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# Improvement in Function for Community-Dwelling Individuals with Cognitive Impairments Greater than 1 year post injury: A Randomized Study of PEAT Compared to Standard Treatment --Manuscript Draft--

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# Improvement in Function for Community-Dwelling Individuals with Cognitive

# Impairments Greater than 1 year post injury: A Randomized Study of PEAT

# **Compared to Standard Treatment**

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# ABSTRACT

**Purpose:** To examine whether individuals with cognitive impairments who utilized an electronic aid known as the Planning and Execution Assistant and Trainer (PEAT) demonstrated better outcomes, 3 and 6 months after training to use PEAT, than individuals with equivalent amount of training, using "community standard" cognitive strategies.

**Methodology/Approach:** Randomized controlled clinical trial with follow-up at 3 and 6 months of 125 community-dwelling individuals with cognitive impairments. A number of measures were utilized to evaluate outcomes at 3 and 6 months post intervention.

**Findings:** Over time, all participants showed improvements, at 3 and 6 months, in depressive symptomatology, cognitive functioning and social integration, disability, basic living skills, and supervision needs. Additional improvements were noted with regard to life satisfaction between baseline and 6 months. For the PEAT group, participation as measured by the M2PI was better at 3 and 6 months compared to the control group.

**Originality/Value:** PEAT is a useful electronic tool, original in that it allows for flexible task scheduling; in particular, a global measure of participation showed enhanced effects of PEAT. The PEAT device should be added to the repertoire of rehabilitation therapists who help individuals with cognitive deficits manage their ADLs in the community and home environments.

**Practical Implications:** Identification of a valid and reliable technologically-based cognitive orthotic will allow individuals with cognitive disabilities more independence and clinicians an additional training tool for cognitive rehabilitation.

**Key words:** Memory Disorders, Brain Injuries, Multiple Sclerosis, Technology, Cognitive Orthotics, Memory Strategies.

# **INTRODUCTION**

Individuals with brain injury experience deficits across a number of functional domains – physical, emotional, behavioral, and cognitive. Cognitive deficits, memory dysfunction and the inability to plan and complete activities of daily living (ADL) can be some of the most disabling problems, and can prevent a person from resuming many pre-injury activities[1-3]. Rehabilitation professionals often encourage individuals with cognitive impairments to ameliorate such deficits with the use of compensatory strategies or devices.

Compensatory devices, also known as cognitive orthotics, have been developed and expanded due to technological advances to compensate for the previously mentioned disabling deficits, particularly in the arena of personal and hand-held computers. These devices can be categorized into three main areas as described by Lynch[4]: reminding systems; recording/storage systems; and scheduling/planning devices. Examples of reminding systems are event calendars, tone or voice alarms, timers, cell phones, and pagers. Often another person is instrumental in providing reminders. Recording/storage systems include watches with data storage capacity, answering machines, and dictation devices. Scheduling/planning systems include such paper-based methods as notebooks, diaries, and calendars, as well as the electronic alternatives of desktop computers and personal device assistants (PDAs). However, some devices may fall into more than one category; for example, a PDA may contain the algorithms for cueing when an activity should begin (reminding), as well as the steps that should take place to successfully accomplish the activity (scheduling/planning). Due to the advanced nature of these devices, individuals are able to customize their system to enable increased independence and feelings of control over ADL's. The increased independence is an enormous benefit to the individuals.

Commercially available PDAs have also been used to provide cognitive assistance to individuals with such deficits. Gentry et al[5] reported that 23 community-dwelling individuals, at least one year post severe traumatic brain injury, showed improvements in self-ratings of occupational performance and community participation after eight weeks using a PDA. Similarly, individuals with multiple sclerosis with cognitive impairment showed improvements in functional performance after eight weeks using a PDA[6].

Additional evidence shows that PDA's are of more value to individuals with cognitive impairment then the community standard of paper calendars and notebooks. Dowds et al[7] reported 36 individuals with traumatic brain injury utilizing a paper cueing system consistently completed tasks on time 26% of the time. When switched to receiving cues on a handheld PDA, they consistently completed tasks on time more often they had with their previous method. Specifically, 38% of individuals utilizing the Microsoft Operating System and 56% using the Palm Operating System completed task more efficiently. To further lend evidence to the usefulness of electronic devices, in a study by De Pompei et al[8] looking at the ability of school aged children with a brain injury or intellectual disability and their ability to complete a specific task on time, results show that a daily planner was the least effective method at a response rate of 42% and a Palm PDA was the most efficient at 77%.

While it is clear that the types of cognitive orthotics described above can provide some benefit to individuals with memory and functional deficits, the ability to provide support for higher level executive function, such as flexibility in task scheduling, is lacking. One commercially available device, the Planning and Execution Assistant and Trainer (PEAT), was developed to serve as an orthotic device to support adaptability and accommodation to changing situations. PEAT automatically generates schedules, detects and corrects schedule errors, cues

the user to start and stop tasks, monitors performance and adjusts to changes. As such, PEAT has great potential for improving outcomes across multiple functional domains for individuals with cognitive impairments.

Therefore, this randomized controlled clinical trial examined whether individuals with cognitive impairments who utilized PEAT demonstrated improvement at 3 and 6 months after initiation of use, and whether the intervention group showed better outcomes than comparable individuals using current "community standard" cognitive/memory strategies. The outcomes that were examined were functional abilities, subjective quality of life, and productive activity.

## **METHODS**

#### **Participants**

One hundred and twenty-five community-dwelling individuals with cognitive impairments were recruited prospectively from the community of individuals with brain injuries or multiple sclerosis. Those with brain injuries were at least one year post event. Participants were required to indicate their willingness to use the PEAT device, to be at least 15 years of age, and to sign informed consent and HIPAA certifications. Individuals were excluded if they were unable to physically operate the PEAT device, had no working knowledge of English, were involved in any cognitively based individual therapy, or had any physical or psychological condition that would interfere with the ability to follow the study protocol.

#### Procedure

This study was approved by the Institutional Review Board for the Protection of Human Research Subjects. Potential participants were screened by research personnel; if eligible, informed consent and HIPAA forms were presented, explained, and signed. The baseline assessment consisted of an intake form which included: age, gender,

marital status, place of residence, level of education, and occupational status at time of diagnosis. For those with TBI, etiology of injury and duration of post-traumatic amnesia was recorded. The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) was administered to the entire sample to document cognitive impairment. Individuals were randomly assigned to either the PEAT or control group.

All outcome assessments were conducted by a research assistant unaware of group assignment. The following measures were assessed serially at baseline, 3 and 6 months after study initiation: the Beck Depression Inventory II (BDI-II), the Craig Handicap Assessment Reporting Technique – Short Form (CHART-SF), the Disability Rating Scale (DRS), the Kohlman Evaluation of Living Skills (KELS), the Participation Index of the Mayo-Portland Adaptability Inventory – Version 4 (M2PI), the Diener Satisfaction with Life Scale (SWLS), and the Supervision Rating Scale (SRS). After completion of the baseline assessment, each participant was randomly assigned to either the PEAT (intervention) or community-standard (control) group.

<u>PEAT group</u>: All of the therapists involved in this research project received in-depth training on the assessment, set-up, training, and refining processes involved in using PEAT. Each participant with the help of their assigned rehabilitation therapist customized their device according to their own schedule and needs. If the individual had a caregiver, their input was also elicited to assist in establishing the system for the participant. The PEAT is an original cognitive orthotic in that it allows the therapist and patient individual flexibility of personalization. Individuals in the study utilized their device in a variety of ways including as a tool to stay on task for ADL's, medication management, appointment and daily schedule reminders, as well as an alarm clock. The PEAT also has the ability to create scripts for daily tasks, such as preparing the participant to leave the house. A phone book was also available with the capability to upload pictures which provided a visual reminder for the PEAT user for each of their contacts. Reminders could include all grooming tasks, getting dressed and taking all needed items with them out of the house as well as time limits on each task so subjects did not lose track of time, The PEAT intervention group received 11 hours of detailed instruction and training, from a rehabilitation therapist, on the use of PEAT. Two additional two-hour sessions were scheduled at month 2 and 4 for any adjustments or re-training required. These individuals were able to keep the PEAT device at the end of the study.

*Control group:* Individual members of the control group were given a customized program, also set-up by their rehabilitation therapist, to provide strategies to compensate for memory deficits and up to \$100 to purchase a custom device. The programs included memory cueing systems such as paper calendars and organizers, and electronic devices that were not the PEAT system. Based on feedback from the individual and caregivers, modifications were made throughout treatment to maximize use and effectiveness of the program. The control group received 11 hours of training during the first 3 months, equivalent to the number of hours received by PEAT users; they also were offered additional treatment time at 2 and 4 months post onset.

#### Assessment Measures

<u>Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)</u>: The RBANS is a brief neurocognitive screening tool which measures immediate and delayed memory, attention, language, and visuospatial skills[9]. There are 12 subtests that are combined and converted to yield five domain index scores. The five domain scores are summed and converted for a total score. Index scores have a mean of  $100 \pm 15$ , with score of 130 and above indicating Very

Superior performance; 120-129 Superior; 110-119 High Average; 90-109 Average; 80-89 Low Average; 70-79 Borderline; and 69 and below Extremely Low performance. It has been used as a neuropsychological screening measure in individuals with head injury and stroke and to track recovery during rehabilitation.

<u>Beck Depression Inventory – II (BDI-II)</u>: The BDI is a 21-item self-report instrument widely used to determine depressive symptomatology[10]. Each item is rated on a scale of "0 – no symptomatology" to "3 – excessive symptomatology". Item scores are totaled and levels of depression are assigned by the following rating system: scores of 5-9 are normal; scores of 10-18 indicate mild to moderate depression; scores of 19-29 signify moderate to severe depression; scores of 30-63 indicate severe depression.

<u>Craig Handicap Assessment and Reporting Technique – Short Form (CHART-SF)</u>: The CHART was designed to provide a simple, objective measure of the degree to which impairments and disabilities result in handicaps in the years after initial rehabilitation[11]. For this study, the CHART – Short Form (CHART-SF) was used which has 19 items that yield the same subscales as the original CHART.

<u>Disability Rating Scale (DRS)</u>: The DRS was developed for use primarily with persons with TBI[12]. It consists of 8-items that assess four categories: arousal and awareness; cognitive ability to handle self-care functions; dependence upon others for cognitive or physical needs/reasons; and psychosocial adaptability for work, housework, and school. The score can range from zero, denoting no disability, impairment, or handicap, to 29, denoting an extreme vegetative state.

Kohlman Evaluation of Living Skills (KELS): The KELS is designed to provide a quick and simple evaluation of an individual's ability to perform basic living skills[13]. The instrument

contains 17 items in five categories: self-care; safety and health; money management; transportation and telephone; and work and leisure. Each item is scored as independent (0) or needs assistance (1.5 or 1 point). It has been used in adolescent and adult populations with psychiatric disorders, mental retardation, brain injury, or cognitive impairment. <u>Participation Index of the Mayo-Portland Adaptability Inventory – Version 4 (M2PI)</u>: The M2PI is designed to rate initiation, social contact, leisure, self-care, residence, transportation, employment, and money management in individuals after brain injury[14, 15]. It is a short, 8item scale that shows good correlation with a composite measure based on the full Mayo-Portland Adaptability Inventory (Pearson r = 0.77).

<u>Satisfaction with Life Scale (SWLS)</u>: The SWLS is a global measure of life satisfaction[16]. The SWLS consists of 5-items that are completed by the individual whose life satisfaction is being measured.

<u>Supervision Rating Scale (SRS)</u>: The SRS is a 13-point ordinal scale that describes the level of supervision actually received by the individual with TBI[17]. The ratings can be collapsed into five categories: 1 or 2 (independent); 3 (overnight supervision); 4 to 7 (part-time supervision); 8 or 9 (full-time indirect supervision); and 10 to 13 (full-time direct supervision).

#### Statistical Analysis

Initial descriptive statistics were calculated for all variables using SPSS Version 18. Hypotheses were tested using repeated measures analysis of variance, examining changes over time. A mixed model was also used to compare group membership with PEAT vs. Control group as the independent variable.

#### RESULTS

Sample

Of the 125 participants, 57 were male (46%) and the average age was 46.8 (SD=12.1) years. At the time of the study, 119 (95%) individuals were living in private residences. Further demographics and injury characteristics are provided in Table 1. The majority of the individuals (N=114; 91%) had at least some college education, with 53 (42%) having achieved at least a bachelor's degree. Fifty-four (43%) of participants were unemployed due to their disability; 60 (48%) were engaged in part-time work, school, or volunteer activities; 11 (9%) were retired. Marital status was divided relatively equally among single (N=48; 38%), married or living with a significant other (N=43; 34%), and divorced, separated, or widowed (N=34; 27%).

The etiology and severity of injury is also shown in Table 1. A majority of the individuals (N=79; 63%) had experienced a TBI with the remainder acquiring their cognitive impairment through other means such as encephalitis, multiple sclerosis, stroke, aneurysm rupture, and anoxia secondary to a heart attack. Length of coma was self reported. Among those who had experienced an event that could induce a coma (N=92; 74%), 17 (18%) had experienced no post-event coma, 26 (28%) reported coma less than one day, and the remainder, 49 (53%), reported coma at least 1 day. The majority (N=89; 71%) of participants were able to give an estimate of the duration of post-traumatic amnesia (PTA), with 17 (19%) reporting no PTA, 10 (11%) reporting PTA less than 1 day, 8 (9%) reporting PTA from 1-14 days, 12 (13%) reporting PTA from 15-30 days, and 42 (47%) reporting PTA greater than 30 days. In this sample 101 (81%) had documented time of injury/impairment. This information was not available for the participants with MS and for some of the participants with nontraumatic brain injury. The average time post injury for the remaining participants was 9.6 years (SD=9.3), however the median time was six years post-injury. Please see Table 1 for a breakdown of time post injury.

With regard to cognitive impairment, RBANS data (see Table 2) for the whole group indicated that the greatest impairment was noted in delayed memory, (M = 78.53; SD=23.3). Visual memory showed the least impairment (M = 90.13; SD = 22.2) with the mean score falling just above the cutoff for the Average range. Three of the four average index scores fell within the Low Average range. However, overall, the mean total RBANS score was 78.26 (SD = 20.18) indicating borderline cognitive functioning for the sample.

Sixty individuals (48%) were enrolled in the control group and 65 (52%) were enrolled in the PEAT group. Cross-tabulations with chi squares were run to compare the PEAT group and control group at baseline. Where one group or the other had fewer than 5 cases in a cell, the distribution for the variable was compared across groups using a nonparametric Kruskal-Wallis rank test. At baseline, PEAT and control groups did not differ on demographics or cognitive impairment characteristics. Six-month drop-out rates were comparable for the control group (32%) and PEAT group (22%), with no measurable differences between those who completed or dropped out with regard to demographics, time since impairment, baseline assessments, or the dependent variables at baseline.

At baseline, participants had low mean scores on KELS, DRS total, DRS Level of Functioning, and SRS measures, indicating little impairment on basic ADLs and little need for supervision on average (Table 2). Participants also had relatively high CHART scores on independence at home and away from home, physical independence and mobility, indicating less handicap and higher social and community participation. Scores on cognitive independence were lower, and scores on social integration and occupation lowest. On average, participants spent about 5 days a week outside the home, and the most time per week in homemaking and self-care. SWLS scores were in the mid-range and BDI-II scores were in the moderate depression

category. There were no differences between the PEAT and control groups in these measurements.

#### **PEAT Intervention Group**

PEAT users made statistically significant improvements over time in several of the outcome measures (See Table 3). Repeated measures Analysis of Variance (ANOVA) showed improvements in BDI depression (p<.001), SRS supervision (p<.05), M2PI participation (p<.001), KELS basic living skills (p<.01), DRS disability (p<.001), CHART Cognitive Independence (p<.005), and CHART Social Independence (p<.005). There was a statistically significant improvement between baseline and 6 months for SWLS (p<.05), but not for the entire time series (improvement was not seen at 3 months).

Statistically significant improvements were not seen for CHART Physical Independence, CHART Mobility, and CHART Occupation.

Clinically, the PEAT group presented at baseline with a mean score representing mild to moderate depression. At six months, the mean BDI score was in the normal range. Mean SRS scores at both baseline and at six months reflected individuals that did not need supervision. The mean DRS scores showed improvement from baseline to six months, but still reflected partial disability. CHART results reflected ceiling effects for both Physical and Mobility subscales with participants starting the study with high scores. Improvements were noted for the CHART Cognitive and Social subscales, although scores were still below normal at 6 months. No improvement was seen for CHART Occupation, which was below normal at all time periods.

# **Disability & Handicap Between Groups**

The hypothesis that the PEAT group would demonstrate less handicap post-intervention than the control group was not supported. For example, improvements were noted in the CHART

Cognitive (mean difference between PEAT & Control = 5.30, SE=4.83) and CHART Social subscales for both groups (mean difference = .007, SE=5.06). Similarly, no significant change was noted across time for either group with regard to the CHART Physical (mean difference = .31, SE=1.38), Mobility (mean difference = 5.30, SE=2.87), or Occupation (mean difference = .57, SE=5.78) subscales. Further, DRS total scores decreased comparably as well, indicating improvement, with significant decreases being maintained at both 3- and 6-months (mean difference = -.24, SE=.30).

#### Subjective Quality of Life Between Groups

It was predicted that the PEAT group would show greater increases in life satisfaction and greater decreases in depression than the control group; this was not confirmed. While SWLS scores improved slightly for the PEAT group over time; scores did not improve consistently for the control group, and no significant difference was noted between the two groups over time (mean difference = 2.90, SE=1.50, p=.058). For the BDI, both the PEAT and Control groups reported decreased depressive symptoms at 3- and 6-month follow-up periods (mean difference = -.33, SE=1.83).

# Living Skills& Supervision Between Groups

The hypothesis that PEAT users would perform basic living skills at higher functional levels and have less supervision needs than non-PEAT users was not supported. For example, KELS Total scores decreased comparably for both groups between baseline, 3 and 6 months (mean difference = -.43, SE=.54). Additionally, SRS ratings decreased marginally for both the PEAT and Control group in the same manner across all time periods (mean difference = -.18, SE=.41).

#### **Productivity and Participation Between Groups**

The hypothesis that a higher percentage of PEAT users would return to productive activity than non-PEAT users was marginally supported. While no between group differences were noted on the CHART Social, Mobility, or Occupation subscales over time, a significant interaction was noted for M2PI scores (Figure 1). Particularly, the PEAT group showed greater improvements at the 3 and 6 month follow-up than the control group.

# DISCUSSION

Overall there was a benefit of cognitive intervention for both groups who participated in this study. Both groups improved with respect to depression, supervision needs, basic living skills, disability, and cognitive independence and social interactions. The PEAT users did demonstrate greater participation using the global measure, M2PI, at 3 and 6 months compared to the controls. Contrary to the study hypotheses, the PEAT users did not demonstrate less handicap or an increase in life satisfaction than the non-PEAT users. In addition, there was no statistical evidence to support higher functioning basic living skills requiring less supervision with PEAT users. A modest advantage was noted for return to productive activity with PEAT users versus non-PEAT users.

Most improvements came 3 months into the study, and all improvements were sustained with no more than 4 hours of treatment to reinforce the earlier intervention. These improvements are noteworthy for several reasons. First, the initial treatment time course was relatively brief at 11 hours over a 3 month period. Second, these results demonstrate that cognitive interventions from skilled therapists can be effective even many years post onset of neurologic events as all participants were at least 1 year post injury and the majority of participants were more than 2 years post-onset[1, 2, 18]. This large sample indicates that motivated individuals with cognitive impairment can continue to make sustainable improvements with cognitive interventions several

years after injury. It lends support to payment for these services by Medicare, Medicaid and other 3<sup>rd</sup> party insurers.

Minimal significant differences in ADLs, IADLs, supervision needs, caregiver burden, subjective quality of life, and productivity may be due to the relatively limited impairments noted at baseline. For example, at study entry participants exhibited minimal impairment on ADLS and little need for supervision on average. Life satisfaction was already in the mid-range, and minimal handicap and relatively high social community participation were noted.

As seen in previous research, various cognitive retraining strategies and external cognitive aids have proven useful in a variety of settings[5, 6, 19, 20]. Given that the control group in the present study received individualized, dynamic cognitive strategy training, the lack of between group differences may simply be due to the quality of training provided to both the control and PEAT intervention groups. Such results advocate for individualized, dynamic, cognitive retraining after brain injury and MS regardless of intervention strategy.

#### Limitations

A few limitations of this study should be noted. The sensitivity and specificity of outcomes measurements may not have been adequate to distinguish between cognitive rehabilitation modalities; however, the selected measures are commonly used as outcomes in in studies of individuals with cognitive impairment. Future studies may include more modality specific functional outcome measures. Data were collected prospectively from a local community-based sample of individuals eager to participate in a study, limiting the generalizability of findings to all individuals with sufficient motivation to participate. In addition, these individuals were relatively highly educated and motivated to use a computerized assistive technology device. Analyses also did not account for differences related to ethnicity or

culture. As the medical center is situated in an ethnically diverse urban area, this may have had an impact on outcomes. Future studies should include a wider catchment area, possibly multicenter in nature, accounting for varied cultural and ethnic backgrounds.

# Conclusion

Therapeutic cognitive intervention, whether traditional or using a PEAT device appears to assist individuals many years post injury to manage their basic living skills in the community and home environments; the intervention also improves mood and community participation. The intensity of intervention was relatively low. It is possible that the differences noted in outcomes over time could have been augmented with more intensive treatment / tune-ups at follow-up intervals, technical support for PEAT and other electronic device users, who could have broadened the applications applied as they become more adept at operating their devices and accessing programs. Future studies should consider lengthening the time of the study to include more extensive periodic "tune-ups" over 6-12 months and longer-term outcomes, e.g. 1-2 year follow-up. It would also be worthwhile to examine whether skilled individual therapy intervention was key in helping these individuals improve as much as 9 years post injury, or if these same outcomes can be obtained with group treatment or peer support.

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	Ν	%
Education		
High school degree or less	11	9%
Some college	61	49%
B.A.	29	23%
M.A. or Ph.D.	24	19%
Productivity		
Unemployed due to disability	54	43%
Part-time work	29	23%
Volunteer	14	11%
Part-time student	14	11%
Homemaker	3	2%
Retired	11	9%
Marital status		
Single	48	38%
Divorced/separated/widowed	34	27%
Married/partnered	43	34%

 Table 1: Demographic and brain injury characteristics

	Ν	%
Time since injury (N=10	1)	
One year	14	14%
Two-five years	36	36%
6-10 years	17	17%
>10 years	34	34%
Etiology of Cognitive Ir	npairı	ment
TBI		
Vehicle accident	45	36%
Fall	17	14%
Pedestrian/Other TBI	17	14%
Other conditions		
Multiple sclerosis	17	14%
Stroke	10	8%
Aneurysm	7	6%
Other Nontraumatic	12	10%

			Ν	%
Duration of coma (n	n = 92)			
None	17	18%		
Less than 1 day	26	28%		
1 to 7 days	10	11%		
8 to 14 days	9	10%		
15 to 30 days	14	15%		
30+ days	16	17%		
Duration of PTA (n = 89)				
None			17	19%
Less than 1 day			10	11%
1 to 7 days			4	5%
8 to 14 days			4	5%
15 to 30 days			12	13%
30+ days			42	47%

Assessments	Ν	M (SD)
RBANS		
Visuospatial/Construction	125	90.13 (22.22)
Language	125	83.86 (17.90)
Attention	125	83.02 (20.69)
Immediate Memory	125	80.89 (21.26)
Delayed memory	125	78.53 (23.34)
Total	125	78.26 (20.18)
ADLs and need for supervision		
KELS ADL Total	125	3.58 (2.52)
Mayo-Portland Adaptability Inventory Total t-score	125	40.18 (8.20)
Disability Rating Scale (DRS) Total	125	3.32 (1.46)
DRS Employability	125	1.56 (.65)
DRS Level of Functioning	125	1.44 (.80)
Supervision Rating Scale (SRS)	125	2.10 (2.00)
CHART Independence at Home	125	5.10 (1.36)
CHART Independence away from Home	125	3.38 (.73)

# **Table 2:** Baseline neuropsychological, functional, and subjective quality of life assessments

# Table 2 (continued)

Assessments	Ν	M (SD)
Handicap		
CHART Physical Independence	124	98.47 (6.64)
CHART Mobility	124	88.45 (15.83)
CHART Cognitive Independence	125	80.82 (23.87)
CHART Social Integration	124	72.10 (31.40)
CHART Occupational	124	70.35 (29.78)
CHART productivity measures		
Days spent outside the home/week	124	5.31 (1.96)
Hours up (daily)	125	14.32 (3.44)
Hours homemaking/week	125	16.30 (17.51)
Hours on the job/week	125	5.32 (12.51)
Hours home repair/week	125	4.56 (8.00)
Hours school/week	125	2.28 (5.96)
Quality of life		
Life satisfaction (SLWS)	124	16.44 (7.69)
Beck Depression Inventory II	123	16.50 (10.45)

Measure	Baseline	3 Months	6 Months
	Mean (SD)	Mean (SD)	Mean (SD)
BDI (N=45) <sup>d</sup>	16.27 (11.05)	10.67 (10.22)	7.24 (9.55)
SRS (N=47) <sup>a</sup>	2.06 (2.06)	1.94 (1.88)	1.66 (1.54)
$M2PI(N=46)^{d}$	40.63 (8.76)	35.48 (10.67)	34.78 (11.65)
KELS (N=42) <sup>b</sup>	3.23 (2.65)	2.67 (2.58)	2.41 (2.13)
DRS (N=47) <sup>d</sup>	3.34 (1.48)	2.53 (1.30)	2.21 (1.35)
CHART Physical (N=46)	97.83 (7.90)	98.61 (7.18)	98.61 (7.27)
CHART Mobility (N=46)	91.26 (13.36)	91.54 (13.5)	92.22 (14.23)
CHART Cognitive (N=46) <sup>c</sup>	83.33 (24.22)	85.65 (23.19)	88.22 (20.51)
CHART Social (N=46) <sup>c</sup>	73.33 (28.57)	84.78 (24.57)	86.91 (22.31)
CHART Occupation	73.04 (29.9)	68.46 (29.16)	69.85 (31.99)
(N=46)			
SWLS (N=44) <sup>e</sup>	17.98 (7.42)	18.86 (7.73)	20.02 (8.07)

**Table 3:** PEAT Group Changes Over Time

a – repeated measures ANOVA p<.05 b – repeated measures ANOVA p<.01 c – repeated measures ANOVA p<.005 d – repeated measures ANOVA p<.001 e – Baseline versus 6 month significant difference p<.05

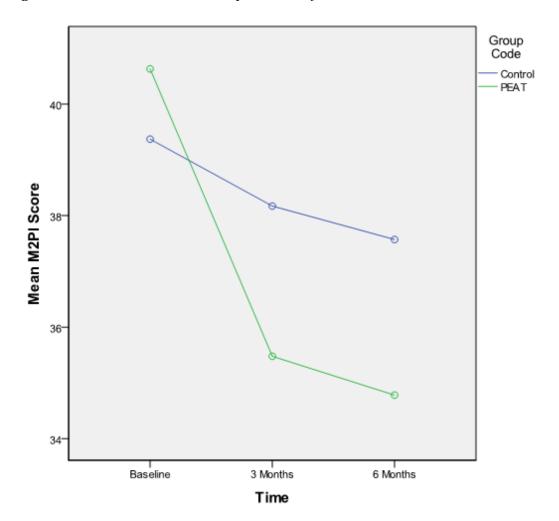


Figure 1. Interaction between Group and Time for M2PI scores

1	ABSTRACT
2	Purpose: To examine whether individuals with cognitive impairments who utilized an
3	electronic aid known as the Planning and Execution Assistant and Trainer (PEAT) demonstrated
4	better outcomes, 3 and 6 months after training to use PEAT, than individuals with equivalent
5	amount of training, using "community standard" cognitive strategies.
6	Methodology/Approach: Randomized controlled clinical trial with follow-up at 3 and 6 months
7	of 125 community-dwelling individuals with cognitive impairments. A number of measures were
8	utilized to evaluate outcomes at 3 and 6 months post intervention.
9	Findings: Over time, all participants showed improvements, at 3 and 6 months, in depressive
10	symptomatology, cognitive functioning and social integration, disability, basic living skills, and
11	supervision needs. Additional improvements were noted with regard to life satisfaction between
12	baseline and 6 months. For the PEAT group, participation as measured by the M2PI was better at
13	3 and 6 months compared to the control group.
14	Originality/Value: PEAT is a useful electronic tool, original in that it allows for flexible task
15	scheduling; in particular, a global measure of participation showed enhanced effects of PEAT.
16	The PEAT device should be added to the repertoire of rehabilitation therapists who help
17	individuals with cognitive deficits manage their ADLs in the community and home
18	environments.
19	Practical Implications: Identification of a valid and reliable technologically-based cognitive
20	orthotic will allow individuals with cognitive disabilities more independence and clinicians an
21	additional training tool for cognitive rehabilitation.
22	Key words: Memory Disorders, Brain Injuries, Multiple Sclerosis, Technology, Cognitive
23	Orthotics, Memory Strategies.

# 24 INTRODUCTION

25 Individuals with brain injury experience deficits across a number of functional domains -26 physical, emotional, behavioral, and cognitive. Cognitive deficits, memory dysfunction and the 27 inability to plan and complete activities of daily living (ADL) can be some of the most disabling 28 problems, and can prevent a person from resuming many pre-injury activities [1-3]. 29 Rehabilitation professionals often encourage individuals with cognitive impairments to 30 ameliorate such deficits with the use of compensatory strategies or devices. 31 Compensatory devices, also known as cognitive orthotics, have been developed and 32 expanded due to technological advances to compensate for the previously mentioned disabling 33 deficits, particularly in the arena of personal and hand-held computers. These devices can be 34 categorized into three main areas as described by Lynch[4]: reminding systems; 35 recording/storage systems; and scheduling/planning devices. Examples of reminding systems are 36 event calendars, tone or voice alarms, timers, cell phones, and pagers. Often another person is 37 instrumental in providing reminders. Recording/storage systems include watches with data 38 storage capacity, answering machines, and dictation devices. Scheduling/planning systems 39 include such paper-based methods as notebooks, diaries, and calendars, as well as the electronic 40 alternatives of desktop computers and personal device assistants (PDAs). However, some 41 devices may fall into more than one category; for example, a PDA may contain the algorithms 42 for cueing when an activity should begin (reminding), as well as the steps that should take place 43 to successfully accomplish the activity (scheduling/planning). Due to the advanced nature of 44 these devices, individuals are able to customize their system to enable increased independence 45 and feelings of control over ADL's. The increased independence is an enormous benefit to the 46 individuals.

Commercially available PDAs have also been used to provide cognitive assistance to
individuals with such deficits. Gentry et al[5] reported that 23 community-dwelling individuals,
at least one year post severe traumatic brain injury, showed improvements in self-ratings of
occupational performance and community participation after eight weeks using a PDA.
Similarly, individuals with multiple sclerosis with cognitive impairment showed improvements
in functional performance after eight weeks using a PDA[6].

53 Additional evidence shows that PDA's are of more value to individuals with cognitive 54 impairment then the community standard of paper calendars and notebooks. Dowds et al[7] 55 reported 36 individuals with traumatic brain injury utilizing a paper cueing system consistently 56 completed tasks on time 26% of the time. When switched to receiving cues on a handheld PDA, 57 they consistently completed tasks on time more often they had with their previous method. 58 Specifically, 38% of individuals utilizing the Microsoft Operating System and 56% using the 59 Palm Operating System completed task more efficiently. To further lend evidence to the 60 usefulness of electronic devices, in a study by De Pompei et al[8] looking at the ability of school 61 aged children with a brain injury or intellectual disability and their ability to complete a specific 62 task on time, results show that a daily planner was the least effective method at a response rate of 63 42% and a Palm PDA was the most efficient at 77%.

While it is clear that the types of cognitive orthotics described above can provide some benefit to individuals with memory and functional deficits, the ability to provide support for higher level executive function, such as flexibility in task scheduling, is lacking. One commercially available device, the Planning and Execution Assistant and Trainer (PEAT), was developed to serve as an orthotic device to support adaptability and accommodation to changing situations. PEAT automatically generates schedules, detects and corrects schedule errors, cues

the user to start and stop tasks, monitors performance and adjusts to changes. As such, PEAT has
 great potential for improving outcomes across multiple functional domains for individuals with
 cognitive impairments.

Therefore, this randomized controlled clinical trial examined whether individuals with cognitive impairments who utilized PEAT demonstrated improvement at 3 and 6 months after initiation of use, and whether the intervention group showed better outcomes than comparable individuals using current "community standard" cognitive/memory strategies. The outcomes that were examined were functional abilities, subjective quality of life, and productive activity.

78 METHODS

# 79 Participants

80 One hundred and twenty-five community-dwelling individuals with cognitive 81 impairments were recruited prospectively from the community of individuals with brain injuries 82 or multiple sclerosis. Those with brain injuries were at least one year post event. Participants 83 were required to indicate their willingness to use the PEAT device, to be at least 15 years of age, 84 and to sign informed consent and HIPAA certifications. Individuals were excluded if they were 85 unable to physically operate the PEAT device, had no working knowledge of English, were 86 involved in any cognitively based individual therapy, or had any physical or psychological 87 condition that would interfere with the ability to follow the study protocol.

## 88 **Procedure**

This study was approved by the Santa Clara Valley Medical Center Institutional Review Board for the Protection of Human Research Subjects. Potential participants were screened by research personnel; if eligible, informed consent and HIPAA forms were presented, explained, and signed. The baseline assessment consisted of an intake form which included: age, gender, marital status, place of residence, level of education, and occupational status at time of diagnosis.
For those with TBI, etiology of injury and duration of post-traumatic amnesia was recorded. The
Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) was
administered to the entire sample to document cognitive impairment. Individuals were randomly
assigned to either the PEAT or control group.

98 All outcome assessments were conducted by a research assistant unaware of group 99 assignment. The following measures were assessed serially at baseline, 3 and 6 months after 100 study initiation: the Beck Depression Inventory II (BDI-II), the Craig Handicap Assessment 101 Reporting Technique – Short Form (CHART-SF), the Disability Rating Scale (DRS), the 102 Kohlman Evaluation of Living Skills (KELS), the Participation Index of the Mayo-Portland 103 Adaptability Inventory – Version 4 (M2PI), the Diener Satisfaction with Life Scale (SWLS), and 104 the Supervision Rating Scale (SRS). After completion of the baseline assessment, each 105 participant was randomly assigned to either the PEAT (intervention) or community-standard 106 (control) group.

107 *PEAT group:* All of the therapists involved in this research project received in-depth 108 training on the assessment, set-up, training, and refining processes involved in using PEAT. 109 Each participant with the help of their assigned rehabilitation therapist customized their device 110 according to their own schedule and needs. If the individual had a caregiver, their input was also 111 elicited to assist in establishing the system for the participant. The PEAT is an original cognitive 112 orthotic in that it allows the therapist and patient individual flexibility of personalization. 113 Individuals in the study utilized their device in a variety of ways including as a tool to stay on 114 task for ADL's, medication management, appointment and daily schedule reminders, as well as 115 an alarm clock. The PEAT also has the ability to create scripts for daily tasks, such as preparing

116 the participant to leave the house. A phone book was also available with the capability to upload 117 pictures which provided a visual reminder for the PEAT user for each of their contacts. 118 Reminders could include all grooming tasks, getting dressed and taking all needed items with 119 them out of the house as well as time limits on each task so subjects did not lose track of time, 120 The PEAT intervention group received 11 hours of detailed instruction and training, from a 121 rehabilitation therapist, on the use of PEAT. Two additional two-hour sessions were scheduled 122 at month 2 and 4 for any adjustments or re-training required. These individuals were able to 123 keep the PEAT device at the end of the study.

124 *Control group*: Individual members of the control group were given a customized 125 program, also set-up by their rehabilitation therapist, to provide strategies to compensate for 126 memory deficits and up to \$100 to purchase a custom device. The programs included memory 127 cueing systems such as paper calendars and organizers, and electronic devices that were not the 128 PEAT system. Based on feedback from the individual and caregivers, modifications were made 129 throughout treatment to maximize use and effectiveness of the program. The control group 130 received 11 hours of training during the first 3 months, equivalent to the number of hours 131 received by PEAT users; they also were offered additional treatment time at 2 and 4 months post 132 onset.

# 133 Assessment Measures

# 134 <u>Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)</u>: The RBANS is

a brief neurocognitive screening tool which measures immediate and delayed memory, attention, language, and visuospatial skills[9]. There are 12 subtests that are combined and converted to yield five domain index scores. The five domain scores are summed and converted for a total score. Index scores have a mean of  $100 \pm 15$ , with score of 130 and above indicating Very

139	Superior performance; 120-129 Superior; 110-119 High Average; 90-109 Average; 80-89 Low
140	Average; 70-79 Borderline; and 69 and below Extremely Low performance. It has been used as
141	a neuropsychological screening measure in individuals with head injury and stroke and to track
142	recovery during rehabilitation.
143	Beck Depression Inventory – II (BDI-II): The BDI is a 21-item self-report instrument widely
144	used to determine depressive symptomatology[10]. Each item is rated on a scale of " $0 - no$
145	symptomatology" to "3 – excessive symptomatology". Item scores are totaled and levels of
146	depression are assigned by the following rating system: scores of 5-9 are normal; scores of 10-18
147	indicate mild to moderate depression; scores of 19-29 signify moderate to severe depression;
148	scores of 30-63 indicate severe depression.
149	Craig Handicap Assessment and Reporting Technique - Short Form (CHART-SF): The CHART
150	was designed to provide a simple, objective measure of the degree to which impairments and
151	disabilities result in handicaps in the years after initial rehabilitation[11]. For this study, the
152	CHART – Short Form (CHART-SF) was used which has 19 items that yield the same subscales
153	as the original CHART.
154	Disability Rating Scale (DRS): The DRS was developed for use primarily with persons with
155	TBI[12]. It consists of 8-items that assess four categories: arousal and awareness; cognitive
156	ability to handle self-care functions; dependence upon others for cognitive or physical
157	needs/reasons; and psychosocial adaptability for work, housework, and school. The score can
158	range from zero, denoting no disability, impairment, or handicap, to 29, denoting an extreme
159	vegetative state.
160	Kohlman Evaluation of Living Skills (KELS): The KELS is designed to provide a quick and

simple evaluation of an individual's ability to perform basic living skills[13]. The instrument

- 162 contains 17 items in five categories: self-care; safety and health; money management;
- 163 transportation and telephone; and work and leisure. Each item is scored as independent (0) or

164 needs assistance (1.5 or 1 point). It has been used in adolescent and adult populations with

- 165 psychiatric disorders, mental retardation, brain injury, or cognitive impairment.
- 166 Participation Index of the Mayo-Portland Adaptability Inventory Version 4 (M2PI): The M2PI
- 167 is designed to rate initiation, social contact, leisure, self-care, residence, transportation,
- 168 employment, and money management in individuals after brain injury[14, 15]. It is a short, 8-
- 169 item scale that shows good correlation with a composite measure based on the full Mayo-
- 170 Portland Adaptability Inventory (Pearson r = 0.77).
- 171 <u>Satisfaction with Life Scale (SWLS)</u>: The SWLS is a global measure of life satisfaction[16]. The
- 172 SWLS consists of 5-items that are completed by the individual whose life satisfaction is being173 measured.
- 174 <u>Supervision Rating Scale (SRS)</u>: The SRS is a 13-point ordinal scale that describes the level of
- supervision actually received by the individual with TBI[17]. The ratings can be collapsed into
- 176 five categories: 1 or 2 (independent); 3 (overnight supervision); 4 to 7 (part-time supervision); 8
- 177 or 9 (full-time indirect supervision); and 10 to 13 (full-time direct supervision).
- 178 Statistical Analysis

Initial descriptive statistics were calculated for all variables using SPSS Version 18.
Hypotheses were tested using repeated measures analysis of variance, examining changes over
time. A mixed model was also used to compare group membership with PEAT vs. Control group
as the independent variable.

- 183 **RESULTS**
- 184 Sample

185	Of the 125 participants, 57 were male (46%) and the average age was 46.8 (SD=12.1)
186	years. At the time of the study, 119 (95%) individuals were living in private residences. Further
187	demographics and injury characteristics are provided in Table 1. The majority of the individuals
188	(N=114; 91%) had at least some college education, with 53 (42%) having achieved at least a
189	bachelor's degree. Fifty-four (43%) of participants were unemployed due to their disability; 60
190	(48%) were engaged in part-time work, school, or volunteer activities; 11 (9%) were retired.
191	Marital status was divided relatively equally among single (N=48; 38%), married or living with a
192	significant other (N=43; 34%), and divorced, separated, or widowed (N=34; 27%).
193	The etiology and severity of injury is also shown in Table 1. A majority of the individuals
194	(N=79; 63%) had experienced a TBI with the remainder acquiring their cognitive impairment
195	through other means such as encephalitis, multiple sclerosis, stroke, aneurysm rupture, and
196	anoxia secondary to a heart attack. Length of coma was self reported. Among those who had
197	experienced an event that could induce a coma (N=92; 74%), 17 (18%) had experienced no post-
198	event coma, 26 (28%) reported coma less than one day, and the remainder, 49 (53%), reported
199	coma at least 1 day. The majority (N=89; 71%) of participants were able to give an estimate of
200	the duration of post-traumatic amnesia (PTA), with 17 (19%) reporting no PTA, 10 (11%)
201	reporting PTA less than 1 day, 8 (9%) reporting PTA from 1-14 days, 12 (13%) reporting PTA
202	from 15-30 days, and 42 (47%) reporting PTA greater than 30 days. In this sample 101 (81%)
203	had documented time of injury/impairment. This information was not available for the
204	participants with MS and for some of the participants with nontraumatic brain injury. The
205	average time post injury for the remaining participants was 9.6 years (SD=9.3), however the
206	median time was six years post-injury. Please see Table 1 for a breakdown of time post injury.

With regard to cognitive impairment, RBANS data (see Table 2) for the whole group indicated that the greatest impairment was noted in delayed memory, (M = 78.53; SD=23.3). Visual memory showed the least impairment (M = 90.13; SD = 22.2) with the mean score falling just above the cutoff for the Average range. Three of the four average index scores fell within the Low Average range. However, overall, the mean total RBANS score was 78.26 (SD = 20.18) indicating borderline cognitive functioning for the sample.

213 Sixty individuals (48%) were enrolled in the control group and 65 (52%) were enrolled in 214 the PEAT group. Cross-tabulations with chi squares were run to compare the PEAT group and 215 control group at baseline. Where one group or the other had fewer than 5 cases in a cell, the 216 distribution for the variable was compared across groups using a nonparametric Kruskal-Wallis 217 rank test. At baseline, PEAT and control groups did not differ on demographics or cognitive 218 impairment characteristics. Six-month drop-out rates were comparable for the control group 219 (32%) and PEAT group (22%), with no measurable differences between those who completed or 220 dropped out with regard to demographics, time since impairment, baseline assessments, or the 221 dependent variables at baseline.

222 At baseline, participants had low mean scores on KELS, DRS total, DRS Level of 223 Functioning, and SRS measures, indicating little impairment on basic ADLs and little need for 224 supervision on average (Table 2). Participants also had relatively high CHART scores on 225 independence at home and away from home, physical independence and mobility, indicating less 226 handicap and higher social and community participation. Scores on cognitive independence were 227 lower, and scores on social integration and occupation lowest. On average, participants spent 228 about 5 days a week outside the home, and the most time per week in homemaking and self-care. 229 SWLS scores were in the mid-range and BDI-II scores were in the moderate depression

category. There were no differences between the PEAT and control groups in thesemeasurements.

## 232 **PEAT Intervention Group**

233 PEAT users made statistically significant improvements over time in several of the 234 outcome measures (See Table 3). Repeated measures Analysis of Variance (ANOVA) showed 235 improvements in BDI depression (p<.001), SRS supervision (p<.05), M2PI participation 236 (p<.001), KELS basic living skills (p<.01), DRS disability (p<.001), CHART Cognitive 237 Independence (p<.005), and CHART Social Independence (p<.005). There was a statistically 238 significant improvement between baseline and 6 months for SWLS (p<.05), but not for the entire 239 time series (improvement was not seen at 3 months). 240 Statistically significant improvements were not seen for CHART Physical Independence, 241 CHART Mobility, and CHART Occupation. 242 Clinically, the PEAT group presented at baseline with a mean score representing mild to 243 moderate depression. At six months, the mean BDI score was in the normal range. Mean SRS 244 scores at both baseline and at six months reflected individuals that did not need supervision. The 245 mean DRS scores showed improvement from baseline to six months, but still reflected partial 246 disability. CHART results reflected ceiling effects for both Physical and Mobility subscales with 247 participants starting the study with high scores. Improvements were noted for the CHART

248 Cognitive and Social subscales, although scores were still below normal at 6 months. No

249 improvement was seen for CHART Occupation, which was below normal at all time periods.

250 Disability & Handicap Between Groups

The hypothesis that the PEAT group would demonstrate less handicap post-interventionthan the control group was not supported. For example, improvements were noted in the CHART

Cognitive (mean difference between PEAT & Control = 5.30, SE=4.83) and CHART Social subscales for both groups (mean difference = .007, SE=5.06). Similarly, no significant change was noted across time for either group with regard to the CHART Physical (mean difference = .31, SE=1.38), Mobility (mean difference = 5.30, SE=2.87), or Occupation (mean difference = .57, SE=5.78) subscales. Further, DRS total scores decreased comparably as well, indicating improvement, with significant decreases being maintained at both 3- and 6-months (mean difference = -.24, SE=.30).

## 260 Subjective Quality of Life Between Groups

It was predicted that the PEAT group would show greater increases in life satisfaction and greater decreases in depression than the control group; this was not confirmed. While SWLS scores improved slightly for the PEAT group over time; scores did not improve consistently for the control group, and no significant difference was noted between the two groups over time (mean difference = 2.90, SE=1.50, p=.058). For the BDI, both the PEAT and Control groups reported decreased depressive symptoms at 3- and 6-month follow-up periods (mean difference = -.33, SE=1.83).

#### 268 Living Skills& Supervision Between Groups

The hypothesis that PEAT users would perform basic living skills at higher functional levels and have less supervision needs than non-PEAT users was not supported. For example, KELS Total scores decreased comparably for both groups between baseline, 3 and 6 months (mean difference = -.43, SE=.54). Additionally, SRS ratings decreased marginally for both the PEAT and Control group in the same manner across all time periods (mean difference = -.18, SE=.41).

# 275 Productivity and Participation Between Groups

The hypothesis that a higher percentage of PEAT users would return to productive activity than non-PEAT users was marginally supported. While no between group differences were noted on the CHART Social, Mobility, or Occupation subscales over time, a significant interaction was noted for M2PI scores (Figure 1). Particularly, the PEAT group showed greater improvements at the 3 and 6 month follow-up than the control group.

#### 281 **DISCUSSION**

282 Overall there was a benefit of cognitive intervention for both groups who participated in 283 this study. Both groups improved with respect to depression, supervision needs, basic living 284 skills, disability, and cognitive independence and social interactions. The PEAT users did 285 demonstrate greater participation using the global measure, M2PI, at 3 and 6 months compared 286 to the controls. Contrary to the study hypotheses, the PEAT users did not demonstrate less 287 handicap or an increase in life satisfaction than the non-PEAT users. In addition, there was no 288 statistical evidence to support higher functioning basic living skills requiring less supervision 289 with PEAT users. A modest advantage was noted for return to productive activity with PEAT 290 users versus non-PEAT users.

291 Most improvements came 3 months into the study, and all improvements were sustained 292 with no more than 4 hours of treatment to reinforce the earlier intervention. These improvements 293 are noteworthy for several reasons. First, the initial treatment time course was relatively brief at 294 11 hours over a 3 month period. Second, these results demonstrate that cognitive interventions 295 from skilled therapists can be effective even many years post onset of neurologic events as all 296 participants were at least 1 year post injury and the majority of participants were more than 2 297 years post-onset[1, 2, 18]. This large sample indicates that motivated individuals with cognitive 298 impairment can continue to make sustainable improvements with cognitive interventions several

years after injury. It lends support to payment for these services by Medicare, Medicaid and
 other 3<sup>rd</sup> party insurers.

Minimal significant differences in ADLs, IADLs, supervision needs, caregiver burden, subjective quality of life, and productivity may be due to the relatively limited impairments noted at baseline. For example, at study entry participants exhibited minimal impairment on ADLS and little need for supervision on average. Life satisfaction was already in the mid-range, and minimal handicap and relatively high social community participation were noted.

As seen in previous research, various cognitive retraining strategies and external cognitive aids have proven useful in a variety of settings[5, 6, 19, 20]. Given that the control group in the present study received individualized, dynamic cognitive strategy training, the lack of between group differences may simply be due to the quality of training provided to both the control and PEAT intervention groups. Such results advocate for individualized, dynamic, cognitive retraining after brain injury and MS regardless of intervention strategy.

312 Limitations

313 A few limitations of this study should be noted. The sensitivity and specificity of 314 outcomes measurements may not have been adequate to distinguish between cognitive 315 rehabilitation modalities; however, the selected measures are commonly used as outcomes in in 316 studies of individuals with cognitive impairment. Future studies may include more modality 317 specific functional outcome measures. Data were collected prospectively from a local 318 community-based sample of individuals eager to participate in a study, limiting the 319 generalizability of findings to all individuals with sufficient motivation to participate. In 320 addition, these individuals were relatively highly educated and motivated to use a computerized 321 assistive technology device. Analyses also did not account for differences related to ethnicity or

culture. As the medical center is situated in an ethnically diverse urban area, this may have had
 an impact on outcomes. Future studies should include a wider catchment area, possibly multi center in nature, accounting for varied cultural and ethnic backgrounds.

325 Conclusion

326 Therapeutic cognitive intervention, whether traditional or using a PEAT device appears 327 to assist individuals many years post injury to manage their basic living skills in the community 328 and home environments; the intervention also improves mood and community participation. The 329 intensity of intervention was relatively low. It is possible that the differences noted in outcomes 330 over time could have been augmented with more intensive treatment / tune-ups at follow-up 331 intervals, technical support for PEAT and other electronic device users, who could have 332 broadened the applications applied as they become more adept at operating their devices and 333 accessing programs. Future studies should consider lengthening the time of the study to include 334 more extensive periodic "tune-ups" over 6-12 months and longer-term outcomes, e.g. 1-2 year 335 follow-up. It would also be worthwhile to examine whether skilled individual therapy 336 intervention was key in helping these individuals improve as much as 9 years post injury, or if 337 these same outcomes can be obtained with group treatment or peer support.

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