significantly outperformed the MCT group on most measures ($p<0.05$). The main findings of the study are listed in the tables below:

Table 1. Baseline Data

	MCT Group	**HIT Group**
Outcome Measure	Baseline (SD), Δ (95% CI)	Baseline (SD), Δ (95% CI)
VO2peak (mL/kg/min)	21.6 (4.0), −1.3 (−4.7, 2.1)	16.0 (4.0), 2.2 (−0.05, 4.5)
Ventilatory threshold (mL/kg/min)	13.9 (2.2), 0.6 (−1.3, 2.5)	10.3 (3.6), 4.4 (3.1, 5.7)
Metabolic cost of gait (mL O2/kg/m)	0.23 (0.07), −0.01 (−0.10, 0.09)	0.40 (0.26), −0.10 (−0.17, −0.03)
Fractional Utilization (%)	84.9 (4.4), −8.8 (−24.7, 7.0)	110.0 (9.9), −36.8 (−49.3, −24.3)
Fastest treadmill speed (m/s)	1.06 (0.48), 0.07 (−0.10, 0.24)	0.88 (0.46), 0.36 (0.25, 0.47)
Fastest 10-m walk (m/s)	0.91 (0.46), 0.01 (−0.04, 0.06)	0.77 (0.54), 0.10 (0.06, 0.13)
Comfortable 10-m walk test (m/s)	0.76 (0.36), 0.02 (−0.03, 0.08)	0.63 (0.48), 0.10 (0.06, 0.14)
6-MWT (m)	247 (121), 15 (−6, 36)	220 (153), 15 (1, 29)

Table 2. Change in Outcome Measures

Outcome Measure	**HIT Δ - MCT Δ**	**Standardized Effect Size**
VO2peak (mL/kg/min)	3.5 (−0.6, 7.6)	0.99 (−0.14, 2.09)
Ventilatory threshold (mL/kg/min)	3.8 (1.5, 6.1)	1.95 (0.62, 3.23)
Metabolic cost of gait (mL O2/kg/m)	−0.09 (−0.21, 0.03)	0.91 (−0.26, 2.04)
Fractional Utilization (%)	−28.0 (−48.2, −7.8)	1.74 (0.38, 3.04)
Fastest treadmill speed (m/s)	0.29 (0.09, 0.49)	1.68 (0.43, 2.88)
Fastest 10-m walk (m/s)	0.08 (0.02, 0.14)	1.44 (0.24, 2.60)
Comfortable 10-m walk test (m/s)	0.08 (0.01, 0.14)	1.27 (0.10, 2.41)
6-MWT (m)	0 (−26, 25)	0.00 (−1.16, 1.16)

Differences between HIT Δ and MCT Δ are group x time contrast interactions. Effect sizes were calculated by dividing mean Δ by SD.

Original Authors' Conclusions

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

- The authors are reserved about making bold conclusions based on the nature of this being a preliminary study. They do insist that based on their findings a larger RCT comparing HIT and MCT in chronic stroke patients is feasible and warranted.
- HIT treadmill training appears to have safety that is comparable to MCT treadmill training in chronic stroke populations.
- Between groups analysis shows moderate to very large effect size differences for most outcome measures in favour of HIT for improving aerobic capacity and dimensions of gait in chronic stroke patients.

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.]

Overall this pilot study is of good quality, earning a score of 8/10 on the Pedro Scale and is level 1b evidence. Many features of this RCT indicate good validity of the study. First, the subjects were randomly allocated to either group, and the person assigning the participants was blinded. Second, the investigators treated the two groups the same in every respect expect for the differences between treadmill protocols being examined. Third, data collection at baseline, during the intervention, and at one week follow up is a reasonable time frame assess gait and aerobic changes[12]. Fourth, the power calculation needed for this pilot study required that they enrol 10 participants into the HIT group to ensure power >80%. After an attrition rate of 2 in the HIT group, n=11, meeting the power calculation threshold. Finally, the author's used a variety of outcome measures that have been shown to be valid in chronic stroke: VO_2 measure at 3-5 min of steady state walking, 10-m Walk Test, and the 6-MWT.

Of course, there are some weaknesses to this pilot study. The subjects were not blinded after group allocation, and the subject's group assignment was not concealed to the investigator (although this would have been difficult given the nature of the intervention). The results of the study would be stronger if the groups had been equivalent across all baseline demographics. Next, because the study was so small it has limited power, and the 95% confidence intervals could in fact be misleading because between group differences may have accounted for some of the variations in outcomes. Of course, this is to be expected of a smaller, preliminary study, and the planned larger RCT would rectify this possible discrepancy.

Because the effect sizes for the outcomes are moderate to very large, it can be said that this study has good internal validity. However, given the small sample size, generalizability to other chronic stroke patients is feasible but larger trials are needed to confirm this.

Interpretation of Results

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

The results of this study are encouraging in utilizing HIT in chronic stoke patients to optimize clinical outcomes in an efficient and effective manner. Certainly, HIT protocols are not suitable for everyone given the 15% attrition rate seen in the HIT group. However, many of the patients reported increased self-efficacy after participation in the intervention[7], and the results are significant. The HIT group significantly outperformed the MCT group in the majority of outcome categories at one week follow up ($p<0.05$). The VO_{2peak} confidence interval crosses the null line, and so it cannot be said that there is a significant difference between groups. Furthermore, there was no significant difference between 6-MWT distances.

I am somewhat reserved about the comparison between HIT and MCT in this study in one sense because one parameter for the MCT does not match many of the protocols outlined by other researchers. For most MCT guidelines the length of training is progressive, increasing to 20-60 minutes per session[3,15]. For the sake of comparison in this study, disregarding warm-up and cool down, all interventions were 20 minutes duration. No statistically significant changes were found in the MCT group, and this is likely due in part to insufficient training volume for the MCT training modality.

I agree that the 2:1 ratio of HIT to MCT was a good decision for this pilot study for the purposes of garnering more information about HIT in chronic stroke given that MCT is already much more thoroughly studied, and MCT protocols matched protocols outlined in previous studies. It is clear that the parameters set for this pilot RCT were born out of research reported in the previous Boyne et al article[5]. In the previous article the authors suggested that a combination of 30 s burst adhering to P60 and P30 recovery parameters may be optimal for improving gait and aerobic capacity in chronic stroke, and that is precisely what was designed here: 3 initial sessions of P60 and then 9 sessions of P30. It is surprising that this group did not improve more given the expectations set forth in the "within-session" study; however, the small sample size could be biasing 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.]

With regard to gait speed, the HIT group significantly outperformed the MCT group. Fastest treadmill speed increased by 0.49 m/s, and both fastest overground walking speed and fastest comfortable walking speed increased by 0.14 m/s in the HIT group. The impact of this 4-week HIT intervention is comparable to the results of 3 months of MCT with intervention sessions that last up to twice as long as the HIT protocols. In an RCT Mackay-Lyons demonstrated that n=36 chronic stroke patients who participated in MCT treadmill training 3x/week for 30-50 min/session at an intensity of 60-80% HHR improved their fastest overground walking speed by 0.14m/s (95% CI 0.08 to 0.20)[15]. Essentially, equivalent outcomes in gait speed were achieved, but the HIT protocols achieved those results in 18-30 less hours of training time (rest intervals included in HIT comparison). Other studies concerning low to moderate intensity steady state exercise corroborate that increases in gait (and aerobic fitness) are observed, but these results typically take a longer time and require more training time compared to the HIT protocols described by Boyne et al. Of course, the results of the HIT study need to be taken with tempered enthusiasm given the small study size, but greater improvements were indeed observed in the HIT compared to MCT group.

The application of HIT as an adjunctive therapy for chronic stroke has clinical appeal for the physical therapist. The results of the study indicate that an equivalent total volume of HIT treadmill training increases gait speed more so than does MCT in a 4 week period. To be fair to MCT, MCT protocols are typically not limited to 25 minutes but rather intervals of 40-60 minutes[9]. However, because HIT protocols require less time, it is feasible that HIT could be integrated more easily alongside other interventions within clinical practice given that outpatient physical therapy treatments often last from 30-60 minutes. The time-condensed, efficiency of HIT literally allows for more time for other physical therapy modalities relevant to the stroke patient such as balance, coordination, motor control, postural alignment, strengthening, and UE concerns.

A potential barrier to integrating HIT into clinical practice in chronic stroke is the topic of safety. The participants of this study were thoroughly vetted and monitored for cardiovascular complications and contraindications. For example, GXT with ECG stress monitoring are not standard practice across outpatient stroke clinics. No cardiovascular complications were reported in the HIT group, but the sample size was small, and 3 of 26 prospective participants were judged to be unfit for inclusion because of abnormal findings upon stress testing. Further guidelines for clinical practice should be examined before recommending HIT.

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

This CAT seeks to determine if the treatment effects of HIT on gait speed in chronic stroke are more effective than traditional physical therapy. The evidence reviewed in these two articles suggests that HIT treadmill walking protocols are more effective than steady-state treadmill exercise in improving both aerobic fitness and gait speed in chronic stroke patients[5,7]. The first study shows that HIT protocols involving 30 s bursts and either 60 s or 120 s recovery intervals results in a significantly increased within-session maximal treadmill walking speed[5]. Furthermore, 30 s bursts punctuated by 30 s rest intervals results in significantly improved VO_{2peak} and allows for a greater step count and repetition of practice. One might expect that if a subject with chronic stroke is able to train at these comparable levels of increased gait capacity on a regular basis, then these efforts should translate into faster overground walking speeds. This is precisely what the investigators in the second study sought to describe. They found that after 4 weeks of HIT, 3 sessions at P60 and 9 sessions at P30, overground walking speed increased by 0.14± m/s[7]. The participants also demonstrated increases in various markers of aerobic fitness which are correlated with increases in gait speed[2,7]. HIT protocols are time efficient. Including warm-up and cool down, interventions require only 25-30 minutes time. Participants trained using MCT protocols at session durations equivalent to the HIT protocols showed no statistically significant improvement in all outcome measures from baseline to post-intervention follow-up.

Implications for Clinical Practice

Implications for clinical practice seem to be that HIT is a preferable mode of aerobic conditioning and enhancement of gait speed in chronic stroke patients. First, improvements in these dimensions appears to occur at a faster rate in HIT compared to MCT. In a comparison between two studies, 4 weeks of HIT produced equivalent results in increased gait speed compared to 3 months of MCT[7,15]. Next, Boyne et al reported that the LEAPs trial found that stroke patients required an average of 25 physical therapy sessions, averaging 54 minutes/session[7]. Because HIT is time-efficient, theoretically more time should be available in therapy for focusing on other physical therapy modes important for stroke patients. For example, if a chronic stroke patient requires supervision for cardiovascular and/or orthopaedic safety concerns, then standard MCT guidelines will require that the patient exercise for a continuous 30-60 minutes which is an amount of time equal to many outpatient physical therapy treatments. Moreover, current guidelines prescribe MCT 3 days/week[3,15]. On the other hand, if the clinician employs an HIT protocol, then the front end of a 45-60 minute treatment session could focus on other concerns such as balance specific training, postural alignment, or any number of other concerns specific to the patient.

However, safety guidelines for HIT in clinical practice have not been established. Although no adverse safety events were reported in either of these studies (and the author is not aware of any other adverse health events in available HIT stroke literature), the participants in these studies are thoroughly vetted through rigorous screening processes, limiting the chance of incident. Patients performing HIT operate at intensities that require 85-95% of HHR and HR_{peak}[5]. The first five exclusion criteria listed for either study are contraindications for intense exercise precisely because intense exercise increases the likelihood of a cardiovascular event in individuals with those contraindications. A second safety concern is that because HIT is so intense, fatigue and mechanical fault must vigilantly monitored to reduce the likelihood of an orthopaedic injury during intervention. Incorporation of HIT into a rehabilitation program for a chronic stroke patient will require specific training and equipment for screening and monitoring and close collaboration with medical services to ensure patient safety and appropriateness of the intervention.

Implications for Future Research

The studies reviewed in this CAT are of moderate to good quality and indicate that HIT is a valid means of improving gait speed in chronic stroke, but these studies pool only 34 subjects, but larger RCTs would increase the power of the studies' conclusions. Together these studies show that HIT is feasible and further investigation is justified.

To date no systematic review or meta-analysis exists that explores HIT's effects (including gait improvements) in stroke patients. At least 20 studies investigate this topic to some degree, and it would be useful explore data trends across pooled results.

Answers to other questions will enhance the applicability of HIT for gait speed enhancement. What are the safety criteria for widespread clinical practice? It is unclear what the ceiling effects are for gait speed in stroke. Does HIT allow for a higher ceiling than MCT? The MCD and MCID for chronic stroke patients has not been determined. The MCID for gait speed among patients with subacute stroke and severe gait speed impairments was determined to be 0.16 m/s in the LEAPS study[11]. The results seen in the Boyne et al pilot study found mean improvements of 0.14 m/s. It might be expected that the MCID for chronic stroke is lower since subacute stroke patients often make great strides in gait speed, but this topic requires investigation.

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