SCHOOL OF MEDICINE
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Impact of intensity from Clinical Practice Guidelines on strategies to improve walking post-stroke, SCI and TBI

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Introduction – what is conventional therapy?

- Therapists utilize multiple varied interventions to treat patients with neurological injury (Lang 2007, 2009, Kimberly 2010, Moore 2010, Zbogar 2016)

Research to provide answers?

- Hundreds of studies have evaluated the efficacy of specific interventions to improve function
  - Many demonstrate positive results
  - Available meta-analyses suggest positive outcomes for many interventions
- Clinical Practice Guidelines may provide a mechanism to delineate specific recommendations to guide clinical practice

Recent guidelines (American Heart Association 2016)

- Recommendations for physical interventions

"Balance training should be provided"

"Intensive, repeated mobility task training is recommended . . . treadmill or overground may be reasonable"

"Incorporating cardiovascular exercise and strength interventions . . . circuit training is reasonable"

"Robotic assisted walking with conventional therapy may be considered"

"Virtual reality may be beneficial"

Recent guidelines (American Heart Association 2016)

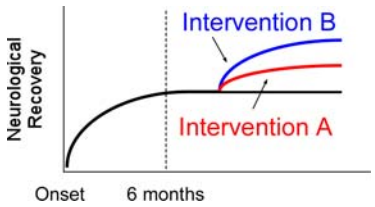
- Recommendations for physical interventions

APTA Clinical Practice Guidelines

- Strategic objective: CPGs enable PTs and PTAs to understand the state of evidence in an effort to:
  - Decrease unwarranted variations in practice
  - Minimize the knowledge translation gap
  - Optimize movement
- Reframing the CPG question
  - Typical focus: What interventions facilitate improvements in function in patients with neurological injury?
  - Current focus: What interventions optimize performance of a specific function?
  - Goal: provide **concise recommendations** supported by **systematic literature review** of the efficacy of **specific interventions to improve locomotor function** in persons **> 6 months following stroke, traumatic brain injury (TBI) or incomplete spinal cord injury (SCI)**

Focus on strategies to improve locomotor function

- Restoration of locomotor function is primary, achievable goal in most stroke and TBI, many incomplete SCI
  - All patients with acute neurological injury, similar upper motoneuron disorders
  - Common pathways and mechanisms underlying motor performance, adaptation and learning in spared neural pathways (Dobkin 2008, Holleran 2018)
  - Tested in chronic stages to reduce variability of outcomes



Consideration of Evidence: study selection

- Decision to accept only randomized clinical trials
  - Many interventions show a positive effect on function (Duncan 1998, 2003, 2011)
  - Non-randomized trials provide little indication of optimal intervention
- Evaluation of the treatment groups?
  - What were the experimental and control interventions?
  - Unequal duration therapies
    - No intervention or intervention unlikely to improve locomotion
    - Additional therapy (X intervention + PT vs PT only)
  - Matched duration therapies
    - Details of conventional strategies often missing (Lohse 2018), benefits unclear (Hornby 2016)
    - Details of alternative interventions

Consideration of Evidence: concept of "dosage"

- "Dose" of therapies may be important - duration is only one aspect (Moore 2010, Lohse 2014, Lang 2015, Hornby 2016)
- FITT principle
  - Frequency – days or sessions/week
  - Intensity – rate of work/power, cardiovascular or neuromuscular demands
  - Time – duration of sessions or entire training period
  - Type – what was actually done
- Concepts don't affect "rating" of article, but likely influence outcomes

Specific terminology for Locomotor CPG recommendations

- Weight of the evidence supports substantial benefit as compared to other or conventional strategies: "**should be provided**"
- Evidence to support intervention vs other strategies is unclear, *or* evidence supports intervention as compared to no intervention: "**may be considered**"
- Weight of the evidence does not indicate a substantial benefit above other strategies: "**should not be provided**"

Literature Search

- Ensure CPG on this topic does not currently exist, refine scope, ensure sufficient information
- PubMed, CINHAL Embase, CENTRAL, 1995-2016

Patient (P)	**Intervention (I)**	**Outcomes (O)**
• Stroke	• Strength	• 10 m walk test
• Spinal cord injury	• Exercise	• 6 min walk test
• Brain injury	• Balance	
	• Tai Chi	
	• Vibration	
	• Aerobic/high intensity	
	• Virtual Reality	
	• Circuit Training	
	• Neurofacilitation	
	• Walking	
	– Treadmill	
	– Over-ground	
	– Robotics	

Development of Appraisal Process

- APTA Critical Appraisal Tool for Experimental Interventions (CAT-EI v. 2016)
  - Part A: contextual information - general articles information
  - Part B (2
    - Items 1-12: overall quality of the study
    - Items 13-20: individual outcomes of the study
  - Part C: impact of the study – details of FITT principles
  - B – score determines Level 1 or Level 2 (<10 or ≥ 10)

Development of Appraisal Process

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Score on B section indicates Level of Evidence

- Evidence Table - for a specific intervention
  - Article, level/score, diagnoses (CVA, SCI, TBI)
  - Outcomes (10 m, 6 min) –
    - "-" not tested
    - "0" – not significantly different between groups
    - "+" – significantly different between groups
  - Intervention (Experimental v Comparison)
    - no or matched vs. unmatched intervention
    - FITT parameters
  - Other findings – additional significant outcomes

Example Evidence Table (strength)

Strengthening exercises									
	Article	Level	Score	Dx	6 MWT	10 MWT	Intervention	Control	Other Findings
Strengthening vs no exercise	Flansbjer 2008	1	13	CVA	0	0	2X 6 to max reps 80% 1RM, 2X/wk, 10 wks	no intervention	strength, TUG
Strengthening vs other exercise									
Etc.									

Strength of Recommendation

Grade	Level of Obligation	Definition
A	Strong	-moderate to high level of certainty of moderate to substantial benefit, harm, risk or cost (most Level 1 or 2)
B	Moderate	-moderate to high level of certainty of slight to moderate benefit, harm, risk or cost (based on most Level 2)
C	Weak	-weak level of certainty for moderate to substantial benefit, harm, risk or cost (Level 2-5)
R	Research	-an absence of research on the topic or disagreement among conclusions from higher-quality studies on the topic

Benefit – improves walking

Harm, risks (safety), costs (equipment, personnel, time/travel, alternative interventions possible

Use of "should" recommendation

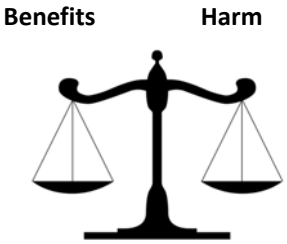
- Strength of Recommendation: **A** (Strong – most Level 1) or **B** (Moderate – most Level 2)
  - moderate to high level of certainty of benefit
- Intervention ***should be performed***
  - Mostly better than conventional or alternative therapy
  - >66% studies show benefit

Benefits **Harm**

Use of "may" recommendation

- Strength of Recommendation:
  C (Weak – Level 1 or 2)
  - weak level of certainty of benefit

- Intervention ***may be considered***
  - Sometimes better than conventional therapy (33-66% studies show benefit)
  - Mostly better than no intervention (>66% show benefit)



Use of "should NOT" recommendation

- Strength of Recommendation:
  A (Strong – most Level 1) or **B** (Moderate – most Level
  - moderate to high level of certainty of harm, risk or cost

- Intervention ***"should not" be performed***
  - Mostly not better than conventional therapy or alternative strategy (< 33% show benefit)

Results: Studies categorized by specific interventions

- Strengthening
- Balance
  - Sitting, standing/pre-gait, with altered sensory input
  - Postural training with vibration
  - Augmented (virtual) reality feedback
- Combined
  - circuit training
  - combined (strength, balance, aerobic)
- Walking
  - Body weight supported treadmill training
  - Aerobic treadmill training
  - Robotic-assisted treadmill training
  - Overground training
  - Virtual reality walking training
  - Variable training
  - Other
- Aerobic tasks (cycling)
- Ankle robotic training
- Other

Strength training

- 10 articles evaluating effects of strength training on walking function in acute-onset CNS injury (8 Level I, 2 Level II)
  - Training interventions mostly similar across articles
  - 9 grouped by unmatched (3 studies) vs matched exercise with minimal LE activity vs matched other therapy
  - 1 concentric vs eccentric strength training
- FITT categories
  - Type – fairly consistent (dynamometer, weight machines) vs 1 functional strength training and one fairly uncertain
  - Frequency/time – indication of control group with none, minimal, or other therapy; duration, frequency
  - Intensity –% 1 repetitions maximum (1RM) with number of sets/repetitions

Strengthening exercises

	Article	Level	Score	Dx	6 MWT	10 MWT	Intervention	Control	Other Findings
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	Yang 2006	1	14	CVA	+	+	fxnl strength exercises, 3X/wk, 1 mo	no intervention	strength, TUG, step test
	Severinsen 2014	1	14	CVA	0	0	3x8 reps 80% 1RM, 3X/wk, 12 wks	2 groups – aerobic, 3X/wk, 12 wks and none	strength
Strengthening vs other exercise	Kim 2005	1	13	CVA	--	0	3x10 reps max effort, 3X/wk, 6 wks	passive LE ROM, 3X/wk, 6 wks	strength (trend)
	Oulette 2004	1	12	CVA	0	0	3x10 reps 70% 1RM, 3X/wk, 12 wk	LE ROM, UE exercise, 3X/wk, 12 wk	strength
	Bourbonnais 2002	1	10	CVA	+	+	up to 70-90%, reps incr, 3X/wk, 6 wks	Upper extremity exercise, 3X/wk, 6 wks	strength
Strengthening vs other LE exercise	Kim 2016	2	9	CVA	0	+	strength 70% 1RM reps not listed, 5X/wk 2 mo	balance training, 5X/wk 2 mo	Ø strength
	Jayaraman 2013	2	9	SCI	+	--	3x10 reps 100% 1RM. 3X/wk, 1 mo	3x12 reps, 60% 1RM), 3X/wk, 1 mo	strength
	Labruyere 2014	1	10	SCI	--	+	3x10-12 reps 70% 1RM, 4X/wk, 1 mo	Lokomat, 4X/wk, 1 mo	strength
Other	Clark 2013	1	14	CVA	--	0	eccentric	concentric	strength

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Summary: Strength training

- **Aggregate Evidence Quality:** 10 articles evaluating effects of strength training on walking function in acute-onset CNS injury (8 Level I, 2 Level II)
  - 4/9 comparing strength training to no/alternative intervention revealed benefit
  - 1 comparing concentric and eccentric strengthening exercises indicated no difference
- **Action Statement:** Clinicians ***may consider*** use of strength training strategies with multiple sets and repetitions of > 70% 1RM or during functioning activities to improve walking function ***(Level 1, Grade C)***.
- **Risks, harm, costs:** Strength training may be more costly if utilizing specialized equipment

Balance training

- 22 articles evaluating effects of balance training on walking function in acute-onset CNS injury (15 Level I, 7 Level II) – grouped by type of exercises
  - 10 articles focused on trunk control, weight shifting exercises, altered sensory inputs (eyes closed/unstable surface) – Pre-gait activities
  - 4 articles on standing balance training with vibration
  - 8 studies on postural stability training with augmented visual input (virtual environment)
- FITT categories
  - Type – subgrouping as above, control groups mixed
  - Frequency/time – indication of control group with matched/unmatched therapy time, duration/frequency
  - Intensity – no intensity data in any of the listed study

Balance/pre-gait

	Article	Level	Score	Dx	6MWT	10MWT	Intervention	Control	Other Findings
Trunk stabilization	Dean 1997	1	12	CVA	--	O	sitting/reaching > arm's length, 5X/wk, 2 wks	sitting/reaching < arm's length, 5X/wk, 2 wks	Incr. sit LE weightbearing
	Kilinc 2016	1	12	CVA	--	O	NDT/trunk exercises, 3X/wk, 3 mo.	PT, 3X/wk, 3 mo.	none
	Chun 2016	2	8	CVA	--	Ø	Lumbar stab. In standing, 3/wk, 7 wks	Standing training (Biodex), 3/wk, 7 wks	none
Standing/weight shifting	Kim 2015	2	9	CVA	--	+	Tai Chi 2X/wk, + regular PT, 10X/wk, 6 wks	regular PT, 10X/wk, 6 wks	FRT, TUG, DGI
	Aruin 2012	2	8	CVA	--	O	Compelled weight shift during PT, 1X/wk, 6 wks	PT activities, 1X/wk, 6 wks	none
	Shiekh 2016	1	14	CVA	--	O	Compelled weight shift during PT, 6X/wk, 6 wks	PT, 6X/wk, 6 wks	increased stand symm
	You, 2012	2	7	CVA	--	O	standing with device, limited parameters	Single limb activities, limited parameters	none
Standing/altered feedback	Bonan 2004	1	10	CVA	--	O	balance w/o vision + PT, 5X/wk, 1 mo.	balance with vision + PT, 5X/wk, 1 mo.	SOT 1,4 (Equitest)
	Bayouk 2006	1	11	CVA	--	O	Dynamic sit/standing with EC/foam, 2X/wk, 8 wks	Dynamic sit/standing, 2X/wk, 8 wks	Decr variability standing sway
	Kim 2016	2	8	CVA	--	+	Biodex Balance System + PT. 5X/wk 2 mo.	Strength training + PT, 5X/wk 2 mo	FRT

Balance: Augmented feedback - Vibration

	Article	Level	Score	Dx	6 MWT	10 MWT	Intervention	Control	Other Findings
Vibration during postural training vs no vibration with/without training	Lau, 2012	1	18	CVA	O	O	WBV (platform), dynamic LE exercise, 3X/wk, 8 wks	Dynamic LE exercise, 3X/wk, 8 wks	none
	Lee, 2013	1	13	CVA	--	+	Segmental Vibration: 30': dynamic standing balance + PT/FES, 5X/wk, 6 wks	dynamic standing balance + PT/FES, 5X/wk, 6 wks	Sway distance, velocity EO/ EC
	Brogardh, 2012	1	17/18	CVA	O	--	Platform 3.75 mm amp, Freq 25 Hz, standing, 2X/wk, 6 wks	Platform 0.2 mm, Freq 25 Hz, standing, 2X/wk, 6 wks	none
	Liao 2016	1	14	CVA	O	O	high intensity (incr amp, freq) WBV + dynamic standing balance, 30 sessions, 2.5 mo	low intensity WBV + dynamic standing balance or none, 30 sessions, 2.5 mo	none

Balance: Augmented Feedback - Virtual Reality									
	Article	**Level**	**Score**	**Dx**	**6 MWT**	**10 MWT**	**Intervention**	**Control**	**Other Findings**
VR + Postural + PT vs. PT Only	Lee, 2014	1	14	CVA	_	+	Augmented postural control (sit/stand); 3X/wk, 1 mo + PT, 5X/wk, 1 mo	PT only, 5X/wk, 1 mo	none
	Kim, 2009	1	13	CVA	_	+	VR dynamic balance 4Xwk/1mo + PT 4X/wk, 1 mo	PT only , 4X/wk, 1 mo	dynamic balance
	Park, 2013	1	10	CVA	_	O	VR supine, sit, stand, 3X/wk, 1mo + PT 5X/wk, 1 mo	PT only, 5X/wk, 1 mo	none
VR Postural vs Postural without VR/other	Chung, 2014	2	9	CVA	_	+	Core stabilization with VR, 5X/wk, 6 wks	Core stabilization without VR, 5X/wk, 6 wks	TUG
	Gil-Gomez, 2011	1	10	TBI, CVA	O	O	Wii sitting and dynamic standing, 20 sessions	PT – balance activities, 20 sessions	none
	Song & Park, 2015	2	5	CVA	_	O	VR-X-box dynamic standing, 5X wk, 2 mo	Ergometer, <40% HRreserve, 5X wk, 2 mo	depression
	Llorens, 2015	1	12	CVA	_	+	30 min VR dynamic standing + PT, 5X/wk, 20 sessions	PT standing, stepping, walking, 5X/wk, 20 sessions	BBS
VR balance vs ∅	Fritz, 2013	1	15	CVA	O	O	Wii + standing, no supervision, 5X/wk, 1 mo	∅	none

Summary: Balance training

- **Aggregate Evidence Quality:** 14 Level I, 8 Level II articles evaluating balance training on locomotor function
  - Pre-gait/balance training – 2/10 showed positive benefit
  - Balance training with vibration - 1/4 showed positive benefit
  - Postural training with augmented visual input (VR) - 4/8 positive benefit

- **Action Statements:**
  A. Clinicians ***should not*** incorporate sitting or dynamic standing (weight-shifting or balance) activities to improve locomotor function ***(Level 1, Grade A)***
  B. Clinicians ***should not*** incorporate balance training interventions with whole body or local vibration to improve locomotor function ***(Level 1, Grade B)***
  C. Clinicians ***may consider*** use of dynamic (non-walking) balance training strategies coupled with augmented (virtual) reality to improve locomotor function ***(Level 1, Grade C)***

- **Risks, harm, costs:** Balance training with augmented (virtual) reality feedback is more expensive than training without augmented feedback

Walking- Aerobic

- 12 Level I articles
  - High intensity vs low intensity (5 articles)
    - high intensity: HIIT or 70-85% HRR/VO_2 peak
    - Low intensity: 40-50% HRR
  - High intensity vs passive/no intervention (5 articles) –
    - 60-80/85% HRR or age predicted HR_{max}
    - stretching, passive exercise, some balance and massage
  - Fast vs slow walking (2 articles) – fast as safely possible vs self-selected speed

- FITT categories
  - Type – all walking or conventional
  - Frequency/time – indication of duration/frequency
  - Intensity – HR parameters described

	Article	Level	Score	Dx	6 MWT	10 MWT	Intervention	Comparison
Hi intensity vs stretching/ massage/passive exercise	Globas, 2012	1	15	CVA	+	+	TM, 60-80% HRR, 3x/week, 3mo	Passive stretch, balance
	Gordon, 2013	1	14	CVA	+	__	OG walking, 60-85% HRmax, 3x/wk, 12 ks	Light massage
	Luft, 2008	1	13	CVA	+	O	TM, 40 min, 60-80% HRR, 3x/week, 6mo	Passive stretch
	Moore, 2010	1	13	CVA	O	O	TM, 80-85%HRmax, 20x/wk, 4 wks	no intervention
	Macko, 2005	1	13/12	CVA	+	O	TM, 60-80 HRR, 40 min, 3x/week, 6mo	Low intensity, 30-40% HRR, stretch
Higher vs lower intensity walking training	Boyne, 2016	1	18	CVA	O	+	TM, HIIT(30 s max, <60 s rec) 3x/wk, 4 wks	TM, 45% HRR, 3x/week, 4 weeks
	Ivey, 2015	1	11	CVA	O	O	TM, 30 min, 80-85% HRR, 3x/week, 6mo	TM, 30 min, <50% HRR, 3x/week, 6mo
	Munari, 2016	1	16	CVA	+	+	TM, HIIT 1 min ints; 85% Vo2pk, 3 min 50% Vo2pk), 3x /wk, 3mo	TM, 50-60 min, 40-60% VO2 peak, , 3x /week, 3mo
	Holleran, 2015	1	12	CVA	+	O	TM&OG, 30min, 70-80% HRR, 3x/week, 4 weeks	TM&OG, 30min, 30-40% HRR, 3x/week, 4 weeks
	Yang, 2014	1	12	SCI	+	O	TM, 60min, 5x/week, 2mo, faster than SSV	precision training OG 5x/week, 2mo
Fast vs slow speed	Awad, 2016	1	13/14	CVA	O	O	TM&OG, Fastest speed 40min, 3x/week, 12 weeks,	TM&OG, SSV40mi, n, 3x/week, 12 weeks
	Sullivan, 2002	1	11	CVA	-	O	TM, 2.0mph, 20 min, 12 sessions over 4-5 weeks	TM, 0.5mph, 20 min, 12 sessions over 4-5 weeks

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	Munari, 2016	1	16	CVA	+	+	TM, HIIT 1 min interval; (85% Vo2pk, 3 min 50% Vo2pk), 3x /wk, 3mo	TM, 50-60 min, 40-60% VO2 peak, , 3x /week, 3mo
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	Yang, 2014	1	12	SCI	+	O	TM, 60min, 5x/week, 2mo, faster than SSV	precision training OG 5x/week, 2mo
Fast vs slow speed	Awad, 2016	1	13/14	CVA	O	O	TM&OG, Fastest speed 40min, 3x/week, 12 weeks,	TM&OG, SSV40mi, n, 3x/week, 12 weeks
	Sullivan, 2002	1	11	CVA	-	O	TM, 2.0mph, 20 min, 12 sessions over 4-5 weeks	TM, 0.5mph, 20 min, 12 sessions over 4-5 weeks

Summary: Walking- Aerobic

Aggregate Evidence Quality:

- High intensity walking vs passive exercise/stretching – 4/5 showed greater benefit
- High intensity walking vs low intensity walking- 4/5 showed greater benefit
- Fast walking vs slow walking (no measure of intensity) -2/2 showed no differences

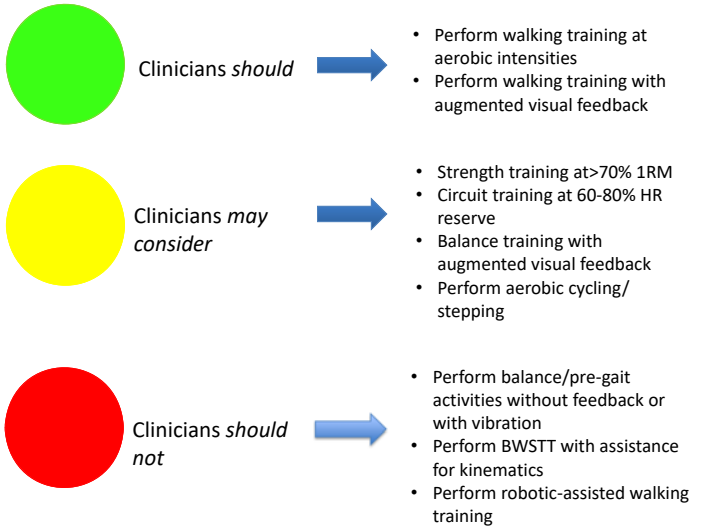
Action Statement: Clinicians ***should use*** moderate to high intensity walking training interventions for improving locomotor function in patients with chronic CNS injury ***(Level 1, Grade A).***

Risks, harm, costs: Potentially increased risk of cardiovascular events during higher intensity training walking training without appropriate cardiovascular monitoring

Other interventions

- Body weight supported treadmill training
  - All patients walk
  - Provision of body weight support and physical assistance to assist normal walking kinematics
- Robotic assisted training
  - All patients walk
  - Provision of body weight support and robotic assistance
- Cycling or circuit training
  - Both typically focus on high intensity
  - Cycling or mixed interventions
- Virtual Reality walking training
  - No intensity measures
  - Engaged in visual/"virtual" task with walking

Summary – CPG for chronic CVA, SCI, TBI to improve walking



Common themes

- Intensity appears to be important
  - Walking/cycling at 60-80% HR reserve should be performed
  - BWSTT/PT assist and robotics not recommended – lower intensities (Israel 2006)

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2. Use it and improve it
3. Specificity matters
4. Repetition matters
5. Intensity matters
6. Time matters
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8. Age matters
9. Transference
10. Interference

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- Salience appears to be important (VR with walking, possibly balance)
- Repetition appears to be important (repeated task practice)

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Common themes

- Specificity of practice may be important
  - Walking practice but only at high intensities
  - Cycling practice (locomotor-like tasks at high intensities)
  - Other non-walking tasks (strength, balance/pre-gait) not highly recommended

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  - Walking practice but only at high intensities
  - Cycling practice (locomotor-like tasks at high intensities
  - Other non-walking tasks (strength, balance/pre-gait) not highly recommended
- Activities directed towards impairments underlying walking do not necessarily improve walking

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Summary

- Intensity/engaging patients during walking = very important!!!
- Intensity with non-walking tasks = iffy?
- Walking tasks without intensity = no-go!!!
- Non-walking, non-intense tasks – might as well take a nap

Clinical Discussion and Questions

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