THE EFFECT OF HYBRID ASSISTIVE LIMB (HAL) ON GAIT VELOCITY IN ADULTS WITH GAIT DISORDERS: A SYSTEMATIC REVIEW

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Overview

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- PRISMA
- Oxford Level of Evidence
- Results
- Conclusion
- Clinical Relevance
- Limitations
- Future Research
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- Acknowledgements

Enhancing Neuroplasticity

- Motor Control and Motor Learning Principles[1]
- <u>Neuroplasticity Factors</u>[1]

→ Salience

→ Time

→ **Intensity**

→ **Repetition**

→ Age

→ **Specificity**

→ Transference

→ Interference

→ **Use it or lose it**

→ **Use it and improve it**

Robotic Exoskeletons

- Provide ambulation training by means of an external passive movement device[2]

- Promote improvements in upright tolerance, locomotion, bone mineral density, edema management, cardiopulmonary outcomes, etc.[2]

Hybrid Assistive Limb (HAL)

- "First cyborg-type wearable robot exoskeleton"[3]
- Integrates human, mechanical, and information technologies
- Enhances voluntary motor control through real-time walking assist[3]
- **HAL Components**[3]
  - → Hybrid system utilization of voluntary control
  - → Motor interpretation of bioelectric signals
  - → Generation of motor patterns reflecting human motion

HAL CVC vs. CAC Modes

Cybernic Voluntary Control (CVC)[7]

- Voluntary electric signals on muscles trigger motion
- Torque control led by tuner commands and flexion/ extension balance

Cybernic Autonomous Control (CAC)[7]

- Force-pressure sensors in shoes sense gait phase to trigger motion

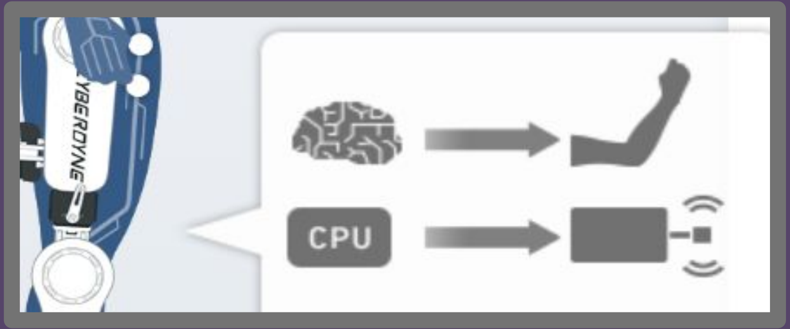
Operative Steps[3]

1.

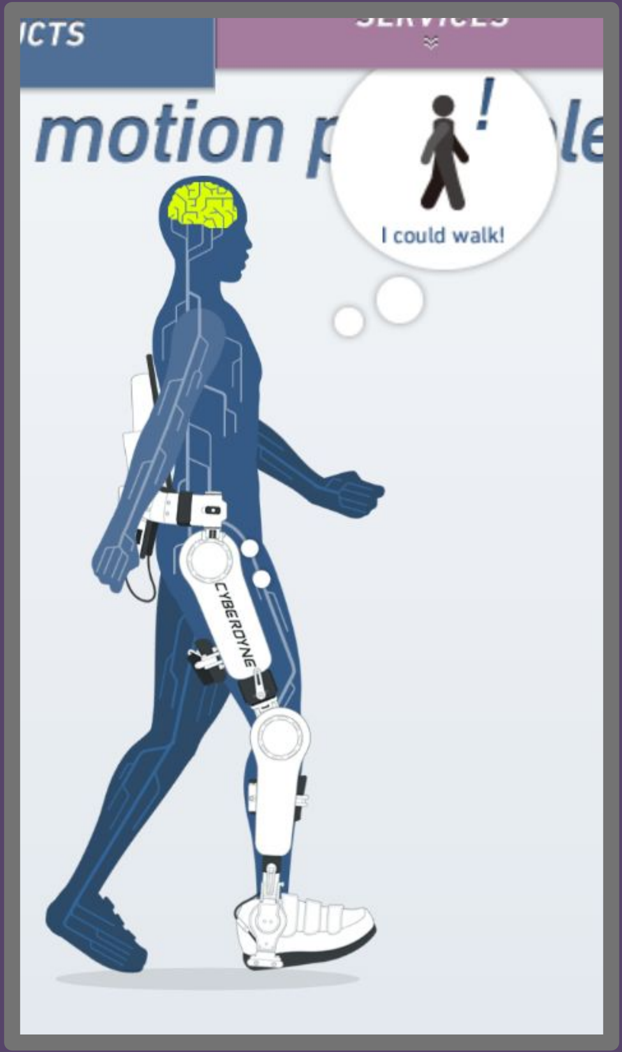
2.

3.

4.




motion
I could walk!
CYBERDYNE


motion
I could walk!
CYBERDYNE


HAL
Power Units
for upper limb
(+Angle Sensor)
Battery Pack
Control Unit on back
Bio-electric Signal Sensors
Power Units
for lower limb
(+Angle Sensor)
Floor Reaction Force Sensor

Impact of HAL on Gait Outcomes

- Improves **independent** walking more efficiently than conventional gait training at 1 and 2 months after intervention[8]
- Promotes safe, early recovery of walking ability compared to conventional gait training[8]
- Supports independent mobility[8]

Purpose

To determine the effectiveness of HAL on improving gait velocity in those with gait disorders

Methods - Databases

- CINAHL
- Academic Search Elite
- Pubmed/MEDLINE
- ScienceDirect

Methods - Search Terms

(“Hybrid assistive limb” OR HAL OR “lower limb model”)

AND

(gait velocity OR gait speed OR walking velocity OR walking speed)

AND

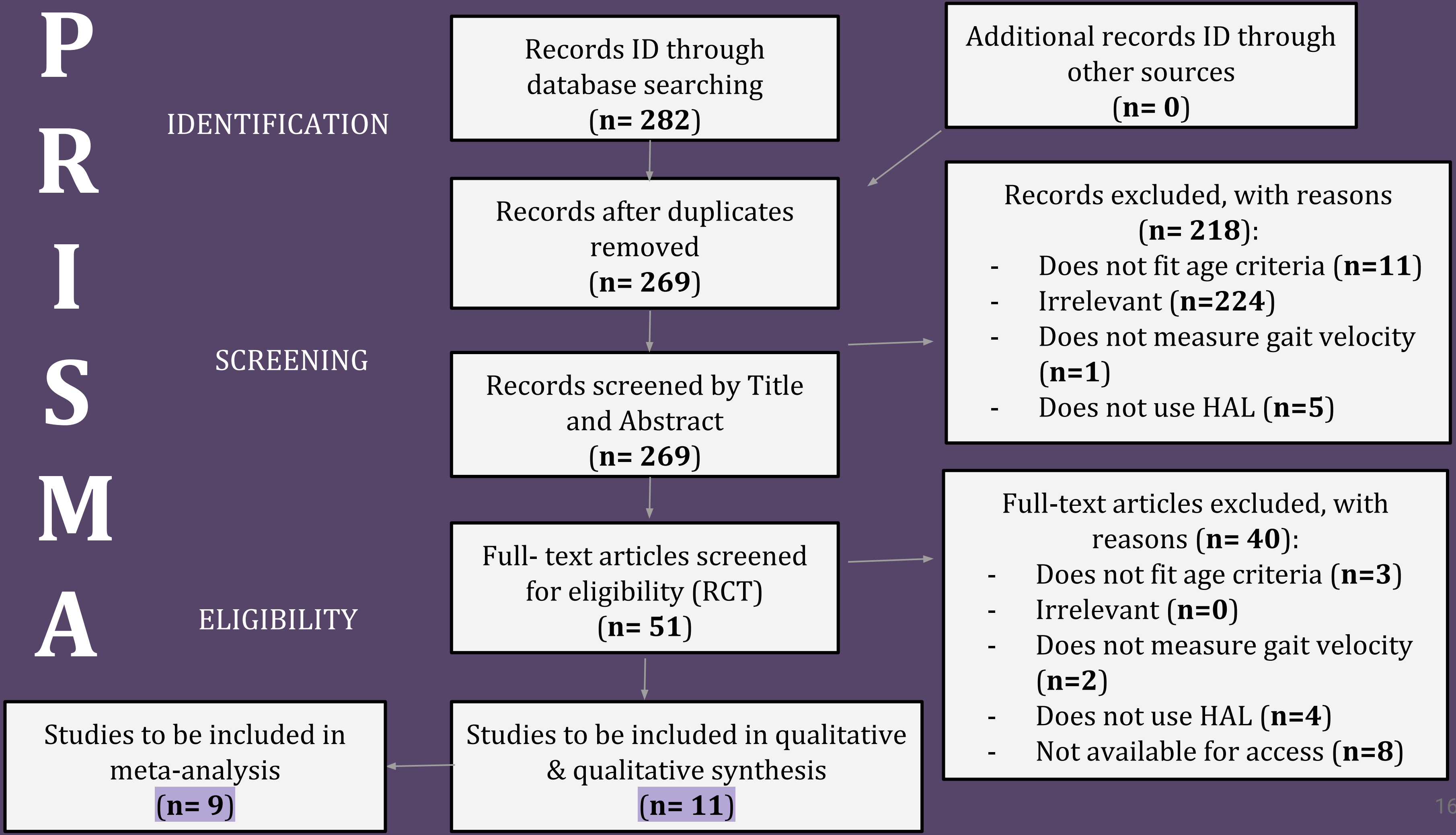
(gait OR gait impairments OR gait deviations OR gait disorders)

Methods - Search Limits

- Human subjects
- Within the last 10 years
- Peer-Reviewed
- English

Methods - Selection Criteria

- Adults 18 years or older
- Diagnosis of gait disorder
- Use of HAL during gait
- Gait velocity outcomes


P R I S M A
IDENTIFICATION
SCREENING
ELIGIBILITY
Records ID through database searching (n= 282)
Additional records ID through other sources (n= 0)
Records after duplicates removed (n= 269)
Records excluded, with reasons (n= 218):
- Does not fit age criteria (n=11)
- Irrelevant (n=224)
- Does not measure gait velocity (n=1)
- Does not use HAL (n=5)
Records screened by Title and Abstract (n= 269)
Full- text articles screened for eligibility (RCT) (n= 51)
Full-text articles excluded, with reasons (n= 40):
- Does not fit age criteria (n=3)
- Irrelevant (n=0)
- Does not measure gait velocity (n=2)
- Does not use HAL (n=4)
- Not available for access (n=8)
Studies to be included in qualitative & qualitative synthesis (n= 11)
Studies to be included in meta-analysis (n= 9)

Oxford Level of Evidence

Author and Title	Study Design	Oxford Level of Evidence
Tanaka et al[7]- Spatiotemporal gait characteristic changes with gait training using the hybrid assistive limb for chronic stroke patients.	Non-Controlled	4
Yoshikawa et al[8]- Gait training with hybrid assistive limb enhances the gait functions in subacute stroke patients: a pilot study.	Non-Randomized Controlled	3
Yoshikawa et al[9]- Training with hybrid assistive limb for walking function after total knee arthroplasty.	Non-Randomized Controlled	3
Taketomi et al[10]- Hybrid assistive limb intervention in a patient with late neurological deterioration after thoracic myelopathy surgery due to ossification of the ligamentum flavum.	Case Report	4

Oxford Level of Evidence Cont.

Author and Title	Study Design	Oxford Level of Evidence
Aach[11]- Voluntary driven exoskeleton as a new tool for rehabilitation in chronic spinal cord injury: a pilot study.	Non-Controlled	4
Yoshimoto et al[5]-Feasibility and efficacy of high-speed gait training with a voluntary driven exoskeleton robot for gait and balance dysfunction in patients with chronic stroke: nonrandomized pilot study with concurrent control.	Non-Randomized Controlled	4
Kubota et al[12]- Hybrid assistive limb (HAL) treatment for patients with severe thoracic myelopathy due to ossification of the posterior longitudinal ligament (OPLL) in the postoperative acute/subacute phase: a clinical trial.	Case Series	4

Oxford Level of Evidence Cont.

Author and Title	Study Design	Oxford Level of Evidence
Maeshima et al[4]- Efficacy of a hybrid assistive limb in post-stroke hemiplegic patients: a preliminary report.	Non-Controlled	3
Yoshikawa et al[13]- Hybrid assistive limb enhances the gait functions in subacute stroke stage: a multi single-case study.	Cross-Over	4
Watanabe et al[14]- Locomotion improvement using a hybrid assistive limb in recovery phase stroke patients: a randomized controlled pilot study.	Randomized Controlled	2
Kawamoto et al[15]- Pilot study of locomotion improvement using hybrid assistive limb in chronic stroke patients.	Non-Controlled	4

Results - Study Design

- Randomized Controlled: 1 study[14]
- Non-Randomized Controlled: 3 studies[5, 8, 9]
- Non-Controlled: 4 studies[4, 7, 11, 15]
- Case Report: 1 study[10]
- Case Series: 1 study[12]
- Cross-Over: 1 study[13]

Results - Sample Size (N)

- Minimum: 1 (case report)[10]
- Maximum: 32 (randomized controlled)[14]
- Average Size: 13.55 participants[4, 5, 7-15]

Results - Age

- Range: 21-89.5 years old[4,14]
- Average Age:
  - 47.63-73.67 years old (range)[4, 5, 7-15]
  - 61.13 years old (overall)[4, 5, 7-15]

Results - Gender

- Total Participants: 139[4, 5, 7-15]
- Men: 80[4, 5, 7-15]
- Women: 59[4, 5, 7-15]

Results - Population

Population	Studies
Hemiplegia following Cerebrovascular Accident (CVA)	Chronic: 3[5,7, 15] Subacute: 4[4, 8,13,14]
Total Knee Arthroplasty (TKA)	1[9]
Ligamentum Flavum Ossification	1[10]
Spinal Cord Injury	1[11]
Posterior Decompression secondary to Posterior Longitudinal Ligament Ossification	1[12]

Results - Training Frequency

- Range: 1 session per week[5] to 5 sessions per week[7,13]
- Frequency Range:
    - 2 to 3 times per week[12]
    - 2 to 5 times per week[7]
    - 4 to 5 times per week[13]
- Not Specified: 1 study[4]

Results - Training Duration

- Range: 3-18 weeks[4, 5, 7-15]
- Average: 6.4 weeks[4, 5, 7-15]
- Mode: 5 weeks[4, 5, 7-15]
- Not Specified: 1 study[12]

Results - Training Intensity

- "According to patient tolerance"[4, 5, 7-15]
  - → Comfortable gait speed vs. maximum speed possible
- Single Leg: 6 studies[5,8,9,13-15]
- Mode:
  - → *Overground*: 8 studies[4,8-10,12-15]
  - → *Treadmill*: 3 studies[5,7,11]
- Time Limit: 1 study capped at 20 minutes per session[8]

Results - HAL Training Mode

- CVC Mode: 8 studies[5,7-12,14]
- CAC Mode: 2 studies (until patient became familiar with CVC)[13,15]
- Not Specified: 1 study[4]

Results - Training Operators

Physical Therapists[4, 5, 7-15]

- Assistants
- Medical Doctors

Results - Total Sessions

- Minimum Sessions: 6 sessions[7]
- Maximum Sessions: 57 sessions[11]
- Average Session Number: 16.4- 20.4 sessions (range) and 18.4 sessions (overall)[4, 5, 7-15]
- Studies with Ranges of Sessions:
  - → From 6 to 15 sessions[7]
  - → From 10 to 12 sessions[9]
  - → From 25 to 40 sessions[8]
  - → From 22 to 24 sessions[13]
  - → From 45 to 57 sessions[11]
- Not Specified: 1 study[4]

Results - Time Spent with HAL

- Minimum Time: 10 minutes[9]
- Maximum Time: 60 minutes[7]
- Average Time: 24.1 minutes[4, 5, 7-15]
- Not Specified: 2 studies[4,11]

Results - Conventional PT Time

- Minimum Time: 20 minutes[14]
- Maximum Time: 120 minutes[9]
- Average Time: 60.625 minutes[4, 5, 7-15]
- No Conventional PT: 3 studies[4,7, 10]

Results - Outcome Measures

- **Primary Outcomes**
  - → 10- Meter Walk Test (10- MWT)[4,5, 7-15]
- **Secondary Outcomes**
  - → Berg Balance Scale (BBS)[5, 8, 15]
  - → Timed Up and Go (TUG)[5, 11, 14, 15]

Results - Adverse Events

No adverse events noted in any of the 11 studies resulting from HAL use.[4,5,7-15]

Results - Statistical Significance for 10 Meter Walk Test (10 MWT)

All HAL Groups	Pre-Training	Post-Training	Change in MWS	MCID for MWS
Tanaka et al[7]**	0.52 +/- 0.32	0.66 +/- 0.42	0.14 +/- 0.10	Equals MCID of 0.14[16]
Yoshikawa et al[8]*	0.83 +/- 0.34	1.02 +/- 0.44	0.19 +/- 0.10	Exceeds MCID of 0.17 (joint pain)[17]
Yoshikawa et al[9]*	1.41 +/- 0.33	1.63 +/- 0.9	0.22 +/- 0.67	Exceeds MCID of 0.16[18]
Taketomi et al[10]*	0.83 +/- not listed	0.97 +/- not listed	0.14 +/- not listed	Exceeds MCID of 0.006[19]
Aach[11]*	0.28 +/- 7.85	0.50 +/- 0.34	0.32 +/- 7.51	Exceeds MCID of 0.006[19]
Yoshimoto et al[5]**	0.39 +/- 0.18	0.60 +/- 0.25	0.21 +/- 0.07	Exceeds MCID of 0.14[16]
Kubota et al[12]*	0.35 +/- 0.18	0.85 +/- 0.23	0.50 +/- 0.05	Exceeds MCID of 0.006[19]
Maeshimi et al[4]**	Not included	Not included	Not included	Not included
Yoshikawa et al[13]*	Not included	Not included	Not included	Not included
Watanabe et al[14]*	0.61 +/- 0.43	0.85 +/- 0.43	0.24 +/- 0	Exceeds MCID of 0.16[18]
Kawamoto et al[15]*	0.41 +/- 0.26	0.45 +/- 0.24	0.04 +/- 0.02	Does not exceed MCID of 0.14[16]

*= $p<0.05$
**= $p<0.01$

Results - Statistical Significance for Berg Balance Scale (BBS) in (points)

	Pre-Training	Post-Training	Change in BBS	MDC for BBS
Yoshimoto et al[5]** **HAL Group**	40.9 +/- 6.13	46.2 +/- 5.97	5.30 +/-0.16	**Exceeds** MDC of 4.66[20]
Kawamoto et al[15]* **HAL Group**	40.6 +/- 13.6	45.5 +/- 8.02	4.90 +/- 5.58	**Exceeds** MDC of 4.66[20]

Results - Statistical Significance for Timed Up and Go (TUG) in (s)

*= p< 0.05
**= p<0.01

	Pre-Training	Post-Training	Change in TUG time	MDC for TUG
Aach[11]* **HAL Group**	55.34 +/- 33.20	38.18 +/- 25.98	17.16 +/- 7.22	**Exceeds** MCD 10.8 seconds[21]
Yoshimoto et al[5]** **HAL Group**	35.6 +/- 14.6	24.1 +/- 7.82	11.5 +/- 6.78	**Exceeds** MDC of 8 seconds[20]
Watanabe et al[14]* **HAL group**	27.8 +/- 14.3	16.8 +/- 7.00	11.0 +/- 7.30	**Exceeds** MDC of 8 seconds[20]
Watanabe et al[14]** **Control group**	45.8 +/- 25.7	29.9 +/- 18.4	15.9 +/- 7.30	**Exceeds** MDC of 8 seconds[20]

Results - Non-Significant Results

Maximal Walking Speed (MWS) in (m/s)	Pre- Training	Post- Training	Change in MWS	MCID for MWS
Yoshikawa et al[9] Control Group	1.35 +/- 0.21	1.35 +/- 0.24	0 +/- 0.03	Does not exceed MCID of 0.14[16]
Yoshikawa et al[8] Control Group	0.80 +/- 0.42	0.84 +/- 0.42	0.04 +/- 0.00	Does not exceed MCID of 0.16[18]
Yoshimoto et al[5] Control Group	0.44 +/- 0.16	0.42 +/- 0.06	0.02 +/- 0.10	Does not exceed MCID of 0.14[16]
Watanabe et al[14] Control Group	0.49 +/- 0.55	0.63 +/- 0.5	0.14 +/- 0.05	Does not exceed MCID of 0.16[18]
Berg Balance Scale (BBS) in (point)	**Pre- Training**	**Post- Training**	**Change in MWS**	**MDC for BBS**
Yoshikawa et al[8] HAL Group*	46.4 +/- 6.6	48.8 +/- 7.8	2.40 +/- 1.20	Does not exceed MDC of 4.66[20]
Yoshikawa et al[8] Control Group	43.8 +/- 9.8	43.8 +/- 8.4	0 +/- 1.40	Does not exceed MDC of 4.66[20]
Yoshimoto et al[5] Control Group	43.2 +/- 5.38	43.3 +/- 5.66	0.10 +/- 0.28	Does not exceed MDC of 4.66[20]
Timed Up and Go (TUG) in (s)	**Pre- Training**	**Post- Training**	**Change in MWS**	**MDC for TUG**
Yoshimoto et al[5] Control Group	31.3 +/- 14.2	31.4 +/- 14.8	0.10 +/- 0.60	Does not exceed MDC of 8[20]
Kawamoto et al[15] HAL Group*	36.0 +/- 30.9	34.9 +/- 29.5	1.90 +/- 1.40	Does not exceed MDC of 8[20]

Outcomes Meta-Analysis

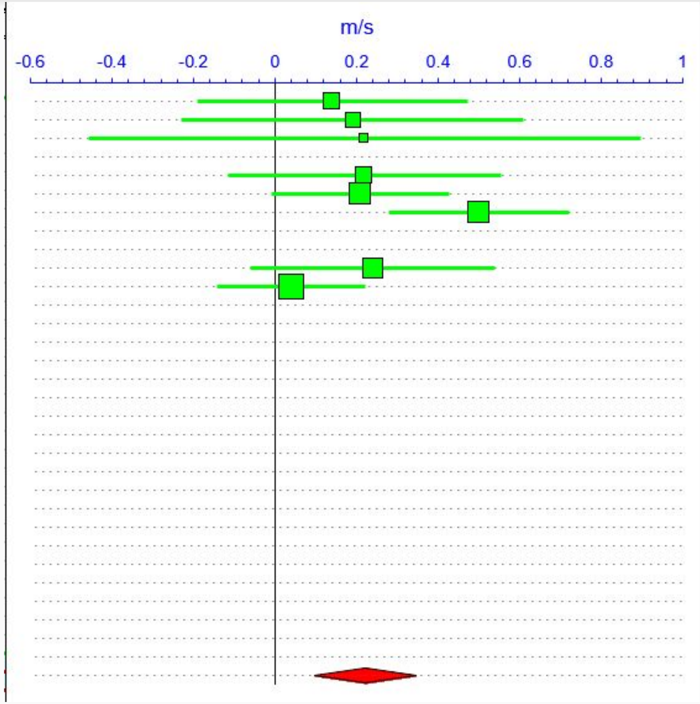
- Mean scores of pre- and post- intervention, standard deviations, and N values integrated into ESCI Meta-Analysis Calculator[4, 5, 7-15]:

→ **10- Meter Walk Test (10- MWT)**

→ **Berg Balance Scale (BBS)**

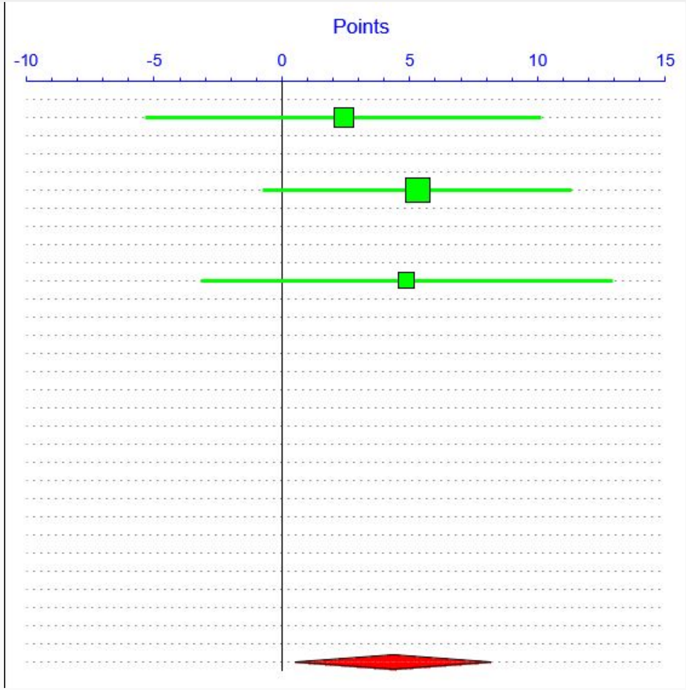
→ **Timed Up and Go (TUG)**

Meta-Analysis- 10-MWT



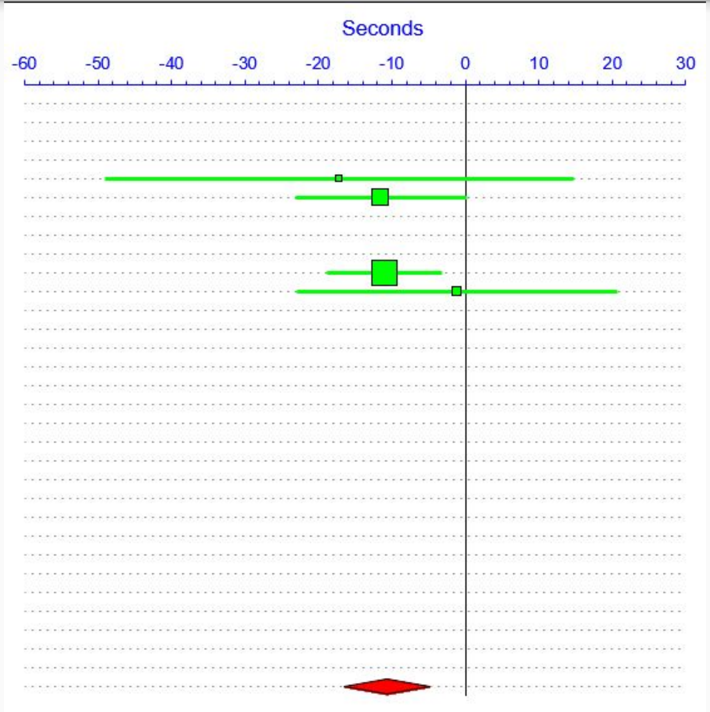
Studies Included in Meta-Analysis	8[4,5,7-15]
Average Change	0.22 meters per second improvement
Confidence Interval	95% CI [0.0988, 0.34669]
MCID	0.006- 0.17 meters per second

Meta-Analysis- BBS



Studies Included in Meta-Analysis	3[5, 8, 15]
Average Change	4.36 point improvement
Confidence Interval	95% CI [0.54355, 8.17665]
MDC	4.25- 4.66 points

Meta-Analysis- TUG Test



Studies Included in Meta-Analysis	4[5, 11, 14, 15]
Average Change	-10.62 seconds
Confidence Interval	95% CI [-16.45, -4.7961]
MDC	8-10.8 second reduction

Meta-Analysis- Implications

- **All primary and secondary outcome measures exceed minimal detectable changes and minimal clinically important differences found in the literature[16-21]**
  → 10-MWT (0.22 meters per second improvement)
  → BBS score (4.36 point improvement)
  → TUG score (10.62 second improvement)

Results - Limitations

- Non randomization
- Not blinded
- Small sample sizes
- No established treatment parameters (wide variation)
- Lack of generalizability
- No follow-up

Results - Further Research

- Randomized, blinded control trials
- Larger sample sizes
- Efficacy of use for a variety of conditions
- Establish HAL training parameters for optimal outcomes
- Long-term use with follow-ups

Results - Conclusion

- **Improvements in outcomes noted in:**

→ 10- Meter Walk Test

→ Berg Balance Scale Score

→ Timed Up and Go Scores

Systematic Review Conclusion

- Low to moderate level evidence supports the feasible and safe use of HAL gait training in adults with gait disorders to improve outcomes like 10-MWT, BBS, and TUG.
- HAL can benefit a variety of populations.

Clinical Relevance/ Take Home

- Improves gait speed, balance and mobility in adults with gait disorders safely and effectively
- Currently laboratory-based
- HAL may enter clinical setting in our lifetime.
- Clinician recognition and implementation of neuromotor benefits of HAL can enhance outcomes.

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DPT faculty & students

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Questions?