

Feasibility of a Home Activity-Based Rehabilitation Program in Chronic Spinal Cord Injury

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General Physical Activity Statistics

- Low Levels of physical activity (PA) in US adults
 - 55% of adults in the US do not get the recommended amount of PA¹
 - Surgeon General's recommendation: 30 min of light to moderate activity on most days of the week²
 - 26% of adults report no PA¹
- Effectiveness of exercise programs to increase PA is marginal
 - Dropout rates are high in the first 3 months, increasing to approximately 50% within 1 year³
 - Mirrors adherence to other health-related behaviors³
 - Medication compliance
 - Smoking cessation
 - Weight reduction

Objectives

- To examine the feasibility of a home activity-based rehabilitation (ABR) program in SCI
- To determine the primary barriers to protocol adherence
- To identify trends of program compliance
- To determine what psychosocial factors may contribute to adherence rates
- To examine subject satisfaction with the functional electrical stimulation (FES) equipment and the ABR program

Design

- Prospective within-subject pilot study based on mixed methodology including focus groups and repeated measures design (baseline, midterm (6 month), and post (1 year) assessments)
- Medically stable individuals with chronic SCI that were not currently receiving therapy were enrolled according to the following criteria:

Inclusion Criteria	Exclusion Criteria
Traumatic SCI	Unable to tolerate FES during initial phase
ASIA Impairment Scale A	Within 2 months of lower extremity long bone fracture
Greater than one year post-SCI	History of malignancy
18 years of age or older	History of cardiovascular disease
Medically stable with physician approval to participate	
Completion of informed consent	

Phase 1 – Focus Group

- Conducted before ABR exercise program was designed
 - Consisted of 9 study personnel, clinicians, and consumers
 - Purpose was to gain insight on consumer's and clinician's views on ABR
 - What are the pros and cons of ABR?
 - What would you want in an ABR program?
 - What are main barriers to doing ABR?
- Consumer views on ABR
 - Pros:
 - Looking forward to something constant everyday: *"I feel like I am living a productive lifestyle"*
 - Continuing pre-accident activity (return to normalcy): *"I loved exercise before so it's like I am continuing that but in a different manner"*
 - Sense of empowerment: *"This is something I can do to take care of my body. This is something I can control, this is something that I can do for myself to make a difference"*
 - Cons:
 - Can lead to false hope of recovery

Phase 1 – Focus Group

- The perfect ABR program
 - Does not promise benefits it cannot deliver
 - Adapts to individual person's needs
 - Must be fun
- Main barriers to ABR
 - Keeping the program going
 - Equipment expensive to buy – time/transportation constraints of coming to the hospital
 - *“How can you feel productive if so much time is spent in the hospital?”*
 - Not knowing what benefits the program will provide
- Study designed to minimize these barriers
 - Home-based exercise program (transportation barrier)
 - Equipment and time compensated (expense barrier)

Phase 2 - Assessment Battery

Neurological	Motor/Sensory Activity	ASIA
		Index of Motor Recovery
	Range of Motion	EMG
		Manual Measurement/Goniometer
Spasticity	Modified Ashworth	
Cardiovascular and Physiological	Body Composition	DXA Scan
		Girth/Circumference Measurements
		Waist-to-hip Ratio
		Body Mass Index
	CVD Risk	Blood Assay Analysis
		Risk Factor Questionnaire: Family History, Age, Tobacco Use
		Framingham Risk Score
Exercise Capacity	VO2 max Exercise Test	
Physical Activity	Physical Activity Scale	
Functional Independence	Functional Status	FIM
		SCIM III
Emotion/Pain	Pain	MPI
	Depression	CES-D
Psychosocial Functioning	Quality of Life	MOS SF-36
	Self-Efficacy	SCI Exercise Self-Efficacy Scale
Evaluation/Feasibility	Satisfaction with FES Program and Assistive Devices	Satisfaction with FES Program
		Satisfaction with FES Bike
		Satisfaction with FES Unit

ABR Intervention

- 1 year, home-based ABR program
- FES equipment (FES bike and a portable FES unit) installed in subjects' homes after baseline assessment
- Subjects were trained to use equipment on their own, and monitored trial sessions were conducted in their homes upon equipment installation
- Subjects exercise 6 days/week for 1 hour (3 bike, 3 portable unit)
 - Instructed to alternate days
- Bike sessions are automatically controlled by the motor and are auto-progressed
 - Once muscle fatigue is noted, FES is discontinued and the motor controls cycling (subjects begin cool-down)
- Portable unit sessions are controlled by the subject
 - Subjects are instructed to increase stimulation percentage until they see or palpate muscle contraction

Phase 2 - Methods

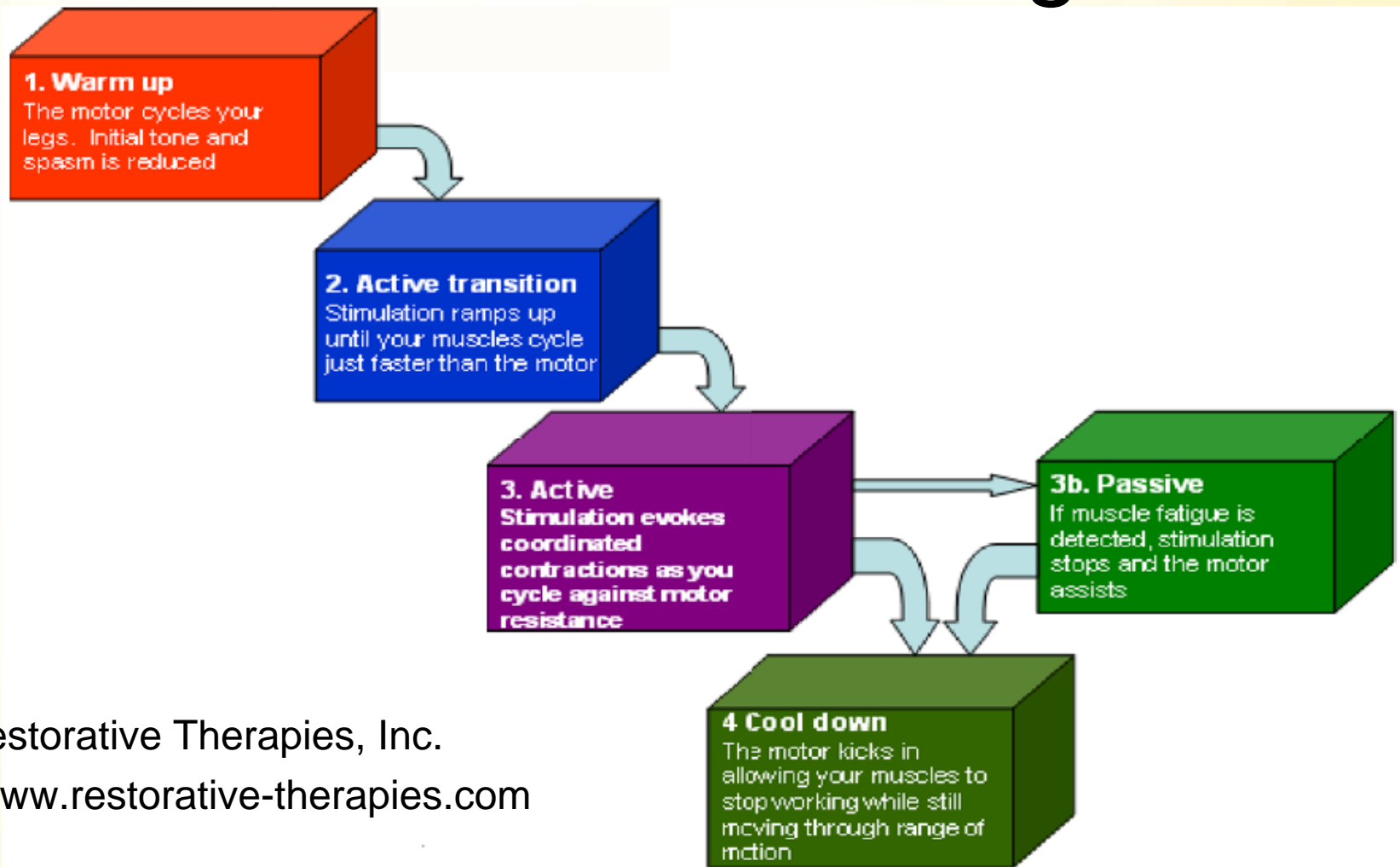
- Subject Monitoring
 - Weekly monitoring forms completed over the phone or in person
 - Subjects completed self-reported physical activity logs (including FES exercise)
 - Home visits completed monthly to download data, inspect and replenish equipment supplies, and resolve any issues
- Adherence/Barrier Determination
 - Calculated as average weekly sessions completed by month
 - Monitoring forms
 - Physical Activity logs
 - Downloaded data from the FES equipment

FES Bike Intervention

- 1 hour sessions 3 days per week
- Stimulates quadriceps, hamstrings, and gluteal muscles on both legs in coordination with cycle (6 channels)
- Cycle has internet connection – uploads all session data to company server for clinician to view and download
- Provides feedback



FES Bike Session Stages



Restorative Therapies, Inc.

<http://www.restorative-therapies.com>

Portable FES Unit Intervention

- 1 hour sessions 3 days per week
- Stimulates 2 channels asynchronously (ramped protocol, 5 sec on, 10 sec off)
- Portable unit stores all session data
 - Data is downloaded from unit monthly during home visit via USB
- Provides limited feedback



CustomKYNetics, Inc.

<http://www.customkynetics.com>

Portable FES Unit Session

- Muscles used:
 - tibialis anterior and gastrocnemius on each leg
 - Abdominals and paraspinals are alternated each session
- Specific muscles chosen for this protocol to compliment the FES bike protocol

Session sample:

20 min	Right Leg	Right TA and Calf
20 min	Left Leg	Left TA and Calf
20 min	Abs or Back	L/R abs L/R back L abs/back R abs/back

Sample Characteristics

- Completed protocol (n=4; 3 male, 1 female)
 - Finished 54-59 wks
- In protocol (n=1; 1 female)
 - Finished 20 wks
- Withdrawn from study (n=2)
 - Participation in study not permitted at living facility
 - Long period of missing data and subject contact due to medical complications
- Active Subjects (n=5):
 - Mean Age: 41.39 ± 11.16 (Range: 25.03 – 55.18)
 - Mean Duration of Injury: 17.40 ± 12.22 (Range: 3.15 – 34.79)
 - Level of Injury: 4 Tetra (3 male, 1 female); 1 Para (1 female)

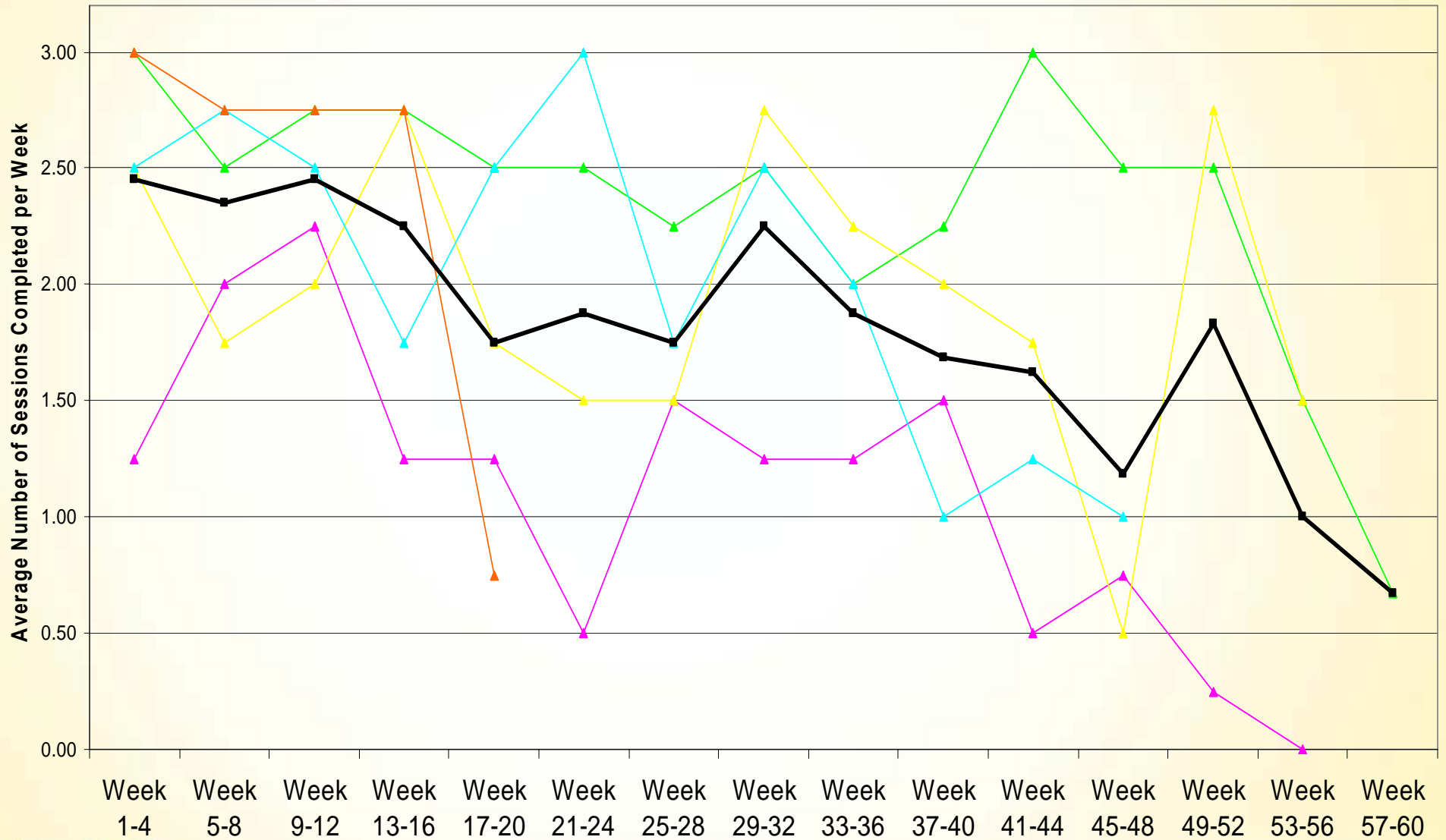
Sample Characteristics

Subject	Gender	Age	Level	AIS	Race	Years of SCI
FES01	Male	25	C4	A	Hispanic	3
FES02	Female	47	C2	A	Caucasian	9
FES04	Male	42	C2	A	Caucasian	22
FES05	Male	38	C4	A	Caucasian	18
FES07	Female	55	T3	A	Caucasian	35

Results: FES Bike Adherence

Subject	Sessions Completed	Total Protocol Sessions	Percent Adherence	Average Sessions per Week
FES01	140	177	79.10%	2.37
FES02	62	165	37.58%	1.13
FES04	106	162	65.43%	1.96
FES05	98	144	68.06%	2.04
FES07	48	60	80.00%	2.40
TOTALS	454	708	64.13%	1.92

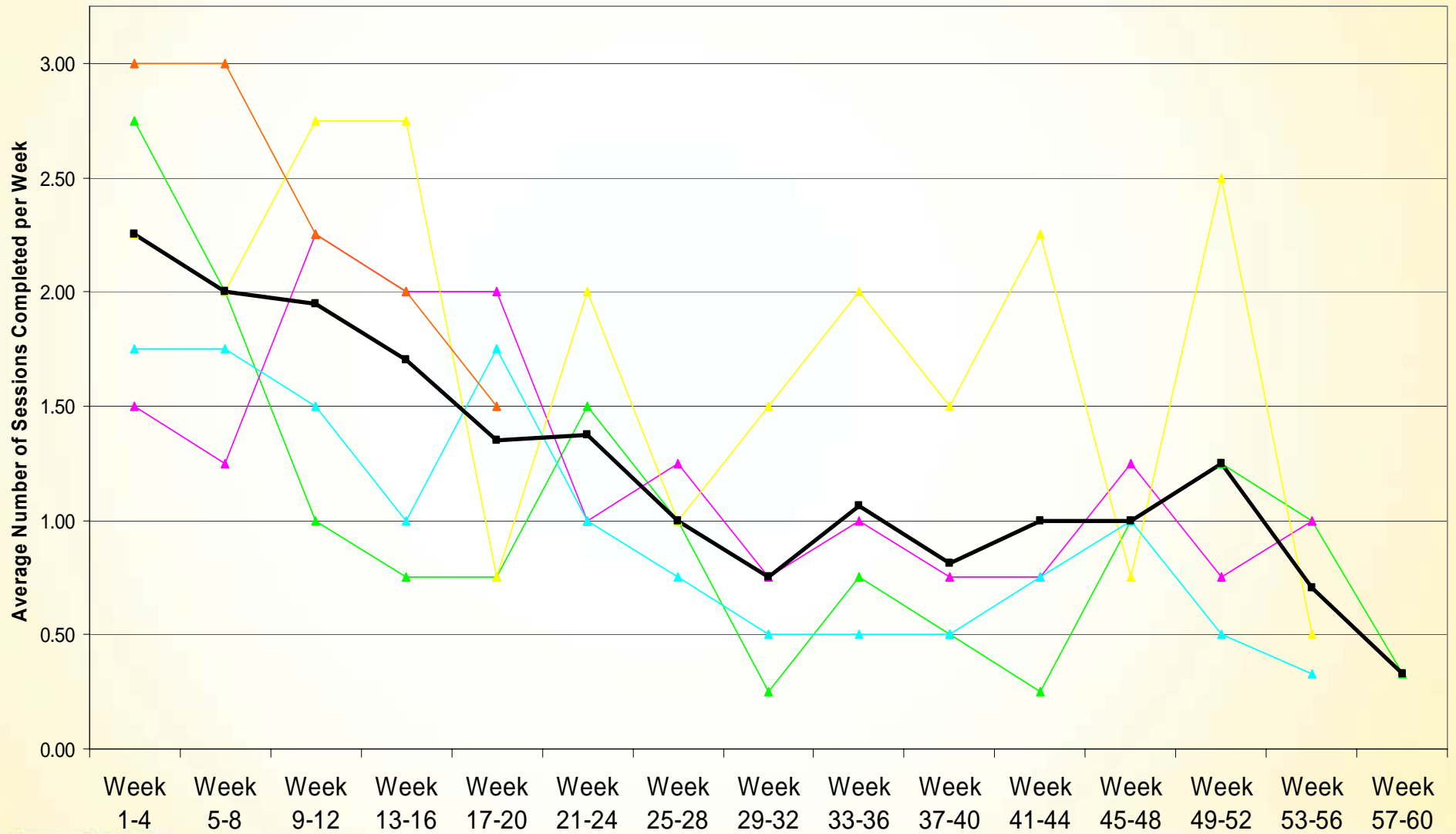
Results: FES Bike Adherence



Results: FES Unit Adherence

Subject	Sessions Completed	Total Protocol Sessions	Percent Adherence	Average Sessions per Week
FES01	60	177	33.89%	1.02
FES02	69	165	41.82%	1.25
FES04	97	162	59.88%	1.80
FES05	54	165	32.72%	0.98
FES07	47	60	78.33%	2.35
TOTALS	327	729	44.85%	1.35

Results: FES Unit Adherence

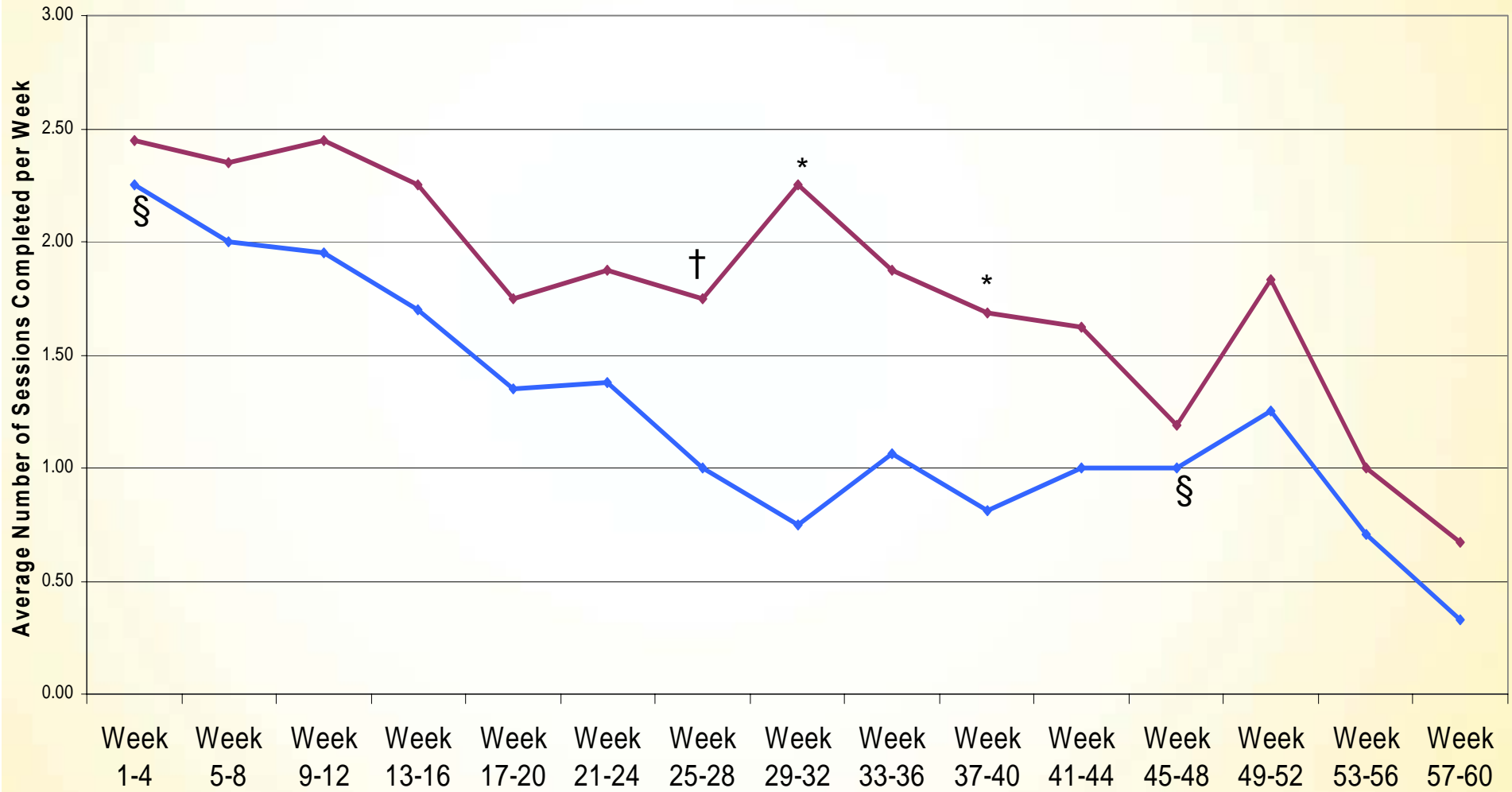


Overall Program Adherence and Trends

	Sessions Completed	Total Protocol Sessions	Percent Adherence	Average Sessions Per Week
FES Bike Total	454	708	64.13%	1.92
FES Unit Total	327	729	44.85%	1.35
Total Protocol	781	1437	54.35%	3.27

- Bike adherence showed no significant changes over the year (Friedman ANOVA)
- § Unit adherence decreased significantly ($p=0.009$) from week 1 to 48 (Friedman ANOVA)
- Largest adherence differences between the bike and unit were found in the middle of the study ($\dagger P<0.05$; $* p<0.10$) (Mann-Whitney)

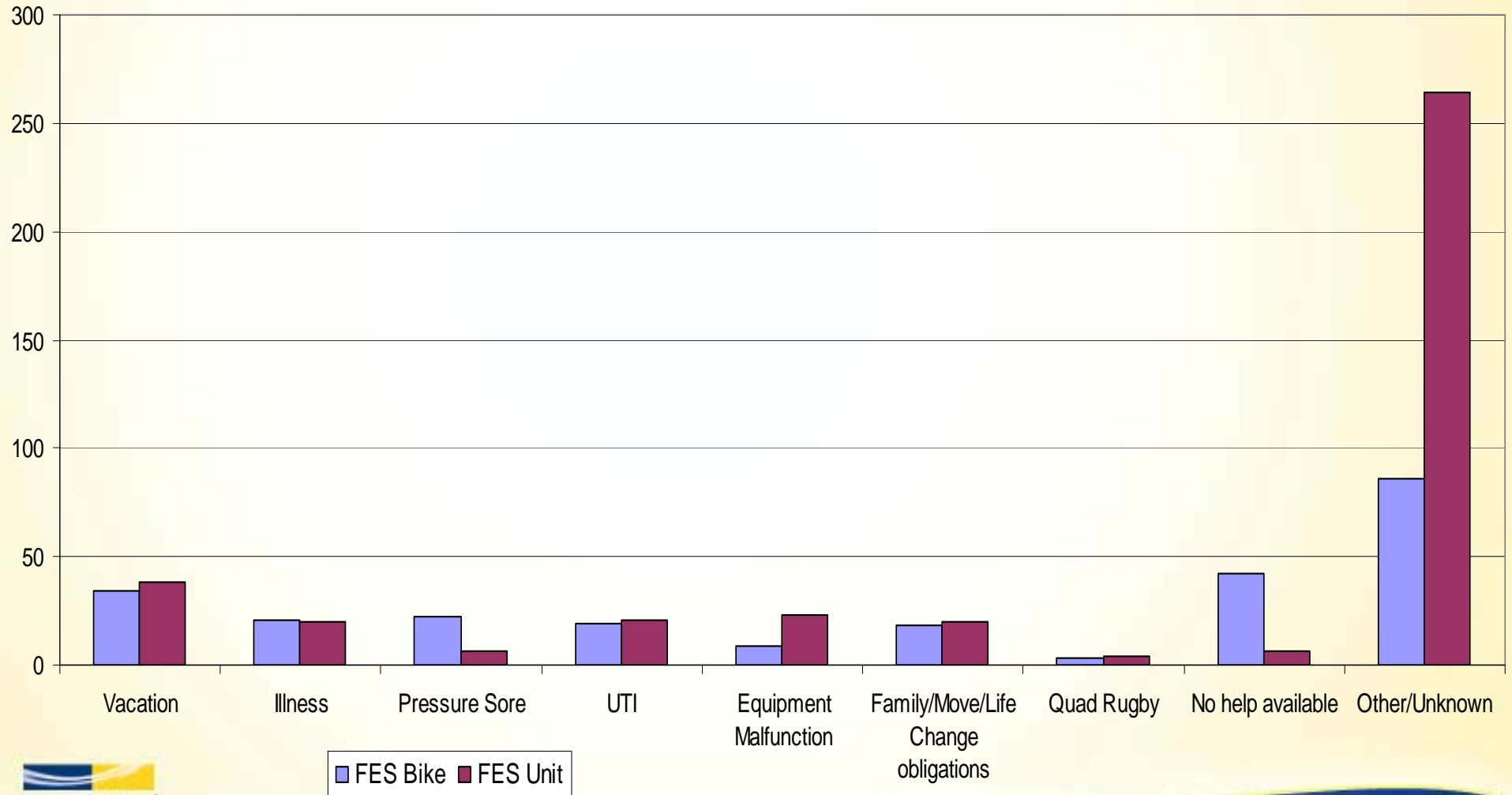
Trends of Adherence



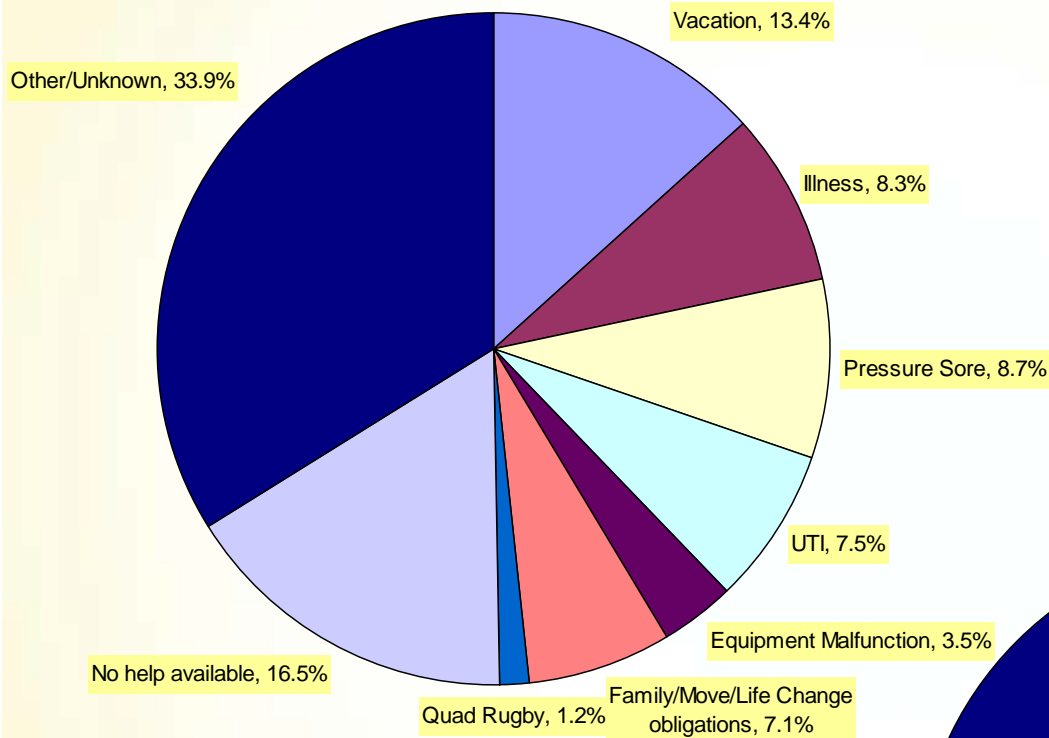
Barriers to Program Adherence

	FES Bike	Bike Percent Missed	FES Unit	Unit Percent Missed	Total	Total Percent Missed
Vacation	34	13.4%	38	9.5%	72	11.0%
Illness	21	8.3%	20	5.0%	41	6.3%
Pressure Sore	22	8.7%	6	1.5%	28	4.3%
UTI	19	7.5%	21	5.2%	40	6.1%
Equipment Malfunction	9	3.5%	23	5.7%	32	4.9%
Family/Move/Life Change Obligations	18	7.1%	20	5.0%	38	5.8%
Quad Rugby	3	1.2%	4	1.0%	7	1.1%
No Help Available	42	16.5%	6	1.5%	48	7.3%
Other/Unknown	86	33.9%	264	65.7%	350	53.4%
Total	254	100.0%	402	100.0%	656	100.0%

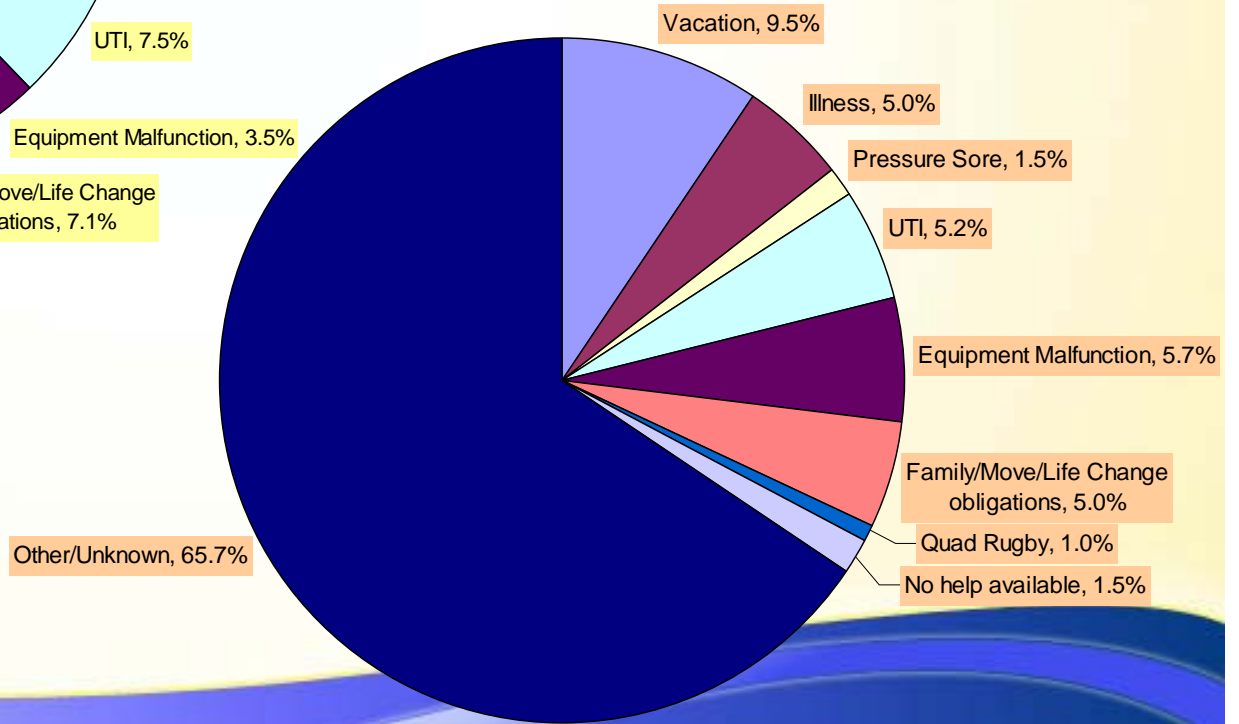
Barriers: Number of Missed Sessions



Barriers: Percent of Missed Sessions



FES Unit ↓



Psychosocial Factors

- Compared assessment scores for depression and self-efficacy to adherence rates
 - Kendall's tau non-parametric rank correlation
- Level of depression and self-efficacy remained constant throughout the year (Friedman ANOVA)
- No correlation between adherence and self-efficacy for either FES bike or unit
- FES unit showed significant negative correlation between adherence and depression ($p=0.009$) over the last 6 months
 - Depression level may influence motivation for FES unit
 - Did not see the same trend with the bike

Program Satisfaction – Quantitative Measures

Average scores on 5-point Likert scales

(1-Not at all; 2-A little bit; 3-So-so; 4-Very much; 5- Extremely)

	FES Bike		FES Unit	
	6 months	1 year	6 months	1 year
Easy to adjust to my needs	4.25	4.00	3.75	3.75
Simple to use	3.75	3.50	4.50	4.25
Safe to use	4.75	4.75	4.75	4.25
Difficult to operate	1.50	1.75	1.25	1.50
Comfortable to exercise with	4.50	4.50	4.25	4.75

(1-Strongly agree; 2-Agree; 3-Undecided; 4-Disagree; 5-Strongly disagree)

	6 months	1 year
Do you feel that the exercise program makes a difference in your daily routine?	2.00	2.25
Would you be willing to continue using the FES bike after the study is over?	2.25	2.50
Would you be willing to continue using the FES unit after the study is over?	3.75	2.75

Program Satisfaction – Qualitative Measures

	FES Bike		FES Unit	
	6 months	1 year	6 months	1 year
What do you think about your interactions with the device in general?	“I enjoyed it” (4)	“I enjoyed it” (2) “It was not bad” (1) “It was very helpful” (1)	“It was not bad” (2) “It was confusing” (1) “It was boring” (1)	“It was boring” (2) “It was not bad” (1) “I enjoyed it” (1)
What do you like about the device?	“Different type of exercise” “I feel more physically charged up” “Feedback and reports helped me to watch my progress over time”		“Easy to use” “My kids can help” “Small and less expensive – better value”	
What don't you like about the device?	“I can't put electrodes on myself” “Takes too long to set up” “The price – not covered by insurance” “Requires a lot of assistance” “Something simpler would be better”		“Time consuming” “No feedback – would be motivating to see more tangible progress” “You don't know when your muscle is tired” “It's a pain to move electrodes every 20 min”	

Program Satisfaction – Qualitative Measures

What has been the greatest challenge of the program?	<p>“Keeping with the schedule”</p> <p>“Having helpers”</p> <p>“The study protocol was not flexible”</p> <p>“Finding the time to do it”</p>
What has been the greatest benefit of the program?	<p>“Spasms – getting my muscles stronger”</p> <p>“Physical endurance”</p> <p>“Not sure. Monitoring my physical fitness after the study is over might change my decision on using the equipment again”</p> <p>“Controls skin breakdown. Usually I get pressure sores when seasons change but not with regular exercise”</p>
Other General Program Comments	<p>“Overall health and well-being improvement”</p> <p>“Don’t feel that all things are different”</p> <p>“Less general discomfort”</p> <p>“Gave me a physical drive that makes me proactive”</p> <p>“Would want more hands-on experience and guidance”</p>

Conclusions

- Adherence
 - Total Program: 54.35%
 - FES Bike: 64.13%
 - FES Unit: 44.85%
 - Significant decreases in portable FES unit use over the year, FES bike use showed a smaller decline
 - Adherence was highest in the first 3 months, parallels trends of general exercise programs
 - Barriers to exercise were different between FES bike and unit
 - Overwhelming barrier was motivational
 - From qualitative interview data and missed session data
- Success of program
 - Home-based ABR program is feasible in SCI
 - Successful compared to general exercise programs
 - No dropouts
 - Completed an average of 3.27 sessions per week

Conclusions

- Implications
 - Adherence varies depending on exercise mode
 - Consider potential personal barriers when prescribing exercise
 - Individualize programs
 - Tailor to patient goals and abilities
 - Integrate exercise into their lifestyle
 - Equipment Pros and Cons:

	FES Bike	FES Unit
PROS	Gives lots of feedback Creates visible movement	Ease of set-up and use Portable Affordable
CONS	Set-up requires assistance Pressure sores Expensive	Gives limited feedback

References

1. Centers for Disease Control. 2003b. Prevalence of physical activity, including lifestyle activities among adults – United States, 2000-2001. *Morbidity and Mortality Weekly* 52(32): 764-769.
2. United States Department of Health and Human Services. Physical activity and health: a report of the Surgeon General, 1996.
3. American College of Sports Medicine (ACSM). 2006. *ACSM's guidelines for exercise testing and prescription*, 7th ed. Philadelphia: Lippincott, Williams, & Wilkins.

Questions?



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