VU Research Portal

Predicting duration of outpatient physical therapy episodes for individuals with spinal cord injury based on locomotor training strategy

Garnier-Villarreal, Mauricio; Pinto, Daniel; Mummidisetty, Chaithanya K.; Jayaraman, Arun; Tefertiller, Candy; Charlifue, Susan; Taylor, Heather B.; Chang, Shuo Hsiu; McCombs, Nicholas; Furbish, Catherine L.; Field-Fote, Edelle C.; Heinemann, Allen W.

Link to publication in VU Research Portal

ORIGINAL RESEARCH

Predicting Duration of Outpatient Physical Therapy Episodes for Individuals with Spinal Cord Injury Based on Locomotor Training Strategy

Check for updates

Mauricio Garnier-Villarreal, PhD,[a] Daniel Pinto, PT, PhD,[b]
Chaithanya K. Mummidisetty, MS,[c] Arun Jayaraman, PT, PhD,[c,d]
Candy Tefertiller, PT, DPT, PhD,[e,f] Susan Charlifue, PhD,[e,f] Heather B. Taylor, PhD,[g]
Shuo-Hsiu Chang, PT, PhD,[g,h] Nicholas McCombs,[c] Catherine L. Furbish, PT, DPT,[i]
Edelle C. Field-Fote, PT, PhD,[i,j] Allen W. Heinemann, PhD[c,d]

From the [a]Sociology Department, Vrije Universiteit Amsterdam, Netherlands; [b]College of Health Sciences, Marquette University, Milwaukee, Wisconsin; [c]Max Näder Center for Rehabilitation Technologies and Outcomes Research, Shirley Ryan AbilityLab, Chicago, Illinois; [d]Physical Medicine and Rehabilitation, Northwestern University Feinberg School of Medicine, Chicago, Illinois; [e]Craig Hospital, Englewood, Colorado; [f]University of Colorado, Denver, Colorado; [g]UT Health Science Center at Houston, Houston, Texas; [h]Neurorecovery Research Center, TIRR Memorial Hermann, Houston, Texas; [i]Shepherd Center, Atlanta, Georgia; and [j]Division of Physical Therapy, Emory University School of Medicine, Atlanta, Georgia.

Abstract

Objective: To characterize individuals with spinal cord injuries (SCI) who use outpatient physical therapy or community wellness services for locomotor training and predict the duration of services, controlling for demographic, injury, quality of life, and service and financial characteristics. We explore how the duration of services is related to locomotor strategy.

Design: Observational study of participants at 4 SCI Model Systems centers with survival. Weibull regression model to predict the duration of services.

Setting: Rehabilitation and community wellness facilities at 4 SCI Model Systems centers.

Participants: Eligibility criteria were SCI or dysfunction resulting in motor impairment and the use of physical therapy or community wellness programs for locomotor/gait training. We excluded those who did not complete training or who experienced a disruption in training greater than 45 days. Our sample included 62 participants in conventional therapy and 37 participants in robotic exoskeleton training.

Interventions: Outpatient physical therapy or community wellness services for locomotor/gait training.

Main Outcome Measures: SCI characteristics (level and completeness of injury) and the duration of services from medical records. Self-reported perceptions of SCI consequences using the SCI-Functional Index for basic mobility and SCI-Quality of Life measurement system for bowel difficulties, bladder difficulties, and pain interference.

Results: After controlling for predictors, the duration of services for the conventional therapy group was an average of 63% longer than for the robotic exoskeleton group, however each visit was 50% shorter in total time. Men had an 11% longer duration of services than women had. Participants with complete injuries had a duration of services that was approximately 1.72 times longer than participants with incomplete injuries. Perceived improvement was larger in the conventional group.

Conclusions: Locomotor/gait training strategies are distinctive for individuals with SCI using a robotic exoskeleton in a community wellness facility as episodes are shorter but individual sessions are longer. Participants' preferences and the ability to pay for ongoing services may be critical factors associated with the duration of outpatient services.

Archives of Physical Medicine and Rehabilitation 2022;103:665−75

Introduction

Over the past half century, inpatient rehabilitation for spinal cord injury (SCI) has been characterized by an increase in medical and rehabilitation sophistication coupled with a decrease in length of stay while aiming to maximize function, mobility, and independence.[1,2] Outpatient services and wellness programs have helped to fill the gap in rehabilitation resulting from decreasing inpatient length of stay and the need to enhance function in the community.[3,4] Whiteneck et al[5,6] investigated outpatient rehabilitation characteristics using a practice-based evidence framework and reported that 44% of all rehabilitation services provided in the first year after SCI occur after inpatient discharge. Additionally, because SCI is a chronic condition, often with permanent functional limitations, considerations for life-long rehabilitation to maintain clinical gains and functional independence are needed but seldom investigated.[7]

Between 249,000 to 363,000 persons live with SCI in the United States[8]; most people experience functional deficits that can improve with rehabilitation therapy.[9] People with SCI have an elevated risk of cardiorespiratory,[10,11] musculoskeletal,[12] and endocrinemetabolic[13,14] health conditions due, in part, to decreased physical activity.[15,16] People with SCI also have an increased risk of chronic pain,[17] anxiety, and depression.[18] Loco-motor/gait training is standard of care in rehabilitation for individuals with incomplete SCI, and recovery of locomotor ability is a high priority by people with SCI regardless of injury severity or time since injury.[19,20] Locomotor training also improves many of the secondary conditions associated with SCI. These benefits may be associated with mechanical loading through the trunk and extremities during upright mobility,[21] muscle elongation-relaxation cycles in the lower extremities,[22] and increasing cardiorespiratory demand and metabolic health.[23]

Since the seminal work of Whiteneck et al in characterizing inpatient and outpatient rehabilitation,[6] there have been significant advances in the development of robotic exoskeletons and the role that exoskeleton-assisted walking can play. Robotic exoskeletons can reduce a physical therapist's effort during over-ground training of people with chronic spinal cord injury, increase intersession reliability, and provide resistance and trajectory guidance.[24] Algorithms for robotic exoskeleton-assisted walking are improving and can apply principles of motor learning to people with chronic motor incomplete spinal cord injury.[25] In 2 users with motor complete thoracic lesions, robotic exoskeleton systems have shown operability across variable terrain and potentially stairs and ramps.[26] Additionally, investigators are exploring features of human-machine interactions.[27]

Investigations continue to support the efficacy of robotic exoskeleton in people with SCI rehabilitation eligible for locomotor training.[28-31] Using an observational design, Sale et al[32] found that robotic exoskeleton-assisted training after complete or incomplete SCI from cervical (C7) to lumbar (L2) resulted in significant gait improvements. Chang et al[33] randomized people with incomplete SCI who were also ambulatory to robotic exoskeleton versus conventional physical therapy (PT) and found that walking endurance, stride length, and step length increased significantly after intervention in the exoskeleton group. In addition to locomotor training, therapy using exoskeletons may improve overall health status, reduce secondary complications, and increase function.[34-37] Other studies report decreases in spasticity, improvements in bowel and bladder function and regularity, sleep, and psychological well-being.[30,38] Based on its effect on comorbid pain and depression, it is plausible that robotic exoskeleton-assisted walking could positively affect the use of rehabilitation services in people with traumatic spinal cord injury.[39] Recently we provided a budget impact analysis for robotic exoskeletons at its current, incremental, technological stage; we showed that robotic exoskeleton use is associated with lower locomotor training costs using base case assumptions.[40] However, the financial structure of our health system creates a circular issue around technology where, reimbursement requires standardization, standardization requires clinical use, and clinical use requires reimbursement or standardization.[41] Owing to a lack of reimbursement and coverage, self-rationing may occur, presenting as canceled appointments and wide gaps in treatment time.[42]

Thus, the objective of this report is to characterize individuals with SCI who use outpatient PT or wellness program services for locomotor/gait training and predict the duration of services (DOS), using demographic, injury, functional, service, and financial characteristics. We were particularly interested in how DOS is related to robotic exoskeletons in locomotor training during an outpatient or wellness episode. This information will guide our understanding of technology use outside of an inpatient SCI setting.

Methods

Four SCI Model Systems centers collaborated on this project: The Shirley Ryan AbilityLab (formerly the Rehabilitation Institute of Chicago), Craig Hospital, Shepherd Center, and TIRR Memorial Hermann. Two Centers, Shirley Ryan AbilityLab and TIRR Memorial Hermann, collected data prospectively using a practice-based evidence design with the goal of comparing participants with SCI using robotic exoskeleton versus usual locomotor training in an outpatient setting.[43]

Services models using robotic exoskeleton assisted locomotor training within the context of wellness have developed and are employed in 2 SCI Model System centers, Craig Hospital and Shepherd Center.[31] Members can participate in exoskeleton training as well as more conventional activity-based training programming such as aerobic training, resistance training, gymnasium activities, and swimming. Eligibility criteria were a diagnosis of a SCI, ability to comprehend English, age 18 years or older, and a goal of improving lower extremity function related to gait, balance or functional mobility. Two centers recruited individuals participating in activity-based health and wellness programs focusing on robotic exoskeleton training or participation in a research project, and recruited outpatients receiving conventional or robotic exoskeleton-assisted therapy. Institutional review boards approved the study for all sites.

Instruments

Centers classified SCI level as cervical (C1-7), thoracic (T1-12), lumbar (L1-5), and sacral injury, and used the American Spinal Injury Association Impairment Scale[44] to characterize motor and

---

List of abbreviations:

AIS	American Spinal Injury Association Impairment Scale
CI	credible interval
OR	odds ratio
PT	physical therapy
SCI	spinal cord injury
SCI-FI	Spinal Cord Injury-Functional Index
SCI-QOL	Spinal Cord Injury-Quality of Life

sensory impairment. For purposes of analysis, we categorized injuries as motor complete or incomplete.

Participants completed 4 instruments that assess their perceptions of SCI consequences. The SCI Functional Index (SCI-FI) Basic Mobility short form measures global aspects of mobility,[45] the SCI Quality of Life (SCI-QOL) Bladder Management Difficulties and SCI-QOL Bowel Management Difficulties measure difficulties managing bladder and bowel programs,[46] respectively, and SCI-QOL Pain Interference measures ways that pain interferes with cognitive, social, and productive domains of life.[47] All instruments demonstrate evidence of adequate reliability and validity.[45-47] Participants completed instruments before their third session of therapy and after discharge.

Staff extracted the dates of outpatient PT or wellness services from participants' billing records and categorized financial responsibility for therapy. We counted the number of sessions and calculated the average minutes per session and the average number of days between sessions. We created a dichotomous variable to distinguish participants who received any robotic exoskeleton training from those who did not. We characterized financial responsibility for therapy as "none owing to research participation," "none because of insurance coverage or community grants," "shared responsibility between the participant and a third party (reference group)," or "entirely self-pay."

Analysis

We used the R platform's brms package,[48,49] which is an interface for the general Bayesian Software Stan,[50] and applied a Bayesian framework. This framework is a means of rational learning from experimental data based on probabilities, and it reflects how we think about issues when presented with new information. For example, in our daily lives, we often have an opinion about an issue and will update our position based upon new facts. Bayesian inferences follows this process using 3 steps: (1) identify your previously held opinion on what you're interested in learning more about through your research question (ie, specify the prior probability of the parameter of interest, referred to as a "prior"; (2) collect and summarize the observed outcome using a likelihood function; (3) produce a posterior distribution representing your updated position about the unknown parameter, referred to as the "posterior."[51] The posterior distribution allows investigators to make statements (inferences) regarding certainty of the parameter of interest (eg, a mean estimate or proportion) for the population of interest (vs the sample distribution using more conventional statistical approaches).[52-56] The uncertainty about the parameter is represented by the Bayesian credible interval (CI). The CI can be interpreted as the level of certainty for a given parameter in the observed sample, a 95% CI represents 95% of the values of the parameter of interest in the posterior distribution. Relevant to this study, computational challenges owing to cell sparseness related to small sample sizes can be overcome easily in the Bayesian framework.[57] Efron,[54] Matthews,[55] Wagenmakers et al,[56] and Kruschke[58] provide a fuller discussion.

We implemented a survival Weibull regression model to predict DOS,[59-61] that are robust to a variety of conditions without imposing strict assumptions.[60] The primary predictor is the therapy group (conventional therapy vs exoskeleton). While every other predictor is considered a covariate (confounding), as the focus is to control for their effect. Predictors are demographic (age, sex), injury (level and completeness), and financial responsibility characteristics; participant-reported aspects of quality of life

(SCI-FI for basic mobility; SCI-QOL for bowel difficulties, bladder difficulties, and pain interference); and service characteristics (average number of sessions, average number of days between sessions). The locomotor training service in which each participant was treated cannot be included as a predictor because it become redundant with other characteristics such as financial responsibility. Because the Weibull model uses a log metric, we transformed parameter estimates to an odds ratio (OR) to interpret the multiplicative increase of each predictor.

At discharge, participants repeated measures of function and activity. We evaluated differences in the 2 therapy groups in the probability of reporting improvement in 4 domains (mobility, activities of daily living, bladder/bowel function, and spasticity) while controlling for the same set of covariates described above. We evaluated group differences using Bayesian logistic regression, specifying a model to predict binary data by the addition of the logit link; this approach predicts the change in log-odds. The logit link function transforms continuous predicted values to the range of probabilities (range, 0-1). Subsequently, log-odds are transformed into OR for interpretation as effect sizes. The OR represents the multiplicative change in the odds of reporting improvement in each of the 4 realms. The results are presented as OR and the probability of reporting improvement in each realm. We plotted the expected change in probability in function for the 4 realms.[62,63] This approach allows us to evaluate the marginal effect of the main predictor of interest, controlling for covariates.

As part of the model definition, we used weakly informative priors for the regression slopes $b \sim N^{0,2}$. This approach defines the parameter space without guiding the posterior distribution. We specified 20,000 iterations of the Markov-Chain Monte Carlo estimation, with 1800 warmup iterations, on 3 chains. As random sample estimations are built-on previous samples it is referred to as a "chain." A phenomenon of Markov-Chain Monte Carlo estimation is initial samples (ie, as the chain is getting started) may be incorrect and should be ignored, which is why warmup iterations are used.[64] Inferences are based on posterior distributions with 6000 samples. We evaluated convergence with the potential scaled reduction factor defined as a value for all parameters below 1.05.[65]

Results

Table 1 reports the descriptive statistics for the conventional and exoskeleton groups. The sample of 99 participants includes 62 who received conventional PT and 37 who used robotic exoskeletons mostly in community wellness programs over a 24-month period. The robotic exoskeleton-assisted group tended to be younger, contained proportionally more women, were less likely to have shared financial responsibility for services, and reported greater bowel management difficulties than the conventional therapy group.

The predictive model converged after 20,000 iterations with the potential scaled reduction factor of <1.05. Table 2 reports the Weibull survival regression results. The model's Bayesian R^2 was 0.49 (95% CI, 0.39-0.54), indicating that, on average, the model accounts for 49% of the variability in DOS.[66] The mean difference between the predicted vs observed DOS was 55.65 days; predicted DOS was within the 95% CI, supporting the predictive accuracy of the model.

Controlling for predictors, DOS for the conventional training group was an average of 63% greater than for the robotic exoskeleton-assisted group, with a 95% CI ranging from 48% lower than

Table 1 Descriptive Statistics

	Conventional PT (N=62)			Exoskeleton (N=37)		
	Mean	SD	Percent	Mean	SD	Percent
Demographic Characteristics						
Age	40.53	17.67		34.03	12.50	
Men			73.4			67.6
Self-Reported Goals						
Health and wellness			83.3			82.9
Standing and stepping			89.4			88.6
Gait			90.9			71.4
Self-control			77.3			57.1
Reduced spasticity			72.7			65.7
Neurorecovery			71.2			65.7
Other			3.0			14.3
SCI-QOL*						
Basic mobility	4.17	1.81		3.68	1.87	
Bowel problems[†]	1.69	0.95		2.13	0.99	
Bladder problems	1.86	1.71		2.14	0.94	
Pain interference	2.59	2.64		2.03	0.89	
SCI Level						
C1-C7			34.4			48.6
T1-T12			50.0			45.9
L1-L5			15.6			5.4
SCI Completeness						
Incomplete			82.8			70.3
Financial Responsibility						
Both participant and third party			100.0			18.9
Research study			0.0			21.6
Self-pay			0.0			40.5
Third party entirely			0.0			18.9
Locomotor Services						
Duration of services	101.17	76.45		118.70	91.18	
Minutes/session	46.43	5.71		87.08	22.57	
Days between sessions	6.24	2.62		6.95	9.99	
Model of Service						
Outpatient setting			100.0			13.5
Wellness program			0.0			86.5
Reason for Discharge						
Attained goals			10.6			22.9
Financial			9.1			8.6
Difficult traveling to appointments		4.5			0.0	
Injury or medical condition		6.1			2.9	
Other[‡]	54.5			62.9		

NOTE. Statistics include premature discharge owing to cessation of services related to the COVID-19 pandemic, schedule conflicts, equipment delivery delays, moved, etc.
* SCI-QOL scores are computed as the average response on a rating scale that ranged from 0 (not at all) to 5 (very much).
† $P<.05$, 2-tailed

robotic exoskeleton group to 278% higher. These results reflect a high level of variability in the predicted DOS. Figure 1 illustrates DOS for the 2 groups. Variability in DOS is greater in the conventional therapy group than for the robotic exoskeleton group. Although DOS is longer for conventional therapy, each visit is 50% shorter in total time. The total minutes of training over the episode is less for the conventional therapy group (281 minutes) than for the robotic exoskeleton group (386 minutes).

Across groups, DOS was unrelated to age, mean minutes of therapy, mean days between sessions, SCI-FI for basic mobility, SCI-QOL for bladder difficulties, SCI-QOL for pain interference, and injury level with b near 0.0. DOS was 11% longer for men

than for women. For SCI-QOL for bowel difficulties, a 1-point increase in the raw score corresponds to an average 13% increase in DOS. DOS for participants with low paraplegia (L1-5) was an average 77% shorter than for participants with high paraplegia (T1-12). Participants with incomplete injuries had an average DOS that was 70% shorter than for participants with complete injuries. A 1-unit increase in SCI-QOL Bladder Management Difficulty score was associated with a 9% average decrease in DOS, and a 1-unit increase in SCI-QOL Pain Interference score was associated with a 7% average decrease. Compared with participants with shared responsibility, DOS for research participants was an average of 58% shorter; the self-pay group was an

Table 2 Duration of Intervention Prediction from Weibull Survival Model Results

	b	SE	OR	2.50%	97.50%
Intercept	3.383	0.885	29.459	4.896	166.505
Conventional therapy (vs exoskeleton)	0.490	0.437	1.632	0.677	3.784
Age	0.006	0.006	1.006	0.994	1.019
Men (vs women)	0.104	0.209	1.110	0.731	1.660
Basic mobility	−0.049	0.059	0.952	0.857	1.081
Bowel problems	−0.119	0.122	0.888	0.707	1.138
Bladder problems	−0.057	0.061	0.944	0.845	1.076
Pain interference	−0.010	0.011	1.010	0.991	1.035
T1-T12 (vs cervical)	−0.006	0.244	0.942	0.580	1.529
L1-L5	−0.570	0.303	0.566	0.312	1.021
Incomplete SCI (vs complete)	−0.542	0.293	0.581	0.323	1.037
PT min/session	0.028	0.009	1.029	1.011	1.048
Days between PT sessions	0.068	0.030	1.071	1.071	1.145
Financial Responsibility*					
Research study	−0.461	0.461	0.630	0.245	1.553
Self-pay	−0.402	0.516	0.669	0.240	1.807
Third party entirely	−1.405	0.524	0.245	0.086	0.675

Abbreviations: b, mean of the posterior distribution; SE, standard error of the posterior distribution; OR, odds ratio (exponent of b); 2.5%, lower boundary of the 95% Credible interval of the odds ratio; 97.5%, upper boundary of the 95% Credible interval of the odds ratio.
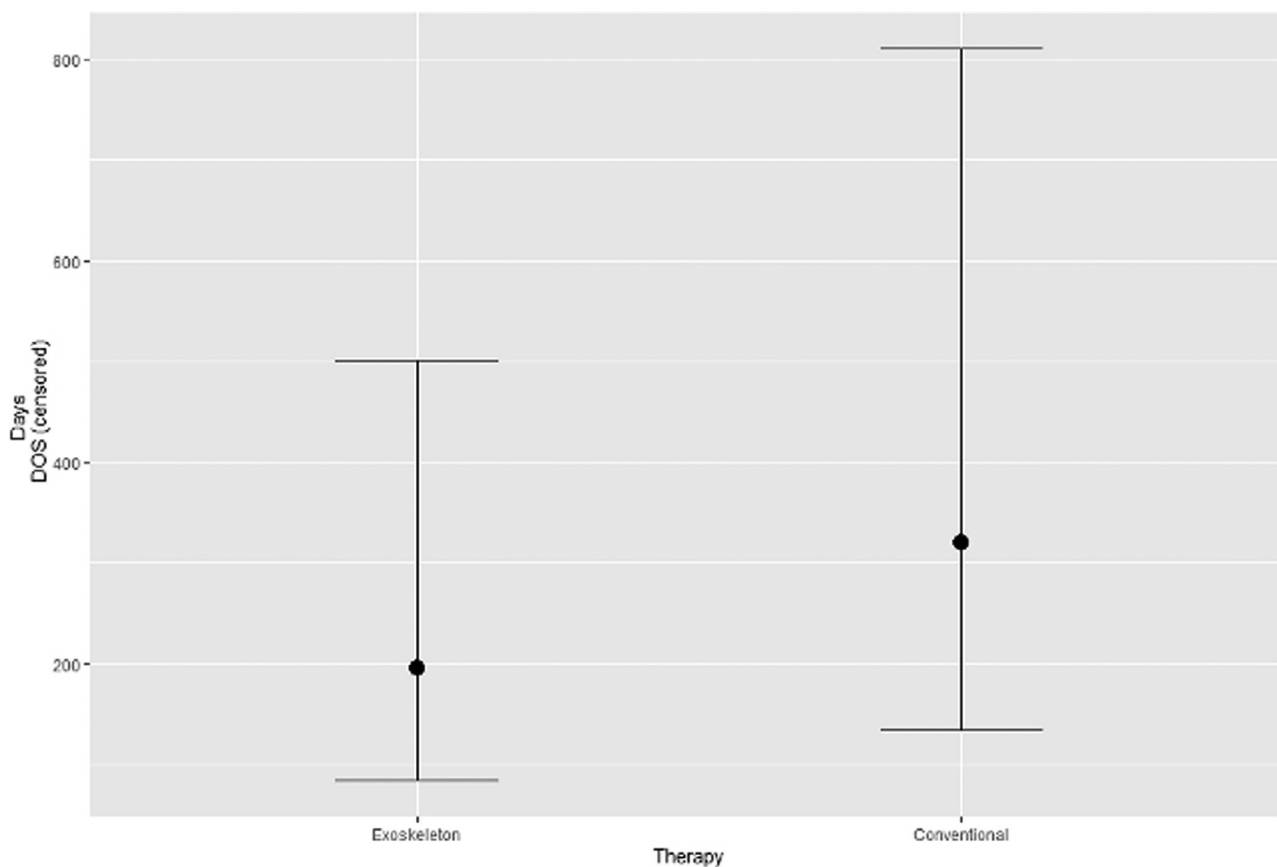* Both Participant and Third Party serve as reference

Fig 1 Conditional predicted duration of episode for conventional therapy vs robotic exoskeleton (main predictor). *Abbreviation*: DOS, duration of services.
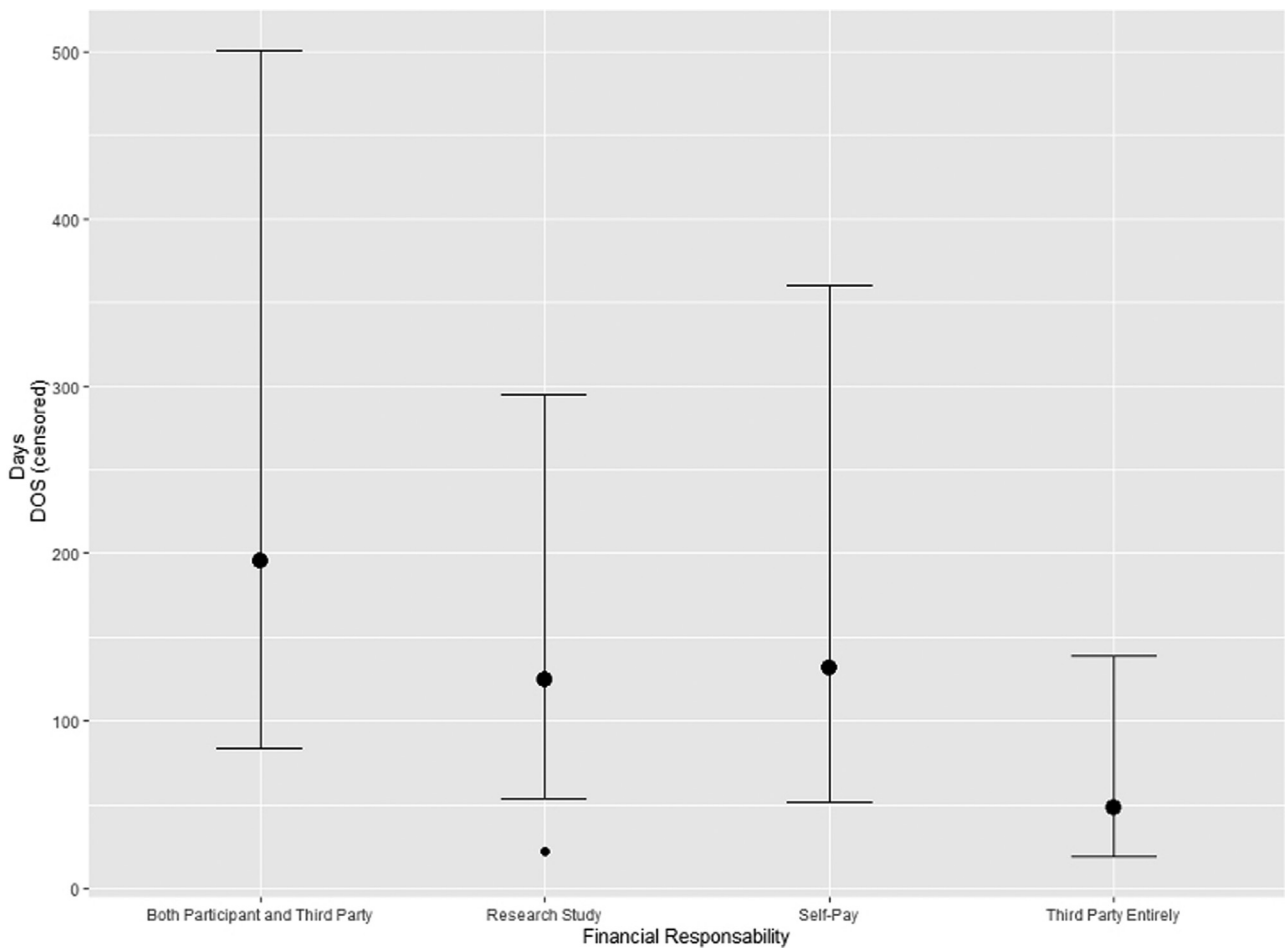
Fig 2 Conditional predicted duration of episode for financial responsibility (covariate). *Abbreviation*: DOS, duration of services.

average of 49% shorter; and the third party-covered group was an average of 74% shorter. Figure 2 illustrates these conditional group differences.

The robotic exoskeleton group was more than twice as likely to terminate services because they attained their goals (36%) than was the conventional therapy group (15%) (table 1). Figure 3 reports the extent of global goal attainment in each group.

Logistic regression results are presented in table 3, with inferences about group differences in perceived improvement, in 4 body function and activity domains while controlling for covariates. We omit the covariate effects in the table to simplify the results. After controlling for covariates, the conventional group was more likely than the exoskeleton group to perceive improvements in all 4 domains. The conventional group reported significant improvement in spasticity, bowel function, activities of daily living, and mobility relative to the exoskeleton group.

Discussion

DOS for participants using robotic exoskeletons was shorter than for those receiving convention therapy, and robotic exoskeleton sessions were longer when controlling for age, sex, injury level, injury completeness, financial characteristics, quality of life (SCI-FI for basic mobility; SCI-QOL for bowel difficulties, bladder difficulties, and pain interference), and service characteristics (average number of sessions, average number of days between

sessions). The shorter DOS may reflect the fact that exoskeleton use was often a component of a wellness program, where most participants self-pay for services, or were part of a research study (over 20% in the exoskeleton group), wherein DOS was determined by the study protocol. Outpatient services were more likely to include conventional therapy, where insurance is available to cover services. Total minutes per session tended to be longer for the exoskeleton group, likely owing to a difference in service delivery models or the time required to set up the robotic device. Most robotic exoskeleton participants received services in a community wellness program where the standard session is 1 to 2 hours, whereas participants receiving conventional therapy were treated in outpatient departments where 1-hour sessions are the norm. Unlike other forms of locomotor training, exoskeleton users may be able to tolerate longer bouts of training without becoming fatigued because the metabolic demand falls within the moderate physical activity range.[67,68]

Important predictors of DOS were level and completeness of injury, sex, SCI-QOL Bladder Management Difficulty and Pain Interference, and financial responsibility. Individuals with greater injury impairment and functional limitations required longer episodes. The finding that those with cervical injuries had shorter DOS than did participants with thoracic and lumbar injuries may seem counter-intuitive, but injuries at the cervical spinal levels were likely less severe (eg, motor incomplete injuries) because severe injuries at higher spinal levels (cervical spine) would likely preclude a participant from locomotor/gait training. Difficulties
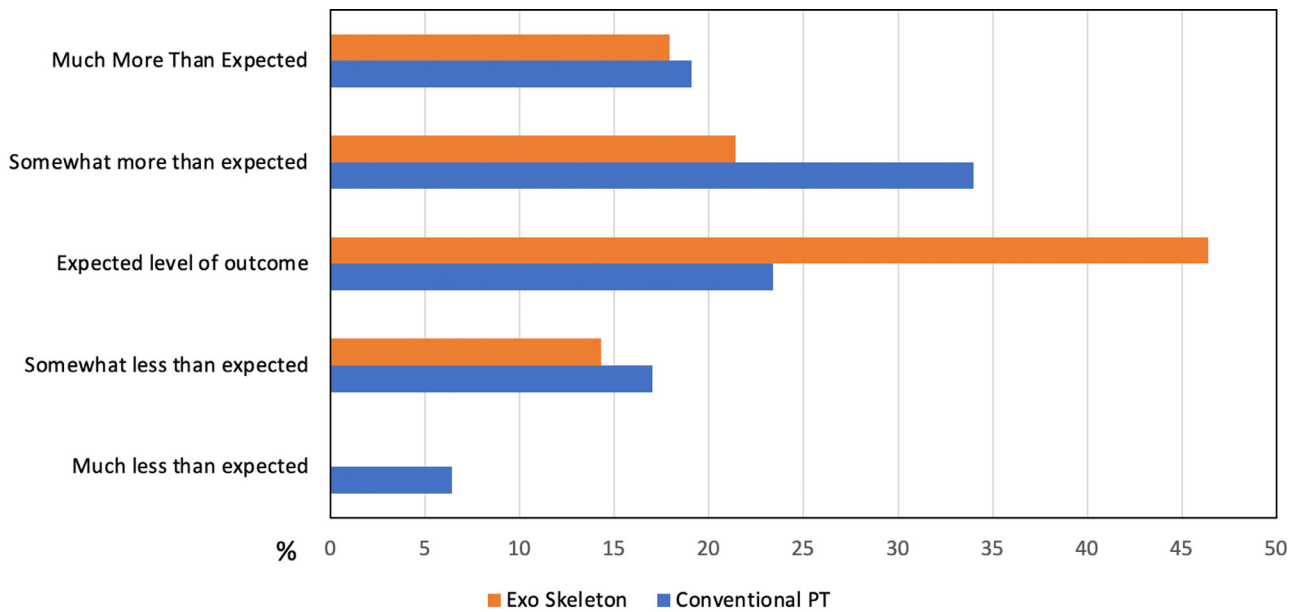
Fig 3   Global ratings of goal attainment (%).

with bladder management and pain are secondary conditions that affect quality of life[69] and may limit full participation in therapies, resulting in a plateau in function.

DOS for the conventional therapy group was characterized by great variability, perhaps reflecting variability in participants' goals, motivation, and financial resources including insurance coverage and access to transportation. Alternatively, variability may reflect eligibility criteria for exoskeleton locomotor/gait training. Thus, DOS variability in this group is likely to be smaller than for the conventional therapy group, for which there are no specific inclusion criteria.

Service characteristics were unrelated to DOS; number of sessions and time interval between sessions were independent of DOS. We expected to find evidence related to self-rationing through differences in time interval between sessions, but the setting differences may have resulted in self-selection where those unable to afford services would choose not to access exoskeleton therapy. The sessions were funded personally or via grants, and
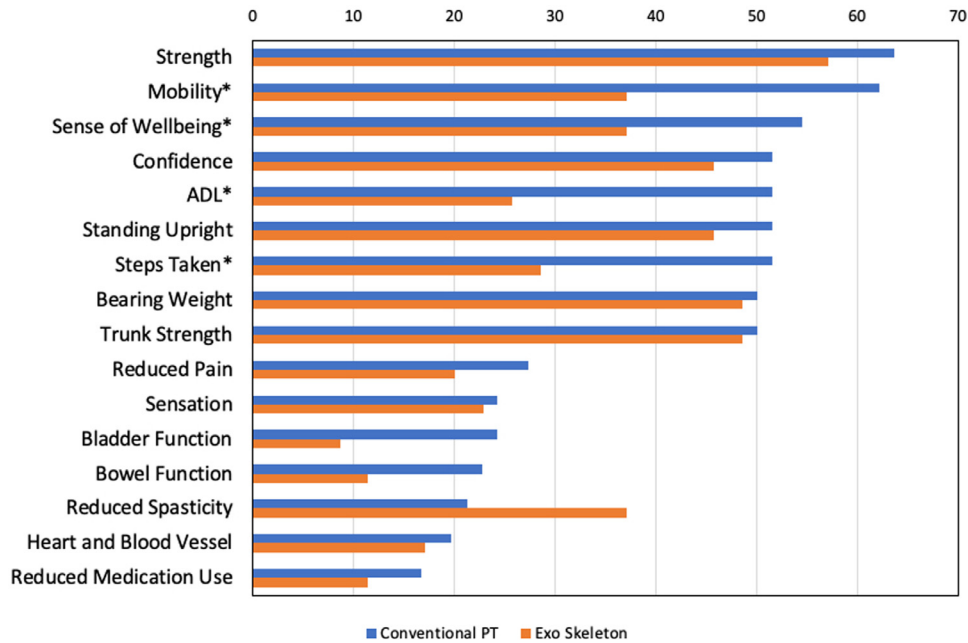
*Chi-square t-test p < .05

Fig 4   Participant-reported improvements. *Abbreviation*: ADL, activities of daily living.

Table 3 Logistic Regression Results of Perceived Improvement in Therapy Goals: Conventional Therapy vs Exoskeleton Group

Predictor*	b	SE	OR	2.5%	97.5%
Bowel	0.45	1.22	1.564	0.139	17.445
Spasticity	0.09	1.02	1.091	0.156	8.209
ADLs	1.98	1.03	7.230	1.003	56.297
Mobility	2.09	0.99	8.054	1.247	59.784

NOTE. The logistic regression model primary predictor is the therapy group (conventional therapy vs exoskeleton). Other predictors are demographic (age, sex), injury (level and completeness), and financial responsibility characteristics; participant-reported aspects of quality of life (SCI-FI basic mobility, SCI-QOL bowel difficulties, bladder difficulties, pain interference); and service characteristics (average number of sessions, average number of days between sessions)

Abbreviation: ADLs, activities of daily living; b, mean of the posterior distribution; SE, standard error of the posterior distribution; OR, odds ratio (exponent of b); 2.5%, lower boundary of the 95% credible interval of the odds ratio; 97.5%, upper boundary of the 95% credible interval of the odds ratio.

* Predictors for which the 95% credibility interval of the OR does not include 0 in logistic regression results: Bowel and Mobility (financial responsibility, research study group), Spasticity (SCI-FI basic mobility), ADLs (sex)

when grants ended, users seldom transitioned to a self-pay model. Therefore, their DOS was dictated by the terms of the grant. Additionally, wellness-based robotic exoskeleton training did not have specific therapy goals and functioned more like supervised exercise training with a personal trainer. Individuals participate in wellness training programs for cardiovascular health benefits, psychosocial wellbeing, or bowel/bladder management. Despite appearing to meet a longer lifestyle need, participants had shorter DOS, which may be explained by cost, self-rationing of services,[42] or achievement of short-term goals.

Participants' perceptions of goal attainment reported on a 5-point Likert scale indicated 52% of the conventional group vs 42% of the exoskeleton group attained "much more" or "somewhat more" than expected (fig 3). Consistent with the results on the Goal Attainment Scale, gains related to specific goals (fig 4) show the conventional group also reported higher percentage gains compared with the robotic exoskeleton group. This difference in perceived gains could be owing to the longer DOS in the conventional group.

The findings are novel and clinically significant because they characterize participant engagement in outpatient settings including a sustainable model of robotic exoskeletal training using a practice-based evidence design.[70] The findings highlight the tension between fidelity and fit,[71] as the lifestyle wellness model used by many for exoskeletal training produces a viable model for participant use in the community under current reimbursement constraints, but may draw concerns on the grounds of fidelity owing to distant supervision by a physical therapist relative to conventional outpatient treatment. Although not a primary purpose of this study, assessing participant health outcomes would provide clarity on questions of fidelity and is a research need. Conversely, we acknowledge this may be the only way those with severe injuries can access these technologies owing to insurance reimbursement constraints. Individuals with more severe injuries often do not have opportunities to engage in locomotor training in conventional therapy,[72] resulting in the need to pay out of pocket in wellness programs. Understanding the long-term health and wellness benefits of exoskeleton gait training for individuals with complete SCI can assist in determining whether these services should be reimbursed.

Self-pay models also have clear equity concerns. Future research should focus on an individual's ability and willingness to pay for exoskeleton services as part of wellness programs and the potential for reducing inequities for those who can only access rehabilitation with private insurance or out-of-pocket payments. Studies should also compare the efficacy of robotic exoskeleton vs conventional locomotor training in maximizing mobility and independence for those with motor incomplete SCIs and the return on investment in using exoskeletons to maintain health and wellness. Future studies should examine variations across rehabilitation centers. Only 2 centers offered wellness programs in our study. The study also highlights that exoskeletal devices can be used to support lifelong rehabilitation through general health and wellness, which conventional care models are not designed to support. This work extends this research to other care models, which will help the continuum of care for people with SCI. Understanding these phenomena will help expand use of these devices and potential reimbursement by insurers leading to more deployment, which will make these devices more affordable and useful as need drives production, decreasing the cost of manufacturing and delivery. Relatedly, Medicare has recently created a procedural code to reimburse medically necessary robotic exoskeleton use.[73]

Clinical implications

Locomotor/gait training strategies and goals are distinctive for individuals using a robotic exoskeleton in a community wellness facility compared with conventional outpatient therapy in an outpatient rehabilitation setting. In the conventional setting, physical therapists typically supervise and manage patient care directly, using a combination of locomotor strategies such as over-ground walking, treadmill training with body weight support, or stationary robotic devices, as needed. The primary goal of conventional therapy is to improve walking independence and function that translates to greater walking outside of supportive devices that provides variable assistance to the end-users tailored to their specific abilities and limitations. This focus on demonstrating improved walking function outside of the supportive devices in conventional therapy justifies continued reimbursable services, which may result in a longer DOS. Wellness models typically employ exercise specialists under the supervision of physical therapists. This model has the potential for employing multiple robotic units and exercise staff supervised by a single physical therapist. The wellness model will likely be shorter in duration as most individuals are paying out of pocket for these services. Generally, they have either demonstrated a plateau in their ability to make functional walking gains or have been diagnosed with a severe injury in which walking improvement is not expected (outside of the exoskeleton) and, therefore, not reimbursed by insurance. Individual wellness sessions last longer because people with SCI include other aspects of health maintenance within a larger wellness session and individuals are very motivated to walk as long and as far as they can each session to improve their wellness and see a return on their investment. Wellness models may also require greater attention to scheduling and coordination, given different supervisory relationships. Although our analysis did not characterize differences between people with complete and incomplete SCI, we identified that DOS was longer for those with complete injury because these individuals are likely using exoskeleton-assisted walking as ongoing health and wellness whereas those

with incomplete injuries are participating in gait training to regain lost function and not relying on this exercise to maintain ongoing health and wellness. This understanding of longer DOS should be incorporated to setting individual expectations related to locomotor training. Women were found to have a shorter DOS compared with men. Further research needs to evaluate these sex differences. It is possibly related to barriers to participation including the need for transportation,[74] less partner/social support,[74,75] and greater effects of pain, fatigue, and consequences of bowel and bladder dysfunction.[74] Clinicians should consider these broader constructs to address a person's capacity to engage in SCI locomotor training with differential attention paid to sex-specific concerns.[74]

With technology, the potential to support people with SCI with lifelong rehabilitation is becoming increasingly possible, although we have yet to realize optimal patterns of engagement with technology. Although there are gaps with respect to affordability of robotic exoskeleton technology, wellness-based programs allow people with SCI to experience the benefits of robotic exoskeletal therapy and its potential advantages at a lower cost than acquiring an exoskeleton for personal use. These models open the opportunity for greater use of technology and greater access to technology despite gaps in access remaining.

Participant preference and the ability to pay for services are important factors associated with the DOS. Therapists must write functional goals and demonstrate progress in their documentation to justify ongoing services to commercial insurance, Medicare, or Medicaid. Individuals who do not demonstrate functional improvement face the decision to stop services or find other resources to continue training. Even though someone may be making functional improvements, outpatient therapy caps set by the Centers for Medicare and Medicaid Services and commercial insurers may limit continuation of services. Individuals using robotic exoskeleton at Craig Hospital and Shepherd Center paid out of pocket for services, but tended to have shorter DOS than participants receiving conventional therapy which is likely associated with the financial burden.

Limitations

Study limitations include a relatively small sample, an analytical approach that is finely tuned to this sample, and recruitment at SCI Model Systems facilities. Generalizing to other sites and samples may be limited. In particular, our sample of people with complete SCI was low, preventing our characterization of their experience based on locomotor training strategy. Unmeasured variables may have affected prediction. We did not include race, and there is preliminary evidence that implicit bias can affect management of individuals with SCI.[76] From Martini and colleague's survey,[7] it appears that secondary health conditions may increase engagement with PT services; but, we did not include secondary health conditions in the model. Several individuals using exoskeletons were covered by a source of funding that restricted the number of visits, or if paid for personally, fell under a budget constraint. Likewise, research study status may have influenced outcomes such as participants' goals.

Conclusions

Locomotor/gait training strategies are distinctive for individuals using a robotic exoskeleton in a community wellness facility compared with conventional outpatient therapy. The duration of the treatment episode was shorter but individual sessions were longer for robotic exoskeleton. Ability to pay likely limits access to exoskeleton programs. Participants' ability to engage in locomotor/gait training needs further study as conventional therapy generally focuses on individuals with incomplete injuries, creating an environment where self-pay wellness models are the most viable opportunity for individuals with complete injuries to engage in locomotor training using robotic exoskeletons.

Corresponding author

Daniel Pinto, PT, PhD, Department of Physical Therapy, Walter Schroeder Complex, Suite 346, Marquette University, P.O. Box 1881, Milwaukee, WI 53201. *E-mail address:* d.pinto@marquette.edu.

References

1. Emerich L, Parsons KC, Stein A. Competent care for persons with spinal cord injury and dysfunction in acute inpatient rehabilitation. Top Spinal Cord Inj Rehabil 2012;18:149–66.
2. Boninger ML, Field-Fote EC, Kirshblum SC, et al. Research progress from the SCI Model Systems (SCIMS): an interactive discussion on future directions. J Spinal Cord Med 2018;41:216–22.
3. Backus D, Gassaway J, Smout RJ, et al. Relation between inpatient and postdischarge services and outcomes 1 year postinjury in people with traumatic spinal cord injury. Arch Phys Med Rehabil 2013;94(4 Suppl):S165–74.
4. Kogos S, DeVivo M, Richards S. Recent trends in spinal cord injury rehabilitation practices and outcomes. Top Spinal Cord Inj Rehabil 2004;10:49–57.
5. Whiteneck G, Gassaway J. The SCIRehab project: what rehabilitation interventions are most strongly associated with positive outcomes after spinal cord injury? J Spinal Cord Med 2012;35:482–3.
6. Whiteneck GG, Gassaway J, Dijkers MP, et al. Inpatient and postdischarge rehabilitation services provided in the first year after spinal cord injury: findings from the SCIRehab Study. Arch Phys Med Rehabil 2011;92:361–8.
7. Martini L, Maus U, Bokel A, et al. Utilization of outpatient physical and occupational therapy in people with spinal cord injury in Germany: results of the German Spinal Cord Injury Survey. Am J Phys Med Rehabil 2020;99:532–9.
8. National Spinal Cord Injury Statistical Center. Spinal Cord Injury Facts and Figures at a Glance. University of Alabama at Birmingham; 2020. Available at https://www.nscisc.uab.edu/Public/Facts%20and%20Figures%202019%20-%20Final.pdf. Accessed August 20.
9. Field-Fote EC. Spinal cord control of movement: implications for locomotor rehabilitation following spinal cord injury. Phys Ther 2000;80:477–84.

10. Simmons OL, Kressler J, Nash MS. Reference fitness values in the untrained spinal cord injury population. Arch Phys Med Rehabil 2014;95:2272–8.

11. Berlowitz DJ, Wadsworth B, Ross J. Respiratory problems and management in people with spinal cord injury. Breathe (Sheff) 2016;12: 328–40.

12. Clark JM, Findlay DM. Musculoskeletal health in the context of spinal cord injury. Curr Osteoporos Rep 2017;15:433–42.

13. Haider IT, Lobos SM, Simonian N, Schnitzer TJ, Edwards WB. Bone fragility after spinal cord injury: reductions in stiffness and bone mineral at the distal femur and proximal tibia as a function of time. Osteoporos Int 2018;29:2703–15.

14. Gibbs JC, Gagnon DH, Bergquist AJ, et al. Rehabilitation Interventions to modify endocrine-metabolic disease risk in Individuals with chronic spinal cord injury living in the Community (RIISC): a systematic review and scoping perspective. J Spinal Cord Med 2017;40:733–47.

15. Ginis KA, Arbour-Nicitopoulos KP, Latimer AE, et al. Leisure time physical activity in a population-based sample of people with spinal cord injury part II: activity types, intensities, and durations. Arch Phys Med Rehabil 2010;91:729–33.

16. Ginis KA, Latimer AE, Arbour-Nicitopoulos KP, et al. Leisure time physical activity in a population-based sample of people with spinal cord injury part I: demographic and injury-related correlates. Arch Phys Med Rehabil 2010;91:722–8.

17. Jensen MP, Hoffman AJ, Cardenas DD. Chronic pain in individuals with spinal cord injury: a survey and longitudinal study. Spinal Cord 2005;43:704–12.

18. Dorsett P, Geraghty T, Sinnott A, Hope Acland R. coping and psychosocial adjustment after spinal cord injury. Spinal Cord Ser Cases 2017;3:17046.

19. Dittuno PL, Ditunno Jr. JF. Walking index for spinal cord injury (WISCI II): scale revision. Spinal Cord 2001;39:654–6.

20. Calhoun CL, Schottler J, Vogel LC. Recommendations for mobility in children with spinal cord injury. Top Spinal Cord Inj Rehabil 2013;19:142–51.

21. Alamro RA, Chisholm AE, Williams AMM, Carpenter MG, Lam T. Overground walking with a robotic exoskeleton elicits trunk muscle activity in people with high-thoracic motor-complete spinal cord injury. J Neuroeng Rehabil 2018;15:109.

22. Baron R, Kneissel M. WNT signaling in bone homeostasis and disease: from human mutations to treatments. Nat Med 2013;19:179–92.

23. Hicks AL. Locomotor training in people with spinal cord injury: is this exercise? Spinal Cord 2021;59:9–16.

24. Harkema SJ, Hillyer J, Schmidt-Read M, Ardolino E, Sisto SA, Behrman AL. Locomotor training: as a treatment of spinal cord injury and in the progression of neurologic rehabilitation. Arch Phys Med Rehabil 2012;93:1588–97.

25. Fleerkotte BM, Koopman B, Buurke JH, van Asseldonk EH, van der Kooij H, Rietman JS. The effect of impedance-controlled robotic gait training on walking ability and quality in individuals with chronic incomplete spinal cord injury: an explorative study. J Neuroeng Rehabil 2014;11:26.

26. Schrade SO, Datwyler K, Stucheli M, et al. Development of VariLeg, an exoskeleton with variable stiffness actuation: first results and user evaluation from the CYBATHLON 2016. J Neuroeng Rehabil 2018;15:18.

27. Molteni F, Gasperini G, Cannaviello G, Guanziroli E. Exoskeleton and end-effector robots for upper and lower limbs rehabilitation: narrative review. PM R 2018;10(9 Suppl 2):S174–88.

28. Aguirre-Guemez AV, Perez-Sanpablo AI, Quinzanos-Fresnedo J, Perez-Zavala R, Barrera-Ortiz A. Walking speed is not the best outcome to evaluate the effect of robotic assisted gait training in people with motor incomplete Spinal Cord Injury: a systematic review with meta-analysis. J Spinal Cord Med 2019;42:142–54.

29. Fang CY, Tsai JL, Li GS, Lien AS, Chang YJ. Effects of robot-assisted gait training in individuals with spinal cord injury: a meta-analysis. Biomed Res Int 2020;2020:2102785.

30. Miller LE, Zimmermann AK, Herbert WG. Clinical effectiveness and safety of powered exoskeleton-assisted walking in patients with spinal cord injury: systematic review with meta-analysis. Med Devices (Auckl) 2016;9:455–66.

31. Heinemann AW, Jayaraman A, Mummidisetty CK, et al. Experience of robotic exoskeleton use at four spinal cord injury model systems centers. J Neurol Phys Ther 2018;42:256–67.

32. Sale P, Russo EF, Scarton A, Calabro RS, Masiero S, Filoni S. Training for mobility with exoskeleton robot in spinal cord injury patients: a pilot study. Eur J Phys Rehabil Med 2018;54:745–51.

33. Chang SH, Afzal T, Group TSCE, Berliner J, Francisco GE. Exoskeleton-assisted gait training to improve gait in individuals with spinal cord injury: a pilot randomized study. Pilot Feasibility Stud 2018;4:62.

34. Cahill A, Ginley OM, Bertrand C, Lennon O. Gym-based exoskeleton walking: a preliminary exploration of non-ambulatory end-user perspectives. Disabil Health J 2018;11:478–85.

35. Arbour-Nicitopoulos KP, Martin Ginis KA, Latimer-Cheung AE, et al. Development of an evidence-informed leisure time physical activity resource for adults with spinal cord injury: the SCI Get Fit Toolkit. Spinal Cord 2013;51:491–500.

36. Hicks AL, Martin Ginis KA, Pelletier CA, Ditor DS, Foulon B, Wolfe DL. The effects of exercise training on physical capacity, strength, body composition and functional performance among adults with spinal cord injury: a systematic review. Spinal Cord 2011;49:1103–27.

37. Hicks AL, Martin KA, Ditor DS, et al. Long-term exercise training in persons with spinal cord injury: effects on strength, arm ergometry performance and psychological well-being. Spinal Cord 2003;41:34–43.

38. Gagnon DH, Vermette M, Duclos C, Aubertin-Leheudre M, Ahmed S, Kairy D. Satisfaction and perceptions of long-term manual wheelchair users with a spinal cord injury upon completion of a locomotor training program with an overground robotic exoskeleton. Disabil Rehabil Assist Technol 2019;14:138–45.

39. Mehta S, Janzen S, McIntyre A, Iruthayarajah J, Loh E, Teasell R. Are comorbid pain and depressive symptoms associated with rehabilitation of individuals with spinal cord injury? Top Spinal Cord Inj Rehabil 2018;24:37–43.

40. Pinto D, Garnier M, Barbas J, et al. Budget impact analysis of robotic exoskeleton use for locomotor training following spinal cord injury in four SCI Model Systems. J Neuroeng Rehabil 2020;17:4.

41. Shirota C, Balasubramanian S, Melendez-Calderon A. Technology-aided assessments of sensorimotor function: current use, barriers and future directions in the view of different stakeholders. J Neuroeng Rehabil 2019;16:53.

42. Mathews KJ. Patient self-rationing, a health system problem. Virtual Mentor 2012;14:835–8.

43. Horn SD, Gassaway J. Practice-based evidence study design for comparative effectiveness research. Med Care 2007;45(10 Supl 2):S50–7.

44. Roberts TT, Leonard GR, Cepela DJ. Classifications In brief: American Spinal Injury Association (ASIA) impairment scale. Clin Orthop Relat Res 2017;475:1499–504.

45. Sinha R, Slavin MD, Kisala PA, Ni P, Tulsky DS, Jette AM. Functional ability level development and validation: providing clinical meaning for Spinal Cord Injury Functional Index scores. Arch Phys Med Rehabil 2015;96:1448–57.

46. Tulsky DS, Kisala PA, Tate DG, Spungen AM, Kirshblum SC. Development and psychometric characteristics of the SCI-QOL Bladder Management Difficulties and Bowel Management Difficulties item banks and short forms and the SCI-QOL Bladder Complications scale. J Spinal Cord Med 2015;38:288–302.

47. Cohen ML, Kisala PA, Dyson-Hudson TA, Tulsky DS. Measuring pain phenomena after spinal cord injury: development and psychometric properties of the SCI-QOL Pain Interference and Pain Behavior assessment tools. J Spinal Cord Med 2018;41:267–80.

48. Bürkner P-C. brms: An R package for Bayesian multilevel models using Stan. J. Stat. Softw 2017;80(1).

49. R Foundation for Statistical Computing. R Core Team. R: A language and environment for statistical computing. Available at: https://www.R-project.org. Accessed December 1, 2020.

50. Carpenter B, Gelman A, Hoffman MD, et al. Stan: A probabilistic programming language. J Stat Softw 2017;76(1).

51. Baig SA. Bayesian inference: an introduction to hypothesis testing using Bayes factors. Nicotine Tob Res 2020;22:1244–6.

52. Adamina M, Tomlinson G, Guller U. Bayesian statistics in oncology: a guide for the clinical investigator. Cancer 2009;115:5371–81.

53. Hespanhol L, Vallio CS, Costa LM, Saragiotto BT. Understanding and interpreting confidence and credible intervals around effect estimates. Braz J Phys Ther 2019;23:290–301.

54. Efron B. Why isn't everyone a Bayesian? Am Stat 1986;40(1).

55. Matthews RAJ. Why should clinicians care about Bayesian methods? J Stat Plan Inference 2001;94:43–58.

56. Wagenmakers E-J, Lee M, Lodewyckx T, Iverson GJ. Bayesian Versus Frequentist Inference. In: Hoijtink H, Klugkist I, Boelen PA, eds. Bayesian Evaluation of Informative Hypotheses, New York, New York: Springer; 2008:181–207.

57. Huo Y, de la Torre J, Mun EY, et al. A hierarchical multi-unidimensional IRT approach for analyzing sparse, multi-group data for integrative data analysis. Psychometrika 2015;80:834–55.

58. Kruschke JK. What to believe: Bayesian methods for data analysis. Trends Cogn Sci 2010;14:293–300.

59. Pires MC, Colosimo EA, Silva AA. Survival Weibull regression model for mismeasured outcomes. Commun Stat Theory Methods 2017;47:601–14.

60. Ying GS, Heitjan DF. Weibull prediction of event times in clinical trials. Pharm Stat 2008;7:107–20.

61. Zhang Z. Parametric regression model for survival data: Weibull regression model as an example. Ann Transl Med 2016;4:484.

62. Gelman A, Hill J. Data Analysis Using Regression and Multilevel/Hierarchical Models (Analytical Methods for Social Research). Cambridge: Cambridge University Press; 2006.

63. Agresti A. An Introduction to Categorical Data Analysis. 2nd ed. Hoboken: Wiley-Interscience; 2007.

64. van Ravenzwaaij D, Cassey P, Brown SD. A simple introduction to Markov Chain Monte-Carlo sampling. Psychon Bull Rev 2018;25:143–54.

65. Gelman A, Carlin J, Stern H, Dunson D, Vehtari A, Rubin D. Bayesian Data Analysis. Third Edition. Third ed: Chapman & Hall/CRC Texts in Statistical Science; 2014.

66. Gelman A, Goodrich B, Gabry J, Vehtari A. R-squared for Bayesian Regression Models. The American Statistician 2019;73:307–9.

67. Evans N, Hartigan C, Kandilakis C, Pharo E, Clesson I. Acute cardiorespiratory and metabolic responses during exoskeleton-assisted walking overground among persons with chronic spinal cord injury. Top Spinal Cord Inj Rehabil 2015;21:122–32.

68. Kressler J, Thomas CK, Field-Fote EC, et al. Understanding therapeutic benefits of overground bionic ambulation: exploratory case series in persons with chronic, complete spinal cord injury. Arch Phys Med Rehabil 2014;95:1878–87.

69. van der Meer P, Post MW, van Leeuwen CM, van Kuppevelt HJ, Smit CA, van Asbeck FW. Impact of health problems secondary to SCI one and five years after first inpatient rehabilitation. Spinal Cord 2017;55:98–104.

70. Green LW, Glasgow RE, Atkins D, Stange K. Making evidence from research more relevant, useful, and actionable in policy, program planning, and practice slips "twixt cup and lip. Am J Prev Med 2009;37(6 Suppl 1):S187–91.

71. Castro FG, Barrera Jr M, Martinez Jr. CR. The cultural adaptation of prevention interventions: resolving tensions between fidelity and fit. Prev Sci 2004;5:41–5.

72. Chay W, Kirshblum S. Predicting outcomes after spinal cord injury. Phys Med Rehabil Clin N Am 2020;31:331–43.

73. Centers for Medicare and Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions: First Biannual, 2020 Coding Cycle for Durable Medical Equipment (DME) and Accessories; Orthotics, Prosthetics (O & P), and Supplies. Available at: https://www.cms.gov/files/document/2020-hcpcs-application-summary-bi-annual-1-2020-durable-medical-equipment-dme-and-accessories.pdf. Accessed January 10, 2021.

74. McColl MA, Charlifue S, Glass C, Lawson N, Savic G. Aging, gender, and spinal cord injury. Arch Phys Med Rehabil 2004;85:363–7.

75. Stapleton JN, Martin Ginis KA, Group S-SR. Sex differences in theory-based predictors of leisure time physical activity in a population-based sample of adults with spinal cord injury. Arch Phys Med Rehabil 2014;95:1787–90.

76. Hausmann LR, Myaskovsky L, Niyonkuru C, et al. Examining implicit bias of physicians who care for individuals with spinal cord injury: a pilot study and future directions. J Spinal Cord Med 2015;38:102–10.