AWARD NUMBER: W81XWH-14-2-0170

TITLE: A Randomized, Crossover Clinical Trial of Exoskeletal-Assisted Walking to Improve Mobility, Bowel Function, and Cardiometabolic Profiles in Persons with SCI

PRINCIPAL INVESTIGATOR: Ann M. Spungen, EdD

CONTRACTING ORGANIZATION: Bronx Veterans Medical Research Foundation
Bronx, NY 10468

REPORT DATE: October 2018

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

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4. TITLE AND SUBTITLE

A Randomized, Crossover Clinical Trial of Exoskeletal-Assisted Walking to Improve Mobility, Bowel Function, and Cardiometabolic Profiles in Persons with SCI

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5b. GRANT NUMBER
W81XWH-14-2-0170

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6. AUTHOR(S)
Ann M. Spungen, EdD

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5d. PROJECT NUMBER

5e. TASK NUMBER

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Bronx Veterans Medical Research Foundation
Bronx, NY 10468

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U.S. Army Medical Research and Materiel Command
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12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The primary objectives of this proposal are to achieve successful walking skills in the exoskeletal-assisted walking devices for an extended period of time and at specific velocities and distances over the course of 36 sessions in three months in people with chronic SCI who are wheelchair users for community mobility. The secondary objectives are to determine if 36 sessions in three months of walking is effective in improving bowel function and body composition. The exploratory objectives are to address additional questions concerning the retention or non-retention of positive changes, the effects of the increased physical activity from exoskeletal-assisted walking on vagal tone, orthostatic tolerance, lipid profile, total testosterone, estradiol levels, and quality of life (QOL).

15. SUBJECT TERMS

None provided

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	23	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

Page

1. INTRODUCTION:

The primary objectives of this proposal are to achieve successful walking skills in the exoskeletal-assisted walking devices for an extended period of time and at specific velocities and distances over the course of 36 sessions in three months in people with chronic SCI who are wheelchair users for community mobility. The secondary objectives are to determine if 36 sessions in three months of walking is effective in improving bowel function and body composition. The exploratory objectives are to address additional questions concerning the retention or non-retention of positive changes, the effects of the increased physical activity from exoskeletal-assisted walking on vagal tone, orthostatic tolerance, lipid profile, total testosterone, estradiol levels, and quality of life (QOL).

2. KEYWORDS:

Powered exoskeletons, paraplegia, tetraplegia, high density lipoprotein, lipid profile, orthostatic tolerance, total testosterone, estradiol, quality of life, ReWalk, and Ekso

3. ACCOMPLISHMENTS:

What were the major goals of the project?

On September 30, 2017 month 36 of the study was completed. The goals for these 36 months are as follows:

Major Task 2: Study recruitment and enrollment.

Subtask 4: Randomize the next 8/6/4 participants at each respective Site (Randomize a total of 48 between study months 25 to 33).

Response: We have randomized 48 of 48 participants (100%) by month 35 of the study.

Subtask 5: Randomize the next 8/6/4 participants at each respective Site (Randomize a total of 64 participants between study months 34 to 42).

Response: We have randomized 64 of 64 (100%) by month 45 of the study.

Major Task 3: Review/complete data forms, data edits and entry

Response: We have completed 85% of the review of the data entry for missing values and errors. This is an ongoing process. We have completed 100% of the data entry for 35 participants to date and about 75% of all data entry for the 76 participants that have been randomized to date

Major Task 4: Review and analyze data

Subtask 2: Analyze preliminary data for primary outcomes (months 24 to 38)

The Primary Aims consist of the following:

1. By session 12 (first month of WALK training), the participants will be able to perform the following exoskeletal-assisted walking tests with or without minimal assistance:
   Response: In 27 participants who have been completed to date the following percentages for each aims were achieved.
   a. 10m WT
      i. 90% in ≤60 seconds (≥0.17 m/s);

Response: 89% (24 of 27) have achieved this goal.

ii. 10% in ≤40 seconds (≥0.25 m/s);

Response: 56% (15 of 27) have achieved this goal.

b. 6min WT

i. 80% at a distance ≥50 m (≥0.14 m/s);

Response: 93% (25 of 27) have achieved this goal.

ii. 20% at a distance ≥80 m (≥0.22 m/s);

Response: 63% (17 of 27) have achieved this goal.

c. TUG

i. 80% in ≤120 seconds);

Response: 93% (25 of 27) have achieved this goal.

ii. 20% in ≤90 seconds);

Response: 67% (18 of 27) have achieved this goal.

2. By session 36 (three months of WALK training), participants will have improved their ability to walk faster and longer distances and will be able to perform exoskeletal-assisted walking tests with or without minimal assistance as follows:

a. 10m WT - 70% in ≤40 seconds (≥0.25 m/s);

Response: 74% (20 of 27) have achieved this goal.

b. 6min WT - 70% at a distance ≥80 m (≥0.22 m/s);

Response: 78% (21 of 27) have achieved this goal.

c. TUG - 60% in ≤90 seconds;

Response: 85% (23 of 27) have achieved this goal.

Subtask 3: Submit abstracts with preliminary data for primary outcomes for national meetings (months 24 to 38).

Response: Dr. Spungen, Dr. Hong, and Mr. Knezevic presented at multiple conferences this past year as listed in Appendix 1 & 2.

Subtask 5: Analyze preliminary data for exploratory outcomes (months 24 to 40)

Response: High density lipoprotein cholesterol (HDL-c) was analyzed in 21 additional participants as well as mobility skills in 29 participants. Please see the ASCIP 2018 Knezevic abstract for the HDL-c results (Appendix 1).

Table 1. Statement of Work	Timeline (months)	Percent Completed	Date Completed
Major Task 1: Study start-up and continuation administrative functions			
Subtask 1: Prepare Regulatory Documents and Research Protocol	1 to 3	100%	30-Dec-14
If Applicable, coordinate with Sites for CRADA* submission	n/a	n/a	n/a
If Applicable, coordinate with Sites for material transfer agreements (MTAs) or clinical trial agreements (CTAs) submission	n/a	n/a	n/a
If Applicable, coordinate with Sites for nondisclosure agreements (NDAs).	n/a	n/a	n/a
If applicable, indicate time required for submission and exemption of an Investigational Device Exemption (IDE) application to the U.S. Food and Drug Administration	1 to 3	100%	30-Dec-14
Refine eligibility criteria, exclusion criteria, screening protocol	1 to 3	100%	30-Dec-14
Finalize consent form & human subjects protocol	1 to 3	100%	30-Dec-14
Coordinate with Sites for Local IRBs** protocol submission	1 to 3	100%	30-Dec-14
Coordinate with Sites for University IRB** review	1 to 6	100%	30-Dec-14
Coordinate with Sites for Military 2nd level IRB** review (ORP/HRPO)	1 to 6	100%	30-Dec-14
Submit amendments, adverse events and protocol deviations as needed	As needed	ongoing	ongoing
Coordinate with Sites for annual IRB** report for continuing review	Annually	ongoing	ongoing
*Milestone Achieved: Local IRB** approval at BVMRF, UMROI, and KFRC*	3	100%	30-Mar-15
*Milestone Achieved: HRPO*** approval for all protocols and local IRB** approvals.*	6	100%	30-Mar-15
Subtask 2: Coordinate with Sites for job descriptions design	1 to 3	100%	30-Dec-14
Advertise and interview for project related staff	1 to 3	100%	30-Dec-14
Coordinate for space allocation for new staff	1 to 3	100%	30-Dec-14
Coordinate with Sites for hiring and training of staff	1 to 6	100%	30-Dec-14
Coordinate with Sites for providing standard training procedures among exoskeletal-trainers	1 to 6	100%	30-Dec-14
Milestone Achieved: Research staff hired and begin staff training	6	100%	30-Dec-14
Subtask 3: Facilitate and Coordinate with Sites for hiring, training, supervision and fidelity checks as needed for study participant attrition	6 to 48	100%	30-Dec-14
Coordinate multi-site training meeting for exoskeletal training, walking assessments standardization, data collection paper forms, data collection web-based forms, and use of log record	3 to 6	100%	9-Apr-15

Table 1. Statement of Work	Timeline (months)	Percent Completed	Date Completed
PI, Lead Engineer and Study Coordinator travel to Sites for staff training of procedures	3 to 6	100%	9-Apr-15
Coordinate multi-site training meeting for standardization of SCI QOL and bowel function assessments	3 to 6	100%	9-Apr-15
Coordinate multi-site training meeting for blood draw procedures (fasting condition, amounts, tubes, mailing to Quest Diagnostics)	3 to 6	100%	9-Apr-15
Coordinate multi-site training meeting for orthostatic tolerance test and Holter monitor assessment	3 to 6	100%	9-Apr-15
Coordinate with Sites for training to maintain 100% concordance with Study protocol	6 to 48	100%	9-Apr-15
Milestone Achieved: Maintained trained Study staff throughout duration of the clinical trial	6 to 48	100%	9-Apr-15
Major Task 2: Study recruitment and enrollment			
Subtask 1: Begin participant screening and consenting process	6 to 7	100%	11-May-15
Milestone Achieved: Participant #1 consented, randomized and enrolled at each Site	6 to 7	100%	14-Aug-15
Subtask 2: Randomize the first 4 participants at each respective Site	7 to 15	100%	22-Sep-15
Complete participant baseline evaluations	7 to15	100%	10-Oct-15
Complete participant weekly and monthly evaluations	7 to 15	100%	1-Apr-16
Complete participant post evaluations	7 to 15	100%	1-Apr-16
Milestone Achieved: 12 participants consented, screened, randomized, and enrolled for the study	7 to 15	100%	22-Sep-15
Subtask 3: Randomize the next 8/6/4 participants at each respective Site	16 to 24	100%	1-Oct-16
Complete participant baseline evaluations	16 to 24	100%	1-Oct-16
Complete participant weekly and monthly evaluations	16 to 24	100%	1-Mar-17
Complete participant post evaluations	16 to24	100%	1-Mar-17
Milestone Achieved: 30 participants consented, screened, randomized, and enrolled for the study	16 to 24	100%	1-Mar-17
Subtask 4: Randomize the next 8/6/4 participants at each respective Site	25 to 33	100%	1-Dec-17
Complete participant baseline evaluations	25 to 33	100%	1-Dec-17
Complete participant weekly and monthly evaluations	25 to 33	100%	1-Feb-18
Complete participant post evaluations	25 to 33	100%	1-Feb-18
Milestone Achieved: 48 participants consented, screened, randomized, and enrolled for the study	25 to 33	100%	1-Feb-18
Subtask 5: Randomize the next 8/4/4 participants at each respective Site	34 to 42	100%	1-Apr-18
Complete participant baseline evaluations	34 to 42	100%	1-Apr-18
Complete participant weekly and monthly evaluations	34 to 42	90%	ongoing
Complete participant Post 1 evaluations	34 to 42	85%	ongoing
Complete participant Post 2 evaluations	34 to 42	70%	ongoing

Table 1. Statement of Work	Timeline (months)	Percent Completed	Date Completed
Milestone Achieved: 64 participants consented, screened, randomized, and enrolled for the study	34 to 42	100%	1-Apr-18
Subtask 6: Complete training and testing of any remaining participants at each respective Site	43 to 45	85%	ongoing
Complete participant weekly and monthly evaluations	43 to 45	85%	ongoing
Complete participant post evaluations	43 to 45	85%	ongoing
Milestone Achieved: All participants at each respective Site completed	43 to 45	85%	ongoing
Major Task 3: Review/complete data forms, data edits and entry			
Subtask 1: Ongoing review of data entry	7 to 45	85%	ongoing
Subtask 2: Ongoing review of adverse and serious adverse	6 to 45	85%	ongoing
Subtask 3: Ongoing data edits for missing values	7 to 45	85%	ongoing
Subtask 4: Ongoing review for data entry errors	7 to 45	85%	ongoing
Subtask 5: Complete all data entry	43 to 45	85%	ongoing
Milestone Achieved: Data entry is completed in the data base	45	75%	ongoing
Major Task 4: Review and analyze data			
Subtask 1: Review of data / analyze data	7 to 15	100%	1-Oct-15
Review data for problems	7 to 15	100%	1-Oct-15
Make necessary protocol adjustments (if needed)	7 to 15	100%	1-Oct-15
Perform sub analyses of walking tests and activity logs in first 12 participants	15 to 16	100%	1-Dec-15
Milestone Achieved: Data reviewed for necessary adjustment	7 to 15	100%	1-Oct-15
Subtask 2: Analyze preliminary data for primary outcomes	24 to 38	75%	ongoing
Perform sub analyses of walking tests and activity logs in the first 20 to 38 participants	24 to 38	75%	ongoing
Subtask 3: Submit abstracts with preliminary data for primary outcomes for national meetings	24 to 38	75%	ongoing
Milestone Achieved: Abstract presentations of preliminary data	28 to 38	75%	ongoing
Subtask 4: Analyze preliminary data for secondary outcomes	24 to 40	75%	ongoing
Perform sub-analyses of body fat mass in the first 30 to 48 participants	24 to 36	75%	ongoing
Subtask 5: Analyze preliminary data for exploratory outcomes	24 to 40	50%	ongoing
In Group 1, perform sub analyses of body fat mass at 3 months follow-up in first 15 to 24 participants	24 to 40	50%	ongoing
Perform sub analyses of blood pressure tests and Holter monitor in the first 30 to 48 participants	25 to 36	50%	ongoing
Perform sub analysis of lipids, and endocrine outcome variables in the first 30 to 48 participants	25 to 36	50%	ongoing

Table 1. Statement of Work	Timeline (months)	Percent Completed	Date Completed
Perform sub analyses of SCI-QOL and bowel function assessments in first 30 to 48 participants	25 to 36	50%	ongoing
Major Task 5: Prepare and write manuscripts			
Subtask 1: Prepare and write manuscripts on full data set of participants	43 to 48		
Prepare and write manuscript of the primary outcomes	43 to 48		
Prepare and write manuscript of the secondary outcomes	43 to 48		
Prepare and write manuscripts for the exploratory outcomes	43 to 48		

Table 2. Projected and Actual Enrollment

Year: Dates:	Year 1 (Oct 1, 2014 to Sep 30 2015)				Year 2 (Oct 1, 2015 to Sep 30 2016)				Year 3 (Oct 1, 2016 to Sep 30 2017)				Year 4 (Oct 1, 2017 to Sep 30 2018)				Year 5 (No Cost Extension) (Oct 1, 2018 to Sep 30 2019)			
Quarter:	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Cum. Month:	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60
Quarter Months:	(10/1-12/30)	(1/1-3/30)	(4/1-6/30)	(7/1-9/30	(10/1-12/30)	(1/1-3/30)	(4/1-6/30)	(7/1-9/30	(10/1-12/30)	(1/1-3/30)	(4/1-6/30)	(7/1-9/30	(10/1-12/30)	(1/1-3/30)	(4/1-6/30)	(7/1-9/30)	(10/1-12/30)	(1/1-3/30)	(4/1-6/30)	(7/1-9/30)
			Projected		Actual	Projected		Actual	Projected		Actual	Projected		Actual						
BVMRF			4		3	8		8	8		8	8		10						
UMROI			4		2	6		7	6		6	4		4						
KF			4		3	4		4	4		4	4		4						
Sub Totals			12		8	18		19	18		18	16		18						
Cumulative Totals			**12**		8	**30**		27	**48**		45	**64**		63						

Table 3.
Detailed Screening, Randomization and Reasons for Screen Failures and Withdrawls

	BRONX	UMROI	Kessler	Total	
Number Pre-screened	58	35	45	**138**	
Number Consented for Screening	58	28	20	**106**	
Number Screen failed	19	8	4	**31**	29.2%
Number Randomized	37	19	20	**76**	71.7%
Number Completed	20	6	9	**35**	
Number Withdrew	5	6	3	**14**	
Number Currently Enrolled	12	7	4	**23**	
Number in Pre-Screening	2	0	0	**2**	
Reasons for Screen Failures					
Low BMD/FxHx	9	5	3	**17**	16.0%
Contractures	4	0	0	**4**	3.8%
Severe spasticity	1	0	0	**1**	0.9%
Schedule conflict/unable	4	2	0	**6**	5.7%
Other	1	1	1	**3**	2.8%
Reasons for Withdrawals					
Schedule conflict/unable	3	3	2	**8**	
Medical (study related)	0	1	0	**0**	
Medical (non-study related)	2	2	1	**5**	

Note: Of the total group screened, 29.2% were Screen Failures and 71.7% were randomized. Of the 106 Screened, 16.0% failed on the bone criteria, 3.8% failed on contractures and 5.7% failed on schedule conflicts or unable to continue.

What opportunities for training and professional development has the project provided?

This project was not intended to provide a training opportunity. However the PI, Dr. Spungen has used this opportunity to provide professional development for two of her staff: 1) Mr. Steve Knezevic (Doctoral candidate, Rutgers University and Research coordinator for this study) and 2) Dr. Eun-Kyoung Hong (Post-doctoral fellow in Dr. Spungen's lab and the database manager for this study). Dr. Spungen has worked one-on-one with both individuals for analyzing, interpreting, writing, and presenting the data at the Academy of Spinal Cord Injury Professionals (ASCIP) 2018 annual meeting in Denver, CO.

How were the results disseminated to communities of interest?

Response: We have presented at multiple scientific conferences:

1. ASCIP 2018 Platform Presentation, Title: HDL-c changes after 50,000 steps in a powered exoskeleton. Presenter: Steven Knezevic, MS (Appendix 1&2).

2. ASCIP 2018 Poster Presentation, Title: FDA exoskeletal-assisted walking velocity: Who can get there? Presenter: EunKyoung Hong, PhD (Appendix 2).

3. Dr. Spungen' s lectures (Appendix 2).

What do you plan to do during the next reporting period to accomplish the goals?

Response:

Complete database entry, edits, and analyses

Prepare manuscripts

4. IMPACT:

Nothing to Report

What was the impact on the development of the principal discipline(s) of the project? Nothing to Report

What was the impact on other disciplines? Nothing to Report

What was the impact on technology transfer? Nothing to Report

What was the impact on society beyond science and technology? Nothing to Report

5. CHANGES/PROBLEMS:

Nothing to Report

Changes in approach and reasons for change Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them Nothing to Report

Changes that had a significant impact on expenditures Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents Nothing to Report

Significant changes in use or care of human subjects Nothing to Report

Significant changes in use or care of vertebrate animals Nothing to Report

Significant changes in use of biohazards and/or select agents Nothing to Report

6. PRODUCTS:

Publications, conference papers, and presentations

Response:

1. ASCIP 2018 Platform Presentation, Title: HDL-c changes after 50,000 steps in a powered exoskeleton. Presenter: Steven Knezevic, MS (Appendix 1&2).
2. ASCIP 2018 Poster Presentation, Title: FDA exoskeletal-assisted walking velocity: Who can get there? Presenter: EunKyoung Hong, PhD (Appendix 2).
3. Dr. Spungen' s lectures (Appendix 2).

Journal publications. Nothing to Report

Books or other non-periodical, one-time publications. Nothing to Report

Other publications, conference papers, and presentations. Nothing to Report

Website(s) or other Internet site(s). Nothing to Report

Technologies or techniques. Nothing to Report

Inventions, patent applications, and/or licenses. Nothing to Report

Other Products. Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Individuals that have worked on the project

Bronx Veterans Medical Research Foundation (BVMRF)		Status
Name:	**Ann M. Spungen, EdD**	No change
Project Role:	Principal Investigator	
Nearest person month worked	1.2	
Contribution to the Project	Principal Investigator	
Funding Support	JJPVAMC	
Name:	**Pierre K. Asselin, MS**	No change
Project Role:	Co-Investigator	
Nearest person month worked	1.2	
Contribution to the Project	Biomedical Engineer	
Funding Support	VA RR&D Center	
Name:	**Stephen D. Kornfeld, DO**	No change
Project Role:	Co-Investigator	
Nearest person month worked	0.6	
Contribution to the Project	Study physician/ medical examinations	
Funding Support	JJPVAMC SCI Service	
Name:	**Jill M. Wecht, EdD**	No change
Project Role:	Co-Investigator	
Nearest person month worked	0.36	
Contribution to the Project	Autonomic and orthostatic outcomes	
Funding Support	JJPVAMC	
Name:	**William A. Bauman, MD**	No change
Project Role:	Co-Investigator	
Nearest person month worked	0.36	
Contribution to the Project	Endocrine outcomes	
Funding Support	JJPVAMC	
Name:	**Steven Knezevic, MS**	No change
Project Role:	Lead Research Coordinator	
Nearest person month worked	6	
Contribution to the Project	Study Coordinator, site primary trainer	
Funding Support	BVMRF and VA RR&D Center	
Name:	**Eun-Kyoung Hong, PhD**	No change
Project Role:	Study Database Manager	
Nearest person month worked	9	
Contribution to the Project	Database developer/manager, Primary trainer	
Funding Support	BVMRF	
Name:	**Denis Doyle-Green**	No change
Project Role:	Research assistant	
Nearest person month worked	6	
Contribution to the Project	Assistant trainer and phlebotomist for study	
Funding Support	BVMRF	
University of Maryland Rehabilitation Orthopedic Institute (UMROI)		**Status**
Name:	**Peter H. Gorman, MD, PhD**	No change
Project Role:	Co-Principal Investigator	
Nearest person month worked	0.6	
Contribution to the Project	Site PI and study physician	
Funding Support	UMROI	
Name:	**Paula R. Geigle, PhD, PT**	No change

Project Role:	Co-Investigator	
Nearest person month worked	0.6	
Contribution to the Project	Physical therapist	
Funding Support	UMROI	
Name:	**William Scott, MA**	No change
Project Role:	Research coordinator	
Nearest person month worked	3	
Contribution to the Project	Primary trainer	
Funding Support	UMROI	
Name:	**Rebecca Webb, PT**	No change
Project Role:	Site research coordinator	
Nearest person month worked	3	
Contribution to the Project	Trainer, physical therapist	
Funding Support	UMROI	
Kessler Foundation Research Center (KF)		**Status**
Name:	**Gail F. Forrest, PhD**	No change
Project Role:	Co-Investigator	
Nearest person month worked	1.2	
Contribution to the Project	Site PI	
Funding Support	KF	
Name:	**Leigh Ann Martinez**	No change
Project Role:	Site research coordinator	
Nearest person month worked	12	
Contribution to the Project	Recruitment, IRB administrative paperwork	
Funding Support	KF	
Name:	**Steven C. Kirshblum, MD**	No change
Project Role:	Site physician	
Nearest person month worked	0.36	
Contribution to the Project	Study physician/ medical examinations	
Funding Support	Kessler Institute for Rehabilitation	
Name:	**Jonathan Augustine**	No change
Project Role:	Research assistant	
Nearest person month worked	4	
Contribution to the Project	Primary trainer	
Funding Support	KF	
Name:	**Erica Garbrini, PT**	No change
Project Role:	Physical therapist	
Nearest person month worked	6	
Contribution to the Project	Primary trainer, physical therapist	
Funding Support	KF	
Name:	**Christopher Cirnigliaro, MS**	No change
Project Role:	Study assistant	
Nearest person month worked	2	
Contribution to the Project	Body composition assessments	
Funding Support	VA RR&D Center	

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period? Nothing to Report

What other organizations were involved as partners? Nothing to Report

Organization Name: Nothing to Report
Location of Organization: Nothing to Report
Partner's contribution to the project Nothing to Report
Financial support; Nothing to Report
In-kind support Nothing to Report
Facilities Nothing to Report
Collaboration Nothing to Report
Personnel exchanges Nothing to Report
Other Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHART:

A Randomized, Crossover Clinical Trial of Exoskeletal-assisted Walking to Improve Mobility, Bowel Function and Cardio-Metabolic Profiles in Persons with SCI

Insert ERMS/Log Number and Task Title (Unknown)
SC130234

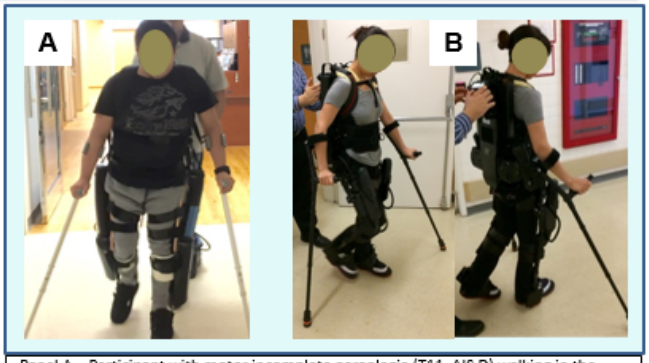
PI: Dr. Ann M. Spungen **Org:** Bronx Veterans Medical Research Foundation **Award Amount:** $1,555,889

Study/Product Aim(s)

The **primary objectives** are to achieve successful walking skills in the exoskeletal-assisted walking devices for an extended period of time and at specific velocities and distances over the course of 36 sessions in three months in people with chronic SCI who are wheelchair dependent for community mobility. The **secondary objectives** are to determine if this amount of walking is effective in improving bowel function and body composition.

Approach

A two-group, Phase III randomized clinical trial (RCT) is being performed using a crossover design with an exoskeletal-assisted walking intervention. Group 1 serves as the intervention follow-up to assess retention/non-retention of change due to the intervention on the outcome variables. Group 2 will serve as a lead-in to assess stability of the outcome variables prior to the intervention.



Panel A – Participant with motor incomplete paraplegia (T11, AIS D) walking in the ReWalk exoskeleton. Panel B - Participant with motor complete paraplegia (T3, AIS A) walking in the Ekso exoskeleton.

Timeline and Cost

Activities	FY 16	17	18	19
Text (12 participants enrolled)	Completed			
Text (30 participants to be enrolled)		Completed		
Text (48 participants to be enrolled)			Completed	
Text (64 participants to be enrolled)				Completed
Estimated Budget ($K)	**$352**	**$371**	**$381**	**$263**

Updated: (October 26, 2018)

Goals/Milestones

FY16 Goals – Startup, kick-off and training meetings at each site; Initiate participant enrollment
☑ Q3-Participant screening and enrollment of 4 participants/site.
FY17 Goal – Continued participant screening and enrollment
☑ Q3-Participant screening, recruitment and enrollment of 8 (JJPVAMC), 4 (KF) and 6 (UMROI) participants per respective sites.
FY18 Goal – Continued enrollment
☑ Q1-Participant enrollment of 8 (JJPVAMC), 4 (KF) & 6 (UMROI)
☑ Q4-Participant enrollment of 8 (JJPVAMC), 4 (KF) & 4 (UMROI)
FY19 Goal – Completion of data collection
☐ Q2-Completion of participants
☐ Q3 to Q4 -Completion of data edits, analysis; Manuscript preparation
Comments/Challenges/Issues/Concerns - None
Budget Expenditure to Date
Projected Expenditure FY16 (Year 1): Approximate $352,335
Actual Expenditure FY16 (Year 1): Approximate $352,335

9. APPENDICES:

Appendix 1. Steven Knezevic's slide Presentation from ASCIP 2018

Academy of Spinal Cord Injury Professionals, Inc.

2018 Educational Conference and Expo
September 2-5, 2018 New Orleans Marriott

NEW ORLEANS

Stronger Together

Passion, Purpose and Possibilities in SCI/D

HDL-c changes after 50,000 steps in a powered exoskeleton.

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Funding Sources

- Department of Defense
  - CDMRP SC130234 Award: W81XWH-14-2-0170
- National Center for the Medical Consequences of Spinal Cord Injury (B9212-C, B2020-C), James J. Peters Veterans Affairs Medical Center
- No Conflicts of Interest to report

An Inconvenient Truth

Sitting vs. Exercise

- A study involving over 100,000 U.S. adults found that those who sat for more than six hours a day had up to a 40 percent greater risk of death over the next 15 years than those who sat for less than three hours a day.

(Patel et al. 2010 - *American journal of epidemiology*).

Sedentary Lifestyles & Adiposity

NON-SCI	SCI
Tremblay MS et al. 2011 TV viewing in excess of 2 hours is associated with reduced physical and psychosocial health	Kocina P et al. 1997 Above-average fat mass for active (16 to 24% and 24 to 32%) and sedentary (above 25 & 32%).
Gomez-Cabello A et al. 2011	Spungen AM et al. 2000
SEDENTARY LIFESTYLE ↓ OBESITY ↑	SCI ↓ OBESITY ↑↑↑
Sedentary behavior and central obesity were associated with individual CVD risk factors in young women	Increased prevalence of abnormalities in carbohydrate and lipid metabolism because of immobilization, muscle atrophy and relative adiposity
Golubic R et al. 2014 Promoting more physical activity and less sedentary time may reduce total and abdominal body fat.	Emmons RR et al. 2010 Greater: trunk fat %, android fat %, waist fat %, and waste to hip ratio.

HDL-c vs LDL-c

- High-density lipoprotein cholesterol (HDL-c), "Good Cholesterol", transports cholesterol to your liver to be expelled from your body.
  - *Anti-Atherosclerotic*
- Low-density lipoprotein cholesterol (LDL-c), "Bad Cholesterol" transports cholesterol to your arteries, where it may collect in artery walls.
- Excess cholesterol in arteries increases risk of:
  - ❑ Stroke
  - ❑ Heart Attack
  - ❑ Kidney Disease
  - ❑ Peripheral Arterial Disease

SCI and HDL-c

- Serum HDL-c levels below 40 mg/dL (an independent risk factor for CVD) have been reported in more than 50% of the SCI population.
- As a result, persons with SCI have an increased risk for the development of cardiovascular disease (CVD), which is one of the leading causes of death in the SCI population.
- Inactivity is an important factor for low serum HDL-c levels.

Bauman, W. A., et al. "Depressed serum high density lipoprotein cholesterol levels in veterans with spinal cord injury." *Spinal Cord* 30.10 (1992): 697-703.

Walking Technologies

Exoskeletons ... ... WHAT WE HAVE IMAGINED ... ... IS BECOMING REAL LIFE PROGRESSION

A "Step" in the right direction

Ekso™ (Ekso Bionics™)

Indego® (©Parker Hannifin Corp.)

ReWalk™ (ReWalk Robotics)

Exercise Intensities

General Population:

- Vigorous Intensity (ACSM): 60 – 85% of Max Predicted HR
  - ✓ Recommendation 75 minutes per week; 25 minutes, 3x/week.

Exoskeleton Assisted Walking (EAW):

- Asselin et al. 2015 (ReWalk):
  - ✓ During WALK, participants attained approximately one half of their estimated maximum HR reserve, which would indicate a moderate level of intensity.
- Evans et al. 2015 (Indego):
  - ✓ Age: 42±9 years (HR_{max} ~178±9).
  - ✓ HR_{peak} (bpm): Walk 1 - 121±30; Walk 2 - 142±35.

American College of Sports Medicine. (2017). *ACSM's guidelines for exercise testing and prescription*. Tenth Edition. Lippincott Williams & Wilkins.

Study Title

A Randomized, Crossover Clinical Trial of Exoskeletal-assisted Walking to Improve Mobility, Bowel Function and Cardio-Metabolic Profiles in Persons with SCI.

PI: Dr. Ann Spungen, EdD
Co PI: Dr. Peter Gorman, MD
CO I: Dr. Gail Forrest, PhD

ClinicalTrials.gov – NCT02314221

Learning Objective

To identify the effect of exoskeletal-assisted walking on the lipoprotein profile, HDL, in persons with chronic SCI.

Design

- Prospective
- Randomized
- Two-group Crossover
- C6-T3 Ekso; T4 and below ReWalk
- 12 Weeks – 3x/Week

Group 1	36 Sessions of EAW	12 Weeks of UA
Group 2	12 Weeks of UA	36 Sessions of EAW

Sites

- James J. Peters VA Medical Center, Bronx, NY
- Kessler Foundation Research Center, West Orange, NJ
- University of Maryland Rehabilitation and Orthopedic Institute, Baltimore, MD

Subject Criteria

INCLUSION CRITERIA	EXCLUSION CRITERIA
1. Males and females, 18-65 years old; 2. Duration of Injury >6 months; 5. Weight <100 kg (<220 lb) 6. Able to hold the crutches; and 7. Able to sign informed consent.	1. Diagnosis of neurological injury other than SCI; 2. Severe concurrent medical disease, illness or condition; 3. Recent lower extremity fracture within the past 2 years; 4. DXA results indicating a t-score below -3.5 at the femoral neck or the total proximal femur physician or physical therapist); 12. Psychopathology documentation in the medical record or history of that may conflict with study objectives; 13. Pregnancy and/or lactating females; 14. Other illness, that the study physician considers in his/her clinical judgment to be exclusionary;

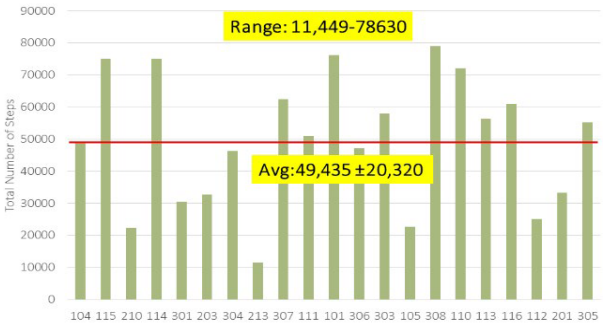
18-65 Years
SCI > 6 Months
Fit in Exoskeleton

Low BMD/Fx Hx
Severe Spasticity
Contractures

Methods

- Outcome Measure
  - ➢ Serum HDL-c levels Pre/Post EAW
- Fasting Blood Draw
  - ➢ 12 Hour (Overnight)
- Quest Diagnostics Laboratory
  - ➢ Auto Analyzer
- Statistical Analysis
  - ➢ Paired Sample T-Test
  - ➢ Chi Square
    - Proportion of subjects who had an increase in HDL ≥ 2.0 mg/dl

Total Number of Steps



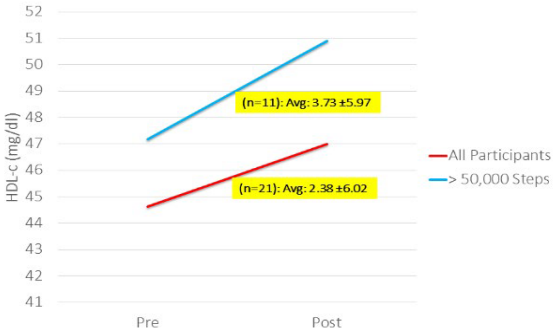
Training Session Overview

- Pre Walk Routine (Empty Bladder/Stretch)
- Pre & Post Vital Signs (Seated & Standing, Seated Recovery in WC).
- One Hour of Training
- Rating of Perceived Exertion

VITAL SIGNS		Time of Day		HR (bpm)	SBP (mmHg)	DBP (mmHg)
Pre-walking	Seated	__ __ : __ __	AM / PM			
	Standing	__ __ : __ __	AM / PM			
Immediate Post EAW	Standing	__ __ : __ __	AM / PM			
Post Session Seated	In Exoskeleton	__ __ : __ __	AM / PM			
	In Wheelchair	__ __ : __ __	AM / PM			

STATIC AND WALKING MOBILITY SKILLS	Performed (Yes/No/NT*)	FIM	RPE
Sit to stand			
Stand to sit			
Standing balance with 2 crutches			
Balancing with left crutch only			
Balancing with right crutch only			
Unweighting of each foot			
360 degree weight shifting			

Average HDL-c Differences



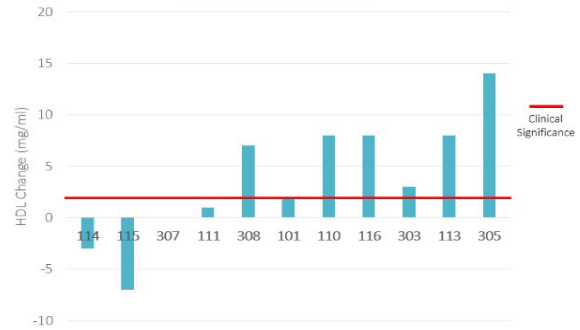
Demographics

- N= 21
- 5 Females
- Age: 40.9±13.87
- DOI: 6.8±4.19

ID	Age (Years)	Gender	Weight (lbs.)	Height (in.)	Level of Injury	DOI (Years)	ASIA
101	24	Male	175	64	2	9	D
104	29	Female	190	65	3	6	D
105	66	Male	201	66	3	7	A
110	42	Male	160	70	3	19	B
111	56	Male	180	71	4	4	A
112	23	Female	160	61	3	3	B
113	64	Male	182	71	1	3	D
114	52	Male	164	76	4	3	A
115	39	Female	111	64	1	3	C
116	45	Male	185	72	3	8	A
201	38	Male	148	72	4	5	A
203	57	Male	202	71	4	13	A
210	28	Male	178	70	3	4	A
213	26	Male	126	66	3	4	A
301	60	Male	152	66	4	6	D
303	21	Male	180	73	3	8	A
304	30	Male	186	72	1	7	B
305	42	Female	148	63	4	3	C
306	36	Male	173	69	1	14	A
307	40	Male	122	66	3	5	A
308	41	Male	173	72	4	8	C

1 = High Tetra (C5 & Above)
2 = Low Tetra (C6-8)
3 = High Para (T1-6)
4 = Low Para (T7 & Below)

HDL-c Changes in participants over 50,000 Steps



Results

- The average HDL-c increase 2.38 ±6.02 mg/dl (p=0.085).
- 11 of 21 (>50%) participants had an increase in serum HDL-c of ≥2.0 mg/dL after the EAW intervention (3.73 ±5.97 mg/dL).
  - 2 of 21 improved from below 40 to above 40
- No significant changes were noted in the serum triglycerides or LDL-c.

Conclusion

In the majority of persons with chronic SCI, EAW of at least 50,000 steps performed in 3 sessions a week, for 12 weeks, resulted in favorable changes in the serum HDL-c.

Limitations

- Level of activity not uniform among all participants.
  - *Walking Independence/Compliance may effected training.*
  - *Participants who struggled in the device typically walked less steps over the course of 36 sessions.*
- Inter-assay Variability
  - *Samples analyzed individually after each blood draw*

SO WHAT?

WHO CARES?

So What?

- Exercising with exoskeletons may increase serum HDL-c and may lead to a reduction in the risk of CVD.
- EAW provides the SCI population with an additional opportunity to exercise lower and upper extremity skeletal muscles.
  - *Engaging larger portion of skeletal musculature.*

Future Research

What is responsible for the favorable change in serum HDL-c level?

- Dosage?
  - Intensity? - Times per week.
  - Duration? - Number of weeks.
  - Total number of steps?

- More frequent assessments?

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- Peter H. Gorman, MD; Rebecca Webb, William Scott
  - University of Maryland School of Medicine, University of Maryland Rehabilitation and Orthopedic Institute, Baltimore, MD
- Gail Forrest, PhD; Erica Garbarini, PT; Leighann Martinez
  - Kessler Foundation, West Orange, NJ
- Center Director - William A. Bauman, MD

References

1. Bauman, W. A., et al. "Depressed serum high density lipoprotein cholesterol levels in veterans with spinal cord injury." Spinal Cord 30.10 (1992): 697-703.
2. Bauman, W. A., and A. M. Spungen. "Coronary heart disease in individuals with spinal cord injury: assessment of risk factors." Spinal Cord 46.7 (2008): 466-476.
3. Brenes, Gilbert, et al. "High density lipoprotein cholesterol concentrations in physically active and sedentary spinal cord injured patients." Archives of physical medicine and rehabilitation 67.7 (1986): 445-450.
4. Gilbert, O., Croffoot, J. R., Taylor, A. J., Nash, M., Schomer, K., & Groah, S. (2014). Serum lipid concentrations among persons with spinal cord injury–A systematic review and meta-analysis of the literature. Atherosclerosis, 232(2), 305-312.
5. Gorgey, A. S., Dolbow, D. R., Dolbow, J. D., Khalil, R. K., Castillo, C., & Gater, D. R. (2014). Effects of spinal cord injury on body composition and metabolic profile–Part I. The journal of spinal cord medicine, 37(6), 693-702.
6. Harnish, C. R., Sabo, R. T., Daniels, J. A., & Caruso, D. (2017). The Effects of Two Weeks of Arm Crank Sprint Interval Training in Men with Chronic Spinal Cord Injury. Int J Sports Exerc Med, 3, 059.
7. La Fountaine, M. F., Cirnigliaro, C. M., Emmons, R. R., Kirshblum, S. C., Galea, M., Spungen, A. M., & Bauman, W. A. (2015). Lipoprotein heterogeneity in persons with Spinal Cord Injury: a model of prolonged sitting and restricted physical activity. Lipids in health and disease, 14(1), 81.
8. Nooijen, C. F., Stam, H. J., Sluis, T., Valent, L., Twisk, J., & van den Berg-Emons, R. J. (2017). A behavioral intervention promoting physical activity in people with subacute spinal cord injury: secondary effects on health, social participation and quality of life. Clinical rehabilitation, 31(6), 772-780.
9. Patel, A. V., Bernstein, L., Deka, A., Feigelson, H. S., Campbell, P. T., Gapstur, S. M., ... & Thun, M. J. (2010). Leisure time spent sitting in relation to total mortality in a prospective cohort of US adults. American journal of epidemiology, 172(4), 419-429.

Appendix 2. ASCIP 2018 Accepted Abstract Presentations

HDL-c changes after 50,000 steps in a powered exoskeleton.

Steven Knezevic, MS1; EunKyoung Hong, PhD1; Pierre Asselin, MS1; Christopher M. Cirnigliaro, MS, CEP, CBDT1; Stephen Kornfeld, DO2; Peter H. Gorman, MD3; Gail F Forrest, PhD4; William A. Bauman, MD1,2,4,5; Ann M. Spungen, EdD1,5

[1]Spinal Cord Damage Research Center, James J. Peters VA Medical Center, Bronx, NY; [2]Spinal Cord Injury Service, James J. Peters VA Medical Center, Bronx, NY; [3]University of Maryland School of Medicine, University of Maryland Rehabilitation and Orthopedic Institute, Baltimore, MD; [4]Kessler Foundation, West Orange, NJ; [5]Departments of Medicine and Rehabilitation Medicine, Icahn School of Medicine at Mount Sinai, New York, NY

Background: Serum high density lipoprotein cholesterol (HDL-c) levels below 40 mg/dL (an independent risk factor for cardiovascular disease) have been reported in 64% of persons with tetraplegia and 60%, with paraplegia. As a result of this lipoprotein abnormality, as well as other risk factors, persons with spinal cord injury (SCI) have an increased risk for the development of cardiovascular disease (CVD), which is one of the leading causes of death in the SCI population. Increased physical activity is an important factor to increase serum HDL-c levels. Previously, we reported HDL-c levels in 15 participants after 36 sessions of exoskeletal-assisted walking (EAW). We now report on 11 additional (N=21) participants after 36 sessions of EAW.
Design: Prospective, three-site (ongoing) interventional study in participants with chronic SCI.
Methods: Twenty-one participants with chronic SCI have completed the study to date. Participants trained in the exoskeleton for 36, one-hour sessions over a 3 month period. Fasting blood samples were collected to determine serum HDL-c levels before and after completion of the training sessions. Serum samples were sent to Quest Diagnostics Laboratory for analysis using an automatic assay analyzer. The absolute change of the serum HDL-c value in a given participant was used to determine a clinically significant change. The minimal significant change accepted for clinical significance was ≥2.0 mg/dL.
Results: Eleven of 21 (>50%) participants had an increase in serum HDL-c of ≥2.0 mg/dL after the EAW intervention (mean±SD = 7±4 mg/dL). Additionally, participants who completed ≥50,000 total steps, 64% (7 of 11) versus 36% (4 of 11) demonstrated a clinically significant change in serum HDL-c levels. In those who completed ≥50,000 total steps, HDL-c improved by an average of 3.5±6.0 mg/dL (range: 2.0 to 14.0 mg/dL) and had slightly more number of steps per session than those who did not have a clinically significant change (1,475±541 vs. 1,230±575 steps, p=0.26). No significant changes were noted in the serum triglycerides or low density lipoprotein cholesterol.
Conclusion: In the majority of persons with chronic SCI, EAW of at least 50,000 steps performed in 3 sessions a week, for 12 weeks, resulted in favorable changes in the serum HDL-c. The observed increase in serum HDL-c would be anticipated to reduce the risk for the development of CVD.
Support: DOD/CDMRP Award: W81XWH-14-2-0170. VA RR&D National Center for the Medical Consequences of Spinal Cord Injury (B9212-C, B2020-C), James J. Peters VA Medical Center.

References:

- La Fountaine, M. F., Cirnigliaro, C. M., Emmons, R. R., Kirshblum, S. C., Galea, M., Spungen, A. M., & Bauman, W. A. (2015). Lipoprotein heterogeneity in persons with Spinal Cord Injury: a model of prolonged sitting and restricted physical activity. Lipids in health and disease, 14(1), 81.
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Learning Objectives: To identify the effect of exoskeletal-assisted walking on the lipoprotein profile in persons with chronic SCI.

Appendix 2. ASCIP 2018 Accepted Abstract Presentations

FDA exoskeletal-assisted walking velocity: Who can get there?

EunKyoung Hong, PhD[1,2]; Steven Knezevic, MS[1]; Pierre Asselin, MS[1-3]; Stephen Kornfeld, DO[1-3]; Peter H. Gorman, MD[4]; Gail Forrest, PhD[5]; and Ann M. Spungen, EdD[1,2,6]

[1]Spinal Cord Damage Research Center, James J. Peters VA Medical Center, Bronx, NY; [2]Department of Rehabilitation Medicine, Icahn School of Medicine at Mount Sinai, New York, NY; [3]Spinal Cord Injury Service, James J. Peters VA Medical Center, Bronx, NY; [4]University of Maryland School of Medicine, University of Maryland Rehabilitation and Orthopedic Institute, Baltimore, MD; [5]Kessler Foundation, West Orange, NJ; [6]Departments of Medicine, Icahn School of Medicine at Mount Sinai, New York, NY

Background: In the VA Spinal Cord Injury Services and some non-VA rehabilitation hospitals, clinical exoskeletal-assisted walking (EAW) programs are offered. As the rate of exoskeleton device usage increases, the staffing needs in the clinical setting are unknown. The number of sessions to achieve a minimal velocity for ambulation or the FDA criteria for personal use prescription in the home and community with these devices is also unknown. The purpose of this study was to determine the proportion of participants who achieved successful EAW velocities at 12, 24 and 36 sessions. **Design:** A three-site, multi-center, interventional study is on-going in participants ≥6 months post SCI. **Methods**: To date, 29 participants completed 36 sessions of EAW training, three sessions per week (4-6 h/week) in a 12-week period. EAW assessments for the 10 meter walk test (seconds) (10MWT), 6-minute walk test (meters) (6minWT), and the timed-up-and-go (seconds) (TUG) are reported at 12 and 36 sessions. A nominal velocity of 0.25m/s was chosen by the investigators as a minimal efficiency for ambulation. For personal use prescription, the FDA requires 0.40 m/s. **Results:** The mean age and duration of injury of all participants were 40±14 years and 4±4 years, respectively. By 12 sessions: for the 10MWT, 16 of 29 (55%) participants walked faster than minimal and 5 (17%) qualified for the FDA criteria; 66% (19) performed ≥80m on the 6minWT; 20 participants (69%) performed the TUG test in <90s. By 36 sessions: 22 (76%) and 8 (28%) participants met the minimal efficiency and FDA criteria, respectively; for the 6minWT, 23 (79%) walked ≥80m; and for the TUG 20 (69%) performed in <90s. **Conclusion**: More than one-half of the participants achieved the minimal velocity for ambulation and less than one-fifth, the FDA criteria by 12 sessions, with only slight increases in the proportion of participants to achieve these same goals at 36 sessions. Depending on the goals of a clinical EAW program, it may not be practical for clinicians to provide 36 sessions of EAW training. An EAW basic mobility skills screening test should be developed to identify those participants most likely to achieve FDA skill criteria in a reasonable number of sessions.

Support: Department of Defense/CDMRP SC130234 Award: W81XWH-14-2-0170 and National Center for the Medical Consequences of SCI (B9212-C, B2020-C) at the James J. Peters Veterans Affairs Medical Center.

Walk Test	Criteria	12 Sessions	36 sessions
		n (%)	n (%)
10MWT	≥0.25 m/s	16 (55%)	22 (76%)
10MWT	≥0.40 m/s*	5 (17%)	8 (28%)
6minWT	≥80 m	19 (66%)	23 (79%)
TUG	<90 s	20 (69%)	25 (86%)

* FDA criteria for Personal use

Appendix 2. Dr. Spungen' s Invited Lectures/Presentations 10/9/17 – 10/28/18.

INVITED LECTURES/PRESENTATIONS

	Type	Date	Institution	Topic
1	Invited Speaker	10/18/2018	4th International Symposium on Wearable Robotics (WeRob2018), Pisa, Italy	Update from on-going exoskeletal-assisted walking clinical trials in chronic and acute spinal cord injury
2	Invited Speaker	10/12/2018	Robotics, Rehabilitation and Caregiving, Brecia, Italy	Exoskeletal-assisted walking for persons with Spinal Cord Injury
3	Invited Presentor	6/19/2018	VA Office of Research and Development Science Fair for Congress, Rayburn Building, Capitol Hill, Washington, DC	Exoskeletoal Technologies for people with walking impairments
4	Workshop Co-Leader	5/2/2018	American Spinal Injury Association Annual Scientific Meeting, Rochester MN	Craig H. Neilson Foundation sponsored workshop on Bowel and Bladder Assessments for SCI
5	Invited Speaker	4/24/2018	U.S. Army Natick Soldier Research, Development & Engineering Center (NSRDEC) and will be held at the Lord Community Center at NSRDEC in Natick, MA	Office of the Under Secretary of Defense for Research and Engineering (OUSD R&E), Department of Defense (DoD) Exoskeleton Technical Interchange. "Exoskeletal-assisted walking for persons with Spinal Cord Injury"
6	Invited Speaker	2/13/2018	VA Breakout at American Academy of Orthotists & Prosthetists Annual Meeting, New Orleans, LA	Exoskeletal-assisted walking for persons with paralysis: What we know and don't know
7	Invited Speaker	11/28/2017	Grand Rounds, Department of Rehabilitation Medicine Icahn School of Medicine at Mount Sinai, NY, NY	Exoskeletal-assisted walking for persons with paralysis: What we know and don't know
8	Invited Speaker	11/5/2017	The 2017 International Symposium of Wearable and Rehabilitation Robotics (WeRob2017), Houston, TX	Advising the organizing committee on the scientific content of the symposium and reviewing abstracts for platform and poster presentations.
9	Invited Speaker	10/24/2017	Internationa Spinal Cord Society Annual Scientific Meetg, Dublin, Ireland	Exoskeletal-Assisted Walking in Acute Inpatient and Chronic Outpatient Spinal Cord Injury Rehabilitation.