

HANDHELD COMPUTERS AS
ASSISTIVE TECHNOLOGY FOR
INDIVIDUALS WITH COGNITIVE IMPAIRMENT
RELATED TO MULTIPLE SCLEROSIS

A Doctoral Dissertation

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By

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ABSTRACT

The purpose of this study was to determine whether people who have cognitive impairment related to multiple sclerosis can learn to operate handheld computers in managing memory and organization tasks, whether they can retain this learning over time, and whether they can utilize these devices to significantly improve functional performance in everyday activities. Twenty individuals with M.S.-related cognitive impairment were enrolled in the study, which was designed to provide an eight-week non-treatment period, followed by a four-session training period and an eight-week post-training period. All participants were provided with a Palm Zire 31 PDA on which they were trained. Assessments of functional performance, satisfaction with functional performance and level of handicap were conducted prior to the non-treatment period, just prior to training, at the conclusion of training and eight weeks after training. A survey and questionnaire were also conducted on final assessment, and measures were taken of actual PDA use during the post-training period, and of participants' ability to demonstrate operation of basic PDA functions.

Data analysis showed that individuals with cognitive impairment related to M.S. can learn to operate basic PDA functions and retain this skill for at least eight weeks. Using a PDA significantly improves functional performance and satisfaction with functional performance of everyday tasks. Using a PDA also significantly reduces level of handicap. These gains are maintained eight weeks after the training period. Additionally, participants reported that they found the


devices useful and incorporated them into their daily routines, citing improved organization and self-efficacy that positively impacted their daily lives.

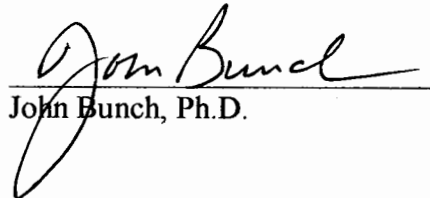
These findings show that a brief, multi-modal training intervention using consumer PDAs can be an effective cognitive rehabilitation therapy. This is the first assistive technology for cognition study to show functional performance gains over time in the community and the first to use unmodified Palm PDAs operated by individuals with cognitive impairment as a rehabilitation tool. It is also the first study of any kind to demonstrate an effective rehabilitation intervention for cognitive disability related to multiple sclerosis. As such the study opens doorways to new clinical practice and research avenues that may improve functional independence for individuals with cognitive disability in their work, home and community settings.

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APPROVAL OF THE DISSERTATION

This dissertation, "Handheld Computers as Assistive Technology for Individuals with Cognitive Impairment Related to Multiple Sclerosis", has been approved by the Graduate Faculty of the Curry School of Education in partial fulfillment of the requirements for the degree of Doctor of Philosophy.


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MARCH 2, 2006 Date

DEDICATION

to Christine,
for your steadfast love, support and inspiration

to Nicholas and Stephen,
for your patience, and for your joy when it's time to play
Grabber Man

to my parents,
For teaching me the meaning of wonder and of caring

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TABLE OF CONTENTS

| | Page |
|--|------|
| DEDICATION..... | vi |
| ACKNOWLEDGEMENTS..... | vii |
| LIST OF TABLES..... | xv |
| LIST OF FIGURES..... | xvii |
| CHAPTER | |
| I. INTRODUCTION..... | 1 |
| Cognitive Disability: A Growing Epidemic..... | 2 |
| Rehabilitation Theory in the Management of Cognitive Disability..... | 3 |
| Cognitive Rehabilitation: Remediation, Support and Compensatory Strategies..... | 4 |
| Cognition and Rehabilitation..... | 4 |
| Medical Treatment for Cognition..... | 5 |
| Remedial Approaches to Cognitive Rehabilitation..... | 6 |
| Tabletop Approaches..... | 6 |
| Computer Assisted Cognitive Retraining Approach..... | 7 |
| Compensatory Approaches to Cognition..... | 7 |
| Positive Behavioral Support Approach..... | 8 |
| Computer-based Compensatory Approaches..... | 8 |
| Multiple Sclerosis and Cognition..... | 10 |
| Purpose Statement..... | 12 |
| Research Questions..... | 12 |
| Rationale for this Study..... | 14 |
| II. REVIEW OF THE LITERATURE..... | 15 |
| Introduction..... | 15 |
| Cognitive Rehabilitation: Theory and Practice..... | 16 |
| A New Profession Evolves..... | 16 |

| | |
|---|-----------|
| Computer Aided Cognitive Rehabilitation..... | 18 |
| Computers as Compensatory Cognitive Aids..... | 20 |
| Theoretical Basis..... | 20 |
| Early Compensatory Strategies: | |
| A Brain on a Desktop..... | 21 |
| PDAs: Truly Portable Computer Aids..... | 25 |
| Other Portable Cognitive Aids: Pagers, Cell Phones, Etc..... | 27 |
| Disability-Specific Handheld Computer Technology... | 28 |
| Research Lags Behind Development..... | 32 |
| The Future of Computers and Cognitive Rehabilitation: | |
| Ongoing Research..... | 33 |
| Theoretical Basis..... | 33 |
| Distributed Cognition Experiments..... | 34 |
| Potential versus Realization: | |
| What's a Clinician to Do?..... | 36 |
| Towards an Assistive Technology Training Model | |
| For Individuals with Cognitive Disability..... | 38 |
| Instructional Design Approach: Theoretical Basis..... | 38 |
| Lessons Learned from "Diffusion Of Innovations" Theory..... | 41 |
| The Need for a Clinical Practice Model that Can Flex with the Evolution of Technological Innovations..... | 42 |
| Assistive Technology for Cognition for Individuals with Multiple Sclerosis..... | 42 |
| III. RESEARCH METHODOLOGY..... | 44 |
| Introduction..... | 44 |
| Approval..... | 44 |
| Design Rationale..... | 45 |
| Study Design..... | 46 |
| Determination of Variables..... | 47 |
| Participants..... | 50 |
| Selection..... | 50 |

| | |
|--|-----|
| Description of the Setting..... | 55 |
| Measures..... | 55 |
| Materials..... | 59 |
| Procedures..... | 59 |
| Initial Assessment..... | 59 |
| Non-Treatment Phase..... | 60 |
| Training Phase..... | 60 |
| Post-Training Phase..... | 62 |
| Statistical Analysis..... | 64 |
| Organization of the Remainder of the Paper..... | 67 |
| IV. RESULTS..... | 69 |
| Learning to Operate a Handheld Computer..... | 70 |
| Long-Term Learning Retention..... | 73 |
| Functional Performance Change Using a PDA..... | 76 |
| Change in Functional Handicap Using a PDA..... | 90 |
| No Change in Behavioral Memory Using a PDA..... | 97 |
| Related Findings: Life Events During the Study..... | 101 |
| Summary..... | 103 |
| V. DISCUSSION..... | 104 |
| Participants Can Learn to Use a PDA..... | 105 |
| Participants Retain Learning Long-Term..... | 106 |
| PDAs Increase Functional Performance..... | 108 |
| PDAs versus Low-Tech Cognitive Aids..... | 109 |
| Cognitive Levels: Are there People who Cannot Benefit?.. | 110 |
| Clinical Relevance..... | 112 |
| Assessment Considerations..... | 113 |

| | |
|--|-----|
| Training Considerations..... | 113 |
| Cost Considerations..... | 114 |
| Multiple Impairment Considerations..... | 115 |
| Severe Cognitive Impairment and Motivational Considerations..... | 116 |
| Considerations Regarding Familiarity with Computers..... | 116 |
| Considerations for the Future..... | 117 |
| Treatment with Other Cognitive Disability Groups..... | 117 |
| Theoretical and Research Implications..... | 118 |
| The Relationship between Instruction and Device..... | 118 |
| The Issue of Self-Efficacy..... | 119 |
| Ecological Validity..... | 120 |
| Future Directions..... | 120 |
| Limitations..... | 121 |
| Sampling Limitations..... | 121 |
| Instrument Limitations..... | 122 |
| Procedure Limitations..... | 123 |
| Summary and Conclusion..... | 124 |
| REFERENCES..... | 126 |
| APPENDICES..... | 134 |
| Appendix A: Human Investigations Committee Protocol and Consent Form..... | 140 |
| <i>Appendix A:1: HIC Protocol</i> | 141 |
| <i>Appendix A:2: Consent Form</i> | 154 |
| Appendix B: Assessment Forms..... | 163 |
| <i>Appendix B:1: Canadian Occupational Performance Measure</i> | 164 |
| <i>Appendix B:2: Craig Handicap Assessment and Rating Scale</i> | 165 |
| <i>Appendix B:3: Rivermead Behavioral Memory Test – Extended</i> | 166 |
| <i>Appendix B:4: Demographic Survey Form</i> | 167 |
| <i>Appendix B:5: Functional Assessment Tool for Cognitive Assistive Technology</i> | 169 |
| Appendix C: Participant Raw Data..... | 174 |
| Appendix D: COPM Deficit Categories..... | 176 |

| | |
|---|-----|
| Appendix E: COPM Item-by-Item T-test..... | 178 |
| Appendix F: RBMT-E Raw Scores..... | 180 |
| Appendix G: RBMT-E Scores Compared To Control Means..... | 182 |
| Appendix H: CHART Sub-Category T-test..... | 184 |
| Appendix I: Mean PDA Entries per Week..... | 186 |
| Appendix J: Participant Mean Scores on FATCAT Likert-Scaled Questionnaire..... | 188 |
| Appendix K: Participant Perceptions: FATCAT Short Answer Summary..... | 190 |

LIST OF TABLES

| TABLE | Page |
|---|------|
| Table 1. Self-Ranking of M.S. Symptom Importance..... | 53 |
| Table 2. Cognitive Strategies or Aids Used Prior to the Study..... | 54 |
| Table 3. Timetable for Assessments..... | 64 |
| Table 4. Ability of Participants to Perform Handheld Computer Tasks..... | 72 |
| Table 5. Ability of Participants to Perform PDA Tasks Eight Weeks after Completion of Training..... | 74 |
| Table 6. Participant Entries on Handheld Software, Week 8..... | 75 |
| Table 7. COPM Performance Score Descriptive Statistics..... | 79 |
| Table 8. COPM Satisfaction with Performance Score Descriptive Statistics..... | 79 |
| Table 9. Overall Repeated Measures ANOVA of COPM Performance Scores..... | 80 |
| Table 10. Overall Repeated Measures ANOVA of COPM Satisfaction with Performance Scores..... | 81 |
| Table 11. Pairwise t-tests for Four Levels of COPM Performance Scores..... | 82 |
| Table 12. Pairwise t-tests for Four Levels of COPM Satisfaction with Performance Scores..... | 83 |
| Table 13. CHART Descriptive Statistics..... | 91 |
| Table 14. Overall Repeated Measures ANOVA of CHART Scores..... | 92 |
| Table 15. Pairwise t-tests of CHART Scores..... | 93 |

| | |
|---|-----|
| Table 16. RBMT-E Descriptive Statistics..... | 99 |
| Table 17. Paired Sample t-test for RBMT-E..... | 100 |

LIST OF FIGURES

| FIGURE | Page |
|---|------|
| Figure 1. COPM Performance Score Change..... | 84 |
| Figure 2. COPM Satisfaction with Performance Score Change.... | 85 |
| Figure 3. CHART Score Change..... | 94 |

CHAPTER ONE

INTRODUCTION

With this dissertation, I aim to provide evidence that people who have cognitive impairment related to multiple sclerosis can learn to operate handheld computers in managing memory and organizational tasks, and that they can utilize these devices to significantly improve their functional independence. With the exception of a four-subject pilot study that I conducted (Gentry, 2005), no such study has previously been reported.

Multiple sclerosis is a degenerative nerve disease, which typically strikes individuals in the prime of their lives. Short-term memory loss, difficulty multi-tasking and mental fatigue are some of the cognitive symptoms that occur in from 45-65% of this population (LaRocca, 2000). Often cognitive impairment is the reason that young workers with M.S. must leave their jobs. An assistive technology that can help these individuals compensate for cognitive impairment may also help them remain on the job or retain functional independence in other areas of their daily lives (medication regimes, household duties, community engagements, etc.). An intervention that involves training in the use of handheld computers as assistive technology would seem to offer a relatively inexpensive and time-saving approach to compensating for functional deficits related to cognitive impairment.

Cognitive Disability: A Growing Epidemic

Cognitive disability is a growing epidemic worldwide. In the U.S., two thirds of the nation's special education students have a thinking skills impairment (Education, 1997). Among adults, cognitive disability related to mental illness, brain injury, diabetes, stroke and the neuro-degenerative diseases (Alzheimer's disease, multiple sclerosis, Parkinson's disease, etc.) are all sharply on the rise (Bischkopf, Busse, & Angermeyer, 2002) (Kraus, Stoddard, & Gilmartin, 1996). Across the U.S., an estimated 20 million people (7% of the general population) suffer cognitive disability, at an annual cost for support, care and lost productivity of \$140 billion (Braddock, 2002).

Though every individual with a cognitive impairment may present differently, confusion, loss of short-term memory, difficulty organizing and sequencing tasks, difficulty making plans and following through on them, and difficulty with communication, judgment and impulse control are all hallmarks of cognitive impairment conditions. These symptoms may impact every area of daily life, including medication compliance, self-care tasks, money management, community mobility and school and job responsibilities, among others. Frustration, withdrawal, maladaptive behaviors and depression are typical secondary sequelae related to cognitive disability.

Though the human brain does appear to have a limited self-repair mechanism or "plasticity" that allows for some recovery of cognitive function in some cases, many diseases that cause cognitive disability (such as multiple

sclerosis and Alzheimer's disease) are degenerative in nature, leading to a gradual or rapid cognitive decline. Other conditions, such as acquired brain injury and cerebral palsy, may cause acute damage too severe for repair. For the vast majority of individuals with cognitive disability there is no cure. As medical care improves and as the world's population ages, the number of people living with cognitive disability may be expected to balloon dramatically over the next several decades. Clearly, the need is great for effective rehabilitative treatments to address this burgeoning epidemic.

Rehabilitation Theory in the Management of Cognitive Disability

Cognitive rehabilitation is a new and expanding field of practice. As Sohlberg and Mateer state in their seminal work, *Introduction to Cognitive Rehabilitation: Theory and Practice* (1989), this emerging practice area has "a limited research base and a lack of professional consensus in terminology, theoretical foundations, and treatment approaches". Recognizing the emergent nature of cognitive rehabilitation, Sohlberg and Mateer define the practice broadly, as "the therapeutic process of increasing or improving an individual's capacity to process and use incoming information so as to allow increased functioning in everyday life" (Sohlberg & Mateer, 1989).

This definition derives from physical rehabilitation theory, which focuses on restoring functional performance in the face of physical or mental impairment (Seidel, 1998). Rehabilitation theory emphasizes "the teaching of compensatory techniques; the use of adaptive and assistive equipment; and the modification of

environments to eliminate barriers to function (Seidel, 1998). Cognitive rehabilitation has emerged as a specialty area of physical rehabilitation, and is developing its own practice models, grounded in theories of brain function that posit sometimes opposing arguments for the potential of cognitive restoration following injury.

Cognitive Rehabilitation: Remediation, Support and Compensatory Strategies

Cognition and Rehabilitation

The American Congress of Rehabilitation Medicine and the American Academy of Physical Medicine and Rehabilitation agree on functional definitions of cognition and cognitive disability:

“Cognition is defined as the process of knowing. It includes the discrimination between and selection of relevant information, acquisition of information, understanding and retention, and the expression and application of knowledge in the appropriate situation.

“Cognitive disability may be seen in reduced efficiency, pace and persistence of functioning, decreased effectiveness in the performance of routine activities of daily living (ADLs); or failure to adapt to novel or problematic situations (Cicerone et al., 2000).

Cognitive rehabilitation is a field that ranges widely across disciplines, medical conditions and theoretical approaches. Practitioners include physicians, psychologists, occupational therapists, speech and language pathologists and special education teachers, among others. Medical conditions, as noted above, range from prenatal syndromes such as mental retardation and cerebral palsy to acquired injuries

such as traumatic brain injury and stroke on to degenerative neurological diseases such as Alzheimer's disease and multiple sclerosis. Each of these conditions may be considered a clinical specialty area, with its own body of knowledge and practice. Yet across clinical disciplines and conditions, the primary theoretical approaches to cognitive disability may be neatly divided into medical, remedial and compensatory fields.

Medical Treatment for Cognition

Medical approaches to cognitive disability include surgery, invasive procedures, such as chemo-therapy, that are outside the interests of this study (neither approach is typically used with multiple sclerosis patients) and medication regimes. Recent pharmaceutical research suggests that the orally-ingested pill Donepezil (Aricept) may improve memory function in some individuals with early-stage Alzheimer's disease (Birks & Harvey, 2003) and multiple sclerosis (Krupp et al., 2004), and claims have been made for a wide variety of nutritional supplements as cognitive stimulants (Kaplan, Greenwood, Winocur, & Wolever, 2000) (Kaplan, Greenwood, Winocur, & Wolever, 2001) (Morley, 2001). Research in these areas is ongoing.

Remedial Approaches to Cognitive Rehabilitation

Tabletop Approaches

For many years, remedial efforts were the primary approach used to rehabilitate cognitive impairment. This approach derives from principles first voiced by the renowned Russian neuropsychologist Alexander Luria, who argued that discrete functional units of the brain work together in an integrated manner to produce functional behavior. Luria believed that recovery of lost cognitive functions could occur through training methods that targeted basic thinking processes disrupted after injury (Sohlberg & Mateer, 1989). His theory led to an explosion of remedial approaches to cognitive disability. Various table-top regimens sought to stimulate mental processes and improve thinking skills, by utilizing maze-drawing, number sequencing, scrambled letter strings and similar tasks (Parente & Herrmann, 1996).

Many clinicians took advantage of desktop computer programs to mechanize direct training regimens intended to improve attention, concentration and memory, and to increase processing speed (Sohlberg & Mateer, 1989). Unfortunately, outcomes-based research on this method has not been encouraging. A meta-analysis conducted by the Agency for Health Care Policy and Research in 1998 showed that highly touted "drill and skill" direct training strategies for cognitive impairment are not ecologically sound in that they do not lead to improved everyday performance of basic life tasks in the brain injured population (Chestnut, 1999). The same findings have been reported for similar

efforts with individuals who have neurodegenerative dementia (Clare, Woods, Moniz-Cook, Orrell, & Spector, 2003).

Computer Assisted Cognitive Retraining Approach

Cognitive retraining conducted using computer programs has been especially disappointing. During the 1980s, clinicians hoped that such programs would improve attention, processing speed and memory among the cognitively impaired, and some users did learn to improve their computer-based scores. Unfortunately, they were still unable to find their socks in a drawer. Real world transfer of learning did not occur, and as similar results have accumulated, cognitive rehabilitation therapists have been advised to wean themselves from computer-based direct training approaches (Cicerone et al., 2000).

Compensatory Approaches to Cognitive Rehabilitation

The failure of direct-training remediation has spurred research into *compensatory* strategies that may enable individuals with cognitive impairment to function more independently within all contexts of everyday life, despite their disability. Derived primarily from rehabilitation theory, which focuses on environmental and adaptive accommodations to impairment, efforts that have shown promise include positive behavioral support (PBS) (focused on managing behavioral antecedents, social supports and the physical environment) (Carr et al., 2002) (Feeney, Ylvisaker, Rosen, & Greene, 2001) and the use of assistive technology (LoPresti, Mihailidis, & Kirsch, 2004).

Positive Behavioral Support Approach

Positive Behavioral Support (PBS) involves a systematic review of an individual's skills, responsibilities, living environment and caregiver activities, aiming to develop a way to improve functional performance and reduce maladaptive behaviors by addressing behavioral antecedents and teaching adaptive strategies (Ylvisaker & Feeney, 1998). The PBS approach is notoriously labor-intensive, however, requiring an ongoing and constantly updated effort by a multi-disciplinary treatment team in order to foster improved behaviors among individuals with cognitive-behavioral challenges. Recognizing these issues, cognitive rehabilitation clinicians have begun to focus attention on assistive technology, which may serve as a relatively inexpensive and potentially liberating approach to improve functional performance by individuals with cognitive disability.

Computer-Based Compensatory Approaches

With the emergence of increasingly powerful and increasingly smaller computer devices over the past decade, investigators have begun to examine how inexpensive laptop computers, personal digital assistants (PDAs) and other electronic products may be used as assistive technology, playing a role in improving functional independence for the cognitively impaired. (A brief history of this approach is offered in Chapter Two of this paper.) The current use of these devices has derived from the pre-computer age, when sticky notes, reminder notebooks and scheduling

calendars were used extensively to help people remember to perform tasks ranging from the straightforward sequence involved in brushing one's teeth to the complex interactions required to negotiate appropriate social behaviors in community settings.

To this day, many individuals with cognitive impairment carry "memory books" that collate their appointments, medication schedules and behavioral strategies. They rely on human supervision, however, to help them enter information in the notebook and to check it throughout the day, when needed. Portable computers would seem to offer improvements on the memory book function, offering more flexibility and information storage, along with reminder alarms and photographic/video data, to help individuals stay on task without so much human supervision.

As detailed in the literature review chapter of this paper, clinicians have utilized computers as compensatory cognitive aids for at least the past quarter century. Their approach has been two-fold: (1) using available computer capabilities to help manage functional behaviors and (2) developing disability-specific programs based on artificial-intelligence concepts. In both cases, the goal has been to provide an assistive technology that will help people with cognitive impairment function more independently in everyday life, without the need for constant, direct supervision. Ongoing improvements in computer capabilities and portability have driven innovations in their use as cognitive aids.

Though early work focused on desktop products, the emergence of handheld computers since the mid-1990s has provided an opportunity to develop computer-based cognitive aids that can accompany users into community, school and vocational

settings. Much of the work in computer-based cognitive rehabilitation over the past decade has focused on developing disability-specific software adapted to the needs of various users. This work is detailed in the following chapter. Unfortunately, most of these projects have not yet produced any marketable product with proven efficacy, and those available are expensive and require a significant time commitment from a clinician or caregiver to program them for use.

An obvious unmet need is for investigations into individualized training programs and adaptations using inexpensive, off-the-shelf, consumer PDAs. These devices can be easily adjusted for multiple input styles, enlarged type, reduced interface demands and vibration alarms. Add-on devices (such as digital cameras) and software (such as text-to-speech programs and video players) can make PDAs user-friendly and appropriate for individuals with a range of physical and cognitive impairments. As consumer devices, there is no stigma associated with their use, and as mass-market products, they are typically more sturdy than devices designed specifically for the disability population. The current study is an effort to address this unmet need, investigating the use of a Palm Zire 31 PDA (shelf price \$128), coupled with a brief, home-based training program, as an assistive technology for cognition.

Multiple Sclerosis and Cognition

Individuals with multiple sclerosis offer a likely population to benefit from such an intervention. The disease typically strikes during the early 20s or 30s, when people are involved in productive work careers and family life. Multiple sclerosis is

not typically a deadly disease. Its ravages may be slow, and people may live long lives with the disability it causes. As the disease progresses, nerve linings are gradually eaten away in the brain and peripheral nerves, through a dimly understood process that seems to be driven by an aberrant auto-immune response. On brain scans, dead spots in brain tissue may appear in a scattershot pattern extending down into the spinal cord. In addition to cognitive changes, symptoms can include chronic fatigue, paralysis, muscle weakness or spasticity, sensory disturbance, pain and/or emotional lability. Every patient seems to be a “universe of one”, with symptoms unique to his/her pattern of neurological disease (Burke & Johnson, 2000).

As previously noted, up to 65% of multiple sclerosis patients experience measurable cognitive impairment and at least 10% of this group say that cognitive impairment is their most debilitating symptom (LaRocca, 2000). Cognitive impairment in multiple sclerosis may express itself functionally as difficulty with short-term memory, prospective memory (making and keeping plans), adjusting to changing circumstances, multi-tasking, name-face recognition, managing mathematical tasks, and functioning in multi-stimuli environments (Thronton & Naftail, 1997). It would be difficult to think of a career that does not require some or all of these skills, which are equally important in family and community settings. In the pilot study conducted prior to this dissertation research, all four subjects had lost their jobs because of cognitive impairment and reported continued functional cognition difficulties at home (Gentry, 2005).

The toll on individuals and families, in terms of lost wages, patient and caregiver stress, injury and self-esteem are enormous. Imagine, in the prime of your

life, gradually losing your ability to remember, to think, to carry out plans, even to find your way on the highway, until at last you lose your job and find yourself depending on loved ones to help you manage everyday tasks. This is the life trajectory of many individuals with multiple sclerosis. For them, a compensatory treatment approach utilizing handheld computers would seem to offer an opportunity for improved functional independence and life satisfaction. This study provides evidence supporting that approach.

Purpose Statement

The purpose of this study is to determine whether individuals with cognitive impairment related to multiple sclerosis can learn to use handheld computers, and to utilize these devices to improve their functional independence and life satisfaction, while also relying less on caregiver support for everyday activities.

Research Questions

This study was designed to provide evidence in support of the following hypotheses:

- (1) Individuals with cognitive impairment related to multiple sclerosis can learn to independently operate calendar, notepad, memo and contact functions on a handheld computer.

- (2) These individuals can retain learning of these skills for at least eight weeks after training is completed.
- (3) These individuals can independently and regularly use a handheld computer to assist in performing everyday life tasks for at least eight weeks after training is completed.
- (4) These individuals can significantly improve their scores on a self-assessment test of functional independence and satisfaction in the performance of everyday life tasks (the Canadian Occupational Performance Measure) after treatment and will retain those gains for at least eight weeks after training is completed.
- (5) These individuals can significantly reduce their level of functional handicap as measured on a self-assessment form (the Craig Handicap Assessment and Rating Tool) after treatment and will retain that reduction for at least eight weeks after training is completed.
- (6) These individuals will not show significant improvement in functional performance, satisfaction with functional performance or functional handicap during a 6-week pre-treatment period, since no intervention will have been initiated during this period
- (7) These individuals will not show an improvement in behavioral memory on a standardized test (the Rivermead Behavioral Memory Test) after treatment (in that the intervention is compensatory and does not address brain function directly).

Rationale for this Study

Remedial efforts at cognitive rehabilitation have not proven successful in helping individuals regain functional independence in everyday life. Low-tech compensatory strategies, such as paper-based memory notebooks, only work when an individual remembers to use them or a caregiver acts as a reminder. With the emergence of affordable PDAs with straightforward secretarial functions onboard, the opportunity arises for such devices to function as assistive technology for cognition, though many clinicians fear that these devices are too complicated for individuals with cognitive impairment to learn to operate independently. As PDAs continue to grow in power and shrink in size, the potential for these devices to provide increasingly useful services for individuals with disability may be expected to expand dramatically.

The rationale for this study is four-fold: (1) It will help to remedy the paucity of evidence supporting the functional efficacy of rehabilitative interventions for cognitive disability; (2) With the exception of my pilot research, there has never been a quantitative study of handheld computers as assistive technology for individuals with cognitive impairment related to multiple sclerosis; (3) The study will provide evidence for this use of handheld computers to compensate for functional deficits related to cognitive impairment related to multiple sclerosis; and (4) The study will provide evidence for the usefulness of a brief, home-based training approach for persons with cognitive disability who wish to utilize handheld computers as assistive technology.

CHAPTER TWO

REVIEW OF THE LITERATURE

Introduction

In this chapter, I examine the history of computer-based cognitive aids, the theoretical foundations for using these tools, research in the field, and the prospects for future applications, with a particular focus on handheld computers as assistive technology for cognition. In the first section, I describe the evolution of the cognitive rehabilitation profession, which emerged from the field of neuropsychology in the 1970s, and has driven the use of computers as cognitive aids since that time.

Cognitive rehabilitation and personal computers were born in the same decade, and the use of computers as tools for cognitive retraining offered great promise then that was not fulfilled. In the second section, I explain what happened to efforts at Computer Aided Cognitive Rehabilitation (CACR) and how the use of computers as “compensatory” cognitive aids arose. The theoretical basis for “assistive technology for cognition” (ATC) is discussed, followed by a review of published research into desktop platforms, handheld models, and disability-specific software designed for use by individuals with cognitive impairment. The section ends with an overview of promising current research in the use of computers as “nurse-robots”, interactive job coaches and nodes of “distributed cognition”.

In the third section, I discuss opportunities for research into untapped, overlooked areas of cognitive rehabilitation, especially with regard to the potential of widely available, off-the-shelf products to be used as cognitive aids, coupled with a formal training protocol that incorporates elements of rehabilitative and instructional design theory. This approach may provide an effective, inexpensive and readily replicated cognitive rehabilitation therapy that can evolve with improvements in handheld platform capabilities, instead of being chained to any particular product.

The chapter concludes with a summary section that describes gaps in the current literature that the proposed study will seek to address.

Cognitive Rehabilitation: Theory and Practice

A New Profession Evolves

Cognitive rehabilitation is a relatively new field, which emerged from the profession of neuropsychology in the late 1970s, coincidentally at about the same time personal computers first gained widespread use. The soundest theoretical principles for cognitive rehabilitation derive from the work of the visionary Russian neuropsychologist Alexander Luria, who developed an "information processing" model of brain function. Luria argued that the brain manages sensory data within interrelated "functional cortical systems that account for the organization of higher level thought processes." Under this model, human behavior is driven by response mechanisms derived from basic processes that

arise from different sites in the brain. Any disruption within these sites must result in behavioral changes. Efforts at rehabilitation, therefore, need to focus on "cognitive retraining exercises specifically targeted, not at the behavior itself, but at the source of...the basic processes that have been destroyed" (Sohlberg & Mateer, 1989).

This "address the process" model of rehabilitation led to widely disseminated protocols for table-top activities intended to assess and restore cognitive functioning. The cognitive process of "attention", for instance, might be assessed and re-trained using a deck of playing cards and a hand buzzer. (Attention, according to Luria, is an underlying thought process that allows sensory data to be presented to the brain's information processing system.) As a clinician turns the cards over face up one-by-one, a subject may be asked to press the buzzer each time a card numbered "8" or "3" turns up. The subject's accuracy and success in attending to the task through the entire deck is a measure of his/her attentional capacity (Sohlberg and Mateer 1989). Retraining of attention, under this model, might include increasing the difficulty or duration of the card-identification task, and improvement in attention is measured by success on these increasingly difficult challenges.

Tabletop protocols of this nature -- gradually adopted by neuropsychologists, speech and language pathologists, occupational therapists and other cognitive rehabilitation practitioners worldwide -- marked the beginning of cognitive rehabilitation as a practice model and profession. By the mid-1980s, cognitive rehabilitation courses were being offered in many professional training

programs and hundreds of cognitive assessment and training products were available. As the following section shows, however, there was a crucial flaw in these efforts to restore cognitive function through tabletop activities designed to address underlying cognitive deficits: They did not result in improved functional performance in everyday life.

Computer Aided Cognitive Rehabilitation

The great technological revolution of the 1980s was the emergence of the personal computer. Tabletop cognitive assessment and training activities proved a natural fit for personal computer platforms. Game-like products that involved the retraining of Luria-based cognitive processes such as orientation, attention, concentration and memory were readily transferred to computers, which proved capable of monitoring user progress and upgrading test challenges automatically. Because computer-based cognitive exercises saved time for therapists (allowing clients to practice as long as they liked, providing automatic testing and increases in task difficulty based on those tests), Computer Aided Cognitive Rehabilitation (CACR) seemed to hold great promise for the rehabilitation field (Gianutsos, 1992) (Lynch, 2002). This promise was mirrored in the field of education by the advent of Computer Assisted Instruction (CAI), which some professors predicted would cause an immediate paradigm shift in instructional practice, with computers assuming many of the roles typically performed by teachers (such as learning drills, tests and grading) (Bork, 2003) (Dede, 1986). Computer programs

designed to address underlying cognitive processing deficits were marketed with the assurance that they could restore impaired cognitive functioning, and improvements were indeed reported on the scores of computerized cognitive tasks (Bracey, 1983) (Sbordonne, 1986) (Wood & Fussey, 1987).

A problem arose, however, with the issue of "ecological validity". This term refers to whether a rehabilitative intervention leads to improved functional performance by a rehabilitation client in home and community settings. It is the gold-standard outcome by which any clinical treatment is measured. Cognitive rehabilitation therapists gradually came to see that higher scores on tabletop or computer-based cognitive activities did not necessarily translate to improved performance in everyday life tasks (Prigatano et al., 1984) (Kerner & Acker, 1985) (W. Lynch, 1992). In fact, as similar findings accumulated during the 1990s, the whole field of cognitive rehabilitation came under scrutiny.

An influential pair of research meta-analyses eventually showed that computer-based therapies intended to improve discrete cognitive processes were not ecologically valid, and argued persuasively for cognitive rehabilitation, if practiced at all, to be intimately linked to the environments and activities that trainees experienced day-to-day, in order to make sure that treatment activities transferred to the real world. One report, by a multi-disciplinary panel of brain injury specialists, found very little evidence to support "restorative" or "remedial" efforts at cognitive rehabilitation and recommended instead "the application of compensatory strategies, adapted to patient groups and to individuals, to improve the functional ability of persons with traumatic brain injury" (Carney et al., 1999).

The other report, a year later, found “no evidence exists that computer-based cognitive remediation provides specific benefits or effectiveness, compared with other forms of cognitive rehabilitation” and went on to recommend that any computer-based practice be richly supplemented by therapeutic efforts to develop compensatory strategies based on “facilitating the transfer of skills from the treatment tasks to real-life situations” (Cicerone et al., 2000).

These reports sent a shock wave through the rehabilitation community that has not settled to this day. The greatest fallout seems to have been a gradual shift away from “restorative” or “remediative” therapies intended to improve underlying cognitive processes towards “compensatory” treatments that do not purport to improve the organic functioning of the brain, but provide assistive technology or environmental adaptations that allow a person to function in everyday life despite cognitive impairment (Parente & Herrmann, 1996).

Computers as Compensatory Cognitive Aids

Theoretical Basis

The use of computers as ATC has progressed in fits and starts over the past twenty years, driven by the evolution of computer technology and the gradual awakening of rehabilitation practitioners to the potential for computer use in this capacity. The theoretical basis for the use of computers as compensatory aids to cognition arises directly from physical rehabilitation theory, which addresses the restoration of functional independence after injury, rather than cure (Dutton, 1995). Rehabilitation theory “focuses on compensatory methods, assistive

devices, and environmental adaptations an individual needs to function in spite of his or her impairment” (Seidel, 1998). Under this theory, in order for computers to function as assistive technology they must act as cognitive aids within the everyday contexts and tasks an individual needs to perform, providing individualized assistance that enables improved function in everyday life tasks. This is a very different challenge than the CACR model, which is clinic-based and focused on restoring brain function through educational strategies. As the following section shows, however, investigators of computer-based ATC have faced many of the same problems in proving the efficacy of their treatment programs.

Early Compensatory Strategies: A Brain on a Desktop

Early efforts at computer-assisted cognitive aids were necessarily based on desktop personal computer platforms, since portable technologies had not yet emerged. In the early 1980s, a variety of programs were developed to help simplify the human-computer interface for use by individuals with cognitive disability, and software was designed to provide reminder alarms linked to activity calendars and task sequencing cues to help people follow a daily schedule (LoPresti et al., 2004). These efforts were simplified in 1984, when the first Windows operating system eliminated the need for DOS line-prompting, reducing the number of steps needed to operate any computer. Some individuals with mild cognitive impairment even found that they were able to pay bills, keep track of

appointments and manage other routine tasks using off-the-shelf consumer software (Bergman, 2002).

The complexity of the personal computer interface has proved daunting for many individuals with cognitive disability, however, so a number of programs have been developed to make desktop systems function as cognitive aids. The two primary functions computers have performed in this capacity include: (1) serving as reminder systems or scheduling aids for individuals with diminished attention or memory and (2) serving as instructional cueing aids or coaches for users who might otherwise forget the steps of a multi-step task (Pollack et al., 2002b). Research literature on ATC primarily addresses methods to provide these two services, and rightly so. These are functions that are typically performed by caregivers, so improving the independence of an individual with cognitive disability while relieving caregivers of these responsibilities is a worthy rehabilitative goal. At the same time, these are functions that computers can readily fill.

The earliest work in this area was completed by software development teams using the new Microsoft Windows personal computer interface. Three different products were introduced that attempted to serve as reminder systems and as task-sequencing coaches. The Visions System (Baesman & Baesman, 2003), ProsthesisWare (Chute, Conn, DiPasquale, & Hoag, 1988) (Chute & Bliss, 1988) (Chute & Bliss, 1994) and the Essential Steps System (Bergman, 2000) (Bergman, 2002) (Bergman, 2003) provide direct personal computer-based auditory prompts for individuals with cognitive disability. The prompts are linked

to an electronic calendar and broadcast by speakers throughout a user's home environment, to cue him/her to perform everyday tasks such as waking up, bathing, getting dressed and grooming. In all three systems, users can access a computer-touchscreen for step-by-step graphic and auditory assistance on complex tasks, such as menu-planning and cooking.

Unfortunately, though these systems seemed to offer exciting new possibilities for individuals with cognitive disability, very little research has been conducted to assess their efficacy as cognitive aids. No formal study has been conducted on the efficacy of the Visions System, a single subject qualitative study of ProsthesisWare showed that the user still had difficulty following its computer-based instructions (Chute & Bliss, 1994), and though a clinic-based study of 41 individuals with traumatic brain injury showed that 36 (88%) could learn to follow instructions using the Essential Steps System (Bergman, 2000), no follow-up study in an ecologically valid home or community setting was reported. Additionally, all three of these systems have proven expensive and time-consuming to set up for individual users. Another shortcoming is a result of their desktop computer platform: None works beyond the home environment. This lack of portability limits their use in mobile community and work settings.

The Institute for Cognitive Prosthetics (ICP) has approached computerized cognitive aids from a different perspective, providing individualized solutions that may include off-the-shelf speech-to-text readers, electronic calendars, money management software and telephonic links to caregivers, among other services, in order to enable more independent functioning in home and work settings. Though

this multi-modal approach suggests a promising use of computers as cognitive aids in ecologically valid home and work environments, only anecdotal case studies support ICP's work (Cole, Dehdashti, Petti, & al., 1994) (Cole, 1997) (Cole, 1999).

The lack of computer portability troubled clinicians during the 1980s, since community access is an essential goal of rehabilitation interventions. One research team bolted a desktop computer onto a rolling cart, added a special software that provided interactive visual cues, and conducted a case study of computers as job coaching aids among a quartet of individuals with brain injury who were working as building custodians. Though this work presaged later efforts to use portable computers as job coaching aids, the results were mixed. Two subjects performed their work better using the computer-aided system, while the other two found it distracting and burdensome to haul around (Kirsch, Levine, Lajiness-O'Neill, & Schnyder, 1992).

Another solution to the portability problem was offered by ISAAC, a mini-laptop system designed specifically for individuals with cognitive disability. The brick-sized ISAAC device can be programmed to provide onscreen neighborhood maps, step-by-step task directions, menus and auditory reminders linked to a calendar. A two-subject case study showed the device worked well as a reminder when programmed by a caregiver, and its portability allowed users to access community activities more independently, but the need to recharge it for hours each day proved troubling for one individual who frequently forgot to do so, causing the system to dump its memory (Gorman, Dayle, Hood, & Rumrell,

2003). The ISAAC system, though still available, is bulky and unwieldy when compared to consumer PDAs, and its significance today is primarily historical, in that it suggested that a portable computer may be able to improve functional independence and community access for individuals with cognitive disability.

PDAs: Truly Portable Cognitive Aids

The possible use of a handheld computer as a compensatory cognitive aid was first suggested in a text on clinical management of memory problems in 1984, a decade before production of the first mass-marketed Palm Pilots (Harris, 1984). The book's author wondered if a reminder alarm linked to a computerized calendar might help individuals with attention and memory deficits to stay on task. In 1988, an occupational therapist/neuropsychologist team published the first research article on the topic. They used an early handheld computer, the Psion Organizer, a half-pound box with a two-line text display and 32 kilobytes of read only memory (ROM). The Psion's calendar, diary, memo pad and alarm features were innovations that have become standard on today's PDAs and electronic personal organizers. The team compared the efficacy of the Psion as a memory aid to a handwritten memory book, with the tools used individually over successive weekends by a 25-year old woman who had a memory deficit caused by a brain hemorrhage. After training in the use of both tools, she showed slightly better adherence to a series of assigned tasks using the Psion (9 of 10

tasks completed on time versus 8 of 10 when using the memory book) and said that she preferred the handheld computer (Giles & Shore, 1989).

Over the next decade, as consumer use of PDAs skyrocketed worldwide, only one other research team reported on their use as cognitive aids. In the first of two studies involving individuals with brain injury, a 22-year old man demonstrated the ability to use a Psion Organizer as a reminder system during his inpatient hospitalization, attending therapy and asking for medication on schedule (Kim, Burke, Dowds, & George, 1999). In the second study, twelve outpatients were trained to use Psions and each loaned a device. Responding to a telephone survey several weeks later, nine reported that they found the Psion "useful" as a memory aid, and seven continued to use the device on a daily basis after the supervised trials ended (Kim, Burke, Dowds, Boone, & Park, 2000). Neither of these studies describes how subjects were trained to use the Psion, and they do not track functional outcomes or record how subjects actually used the devices day-to-day, but they suggest a promising avenue for future applied research with handheld computers.

To this date, however, there are no published studies reporting on the usefulness as cognitive aids of popular consumer PDAs such as those using the Palm operating system (Palm handhelds) or the Microsoft Windows CE operating system (Pocket PCs) that have become ubiquitous in consumer culture over the past decade. These devices are pocket-sized, lightweight and durable. They offer multiple organizational functions, support add-on software and have greatly improved screen-size, readability, and memory capacity over the Psion Organizer

used in the studies cited. The only studies to have used these devices report not on the capabilities of the devices themselves, but on disability-specific software designed to be used with them. This would seem to be a glaring oversight in the assistive technology field, where innovative tools to help individuals with cognitive impairment are greatly needed. The current study, utilizing Palm Zire 31 PDAs, is an effort to remedy that oversight.

Other Portable Cognitive Aids: Pagers, Cell Phones, Etc.

Though researchers have neglected PDAs as cognitive aids, a few have examined other portable devices that seemed to show promise. The largest study involved an electronic paging system called "Neuropage" (B. Wilson, Evans, Emslie, & Malinek, 1997). This randomized control, cross-over study comprising 143 participants is the largest ever conducted to assess the efficacy of any cognitive aid. The Neuropage trial utilized a portable electronic pager given to each of the study participants. A centralized paging system sent timed alarm prompts for individualized daily tasks ("turn on the heat", "let the dog out", etc.) to each participant, and caregivers monitored whether the prompts were obeyed or neglected. At the end of the trial, caregivers reported that over 80% of participants improved their task performance during the 7-week trial phase, as compared to a 7-week baseline (B. A. Wilson, Emslie, Quirk, & Evans, 2001). This promising report led to the establishment of a Neuropage service in one English hospital, which reported on 40 patients, 31 of whom responded to a

telephone survey that they found the Neuropage useful as a reminder system. Limitations noted included the difficulty of updating reminder prompts and the monthly service fee associated with any paging system (B. A. Wilson, Scott, Evans, & Emslie, 2003). This project relied on caregivers to program daily pages, which removed control of paging content from the users. Though not mentioned in the article, this factor would seem to limit the practicality of this approach to individuals with involved caregivers, thus reducing their usefulness as agents of independent functional performance.

A few case studies have examined other portable reminding systems, including cell phones used as paging reminders (Wade & Troy, 2001), a generic paging system (Kirsch, Shenton, & Rowan, 2004) and a portable Voice Organizer used to reinforce therapy goals in an inpatient hospital (Hart, Hawkey, & Whyte, 2002). As with most of the studies cited in this chapter, however, they relied on subjective impressions by participants or caregivers, did not formally track functional outcomes or day-to-day use of the devices, and did not describe how participants were trained to use them. Clearly, more rigorous methodologies are needed to provide support for these findings.

Disability-Specific Handheld Computer Technology

Though researchers have neglected Palm and Pocket PC handhelds as cognitive aids in their off-the-shelf configurations, several teams have designed innovative cognitive aid software to be used on the Pocket PC platform. The

Planning and Execution Assistant and Trainer (PEAT) is a downloadable software that provides a simplified electronic calendar, address book and reminder system for Pocket PC handhelds (Levinson, 1997). Designed specifically for individuals with cognitive impairment who may have difficulty managing the complex screen interface of a Pocket PC, PEAT uses a proprietary "automatic planning software" to help users compensate for impaired prospective memory (remembering things one has planned to do) and executive function (adjusting to changing circumstances). Caregivers can program PEAT to make a variety of decisions based on planned daily activities. The software then revises reminder alarm schedules as situations change. This adaptability to changing circumstances makes PEAT the most flexible cognitive aid currently available, and the only one that provides planned variability in reminder alarm cues. Unfortunately, there is no published research, not even a case study, to support PEAT's use with individuals who have cognitive impairment.

Ablelink Technologies, Inc. has created a suite of cognitive disability software for Pocket PCs that provides customized step-by-step cues for complex tasks. Their Visual Assistant software, for instance, allows a user to tap the computer's touch screen to move through a sequence of pictures and verbal prompts. Caregiver's create these reminder cues by downloading photographs and recorded verbal cues to the Pocket PC, using Task Builder, a desktop computer-based software. In a study with 10 participants who have mental retardation, the Ablelink team compared their ability to complete a pair of multi-step vocational tasks in a controlled, laboratory setting with and without support

from the Visual Assistant software. Participants committed an average of 2.25 errors per task when they did not use the Visual Assistant and .75 when they did (Davies, Stock, & Wehmeyer, 2002a).

Ablelink Technologies has also created a simplified reminding system for Pocket PC called the Schedule Assistant. In a second study the Ablelink team compared the ability of 12 individuals with mental retardation to follow a written daily schedule versus reminder alarm prompts generated by the Schedule Assistant. All participants were trained to use the Schedule Assistant and a written schedule. The study found that participants required less assistance and committed fewer schedule errors when using the Schedule Assistant to complete tasks in a controlled laboratory setting (Davies, Stock, & Wehmeyer, 2002b).

Another development team tested a different customized reminder system loaded onto two Pocket PC platforms, one utilizing a keyboard and the other a touch-screen and stylus interface. Twelve adult volunteers with acquired brain injury were trained to respond to reminder prompts on the two devices, then loaned each computer for two months, with a one-month gap between, in counter-balanced order. The research team reported on their training protocol, which involved a single home visit to train participants in how to use each device, with a follow-up visit to reinforce training one week later.

The team tracked use of the devices day-to-day with an onboard logging system, and found that all twelve participants could remember how to use the devices throughout the trial, and that most used them daily and found them useful (Wright et al., 2001). This is the only published study found that tracked actual

use of a handheld computer in everyday life tasks. Results showed that individuals who made frequent use of the computer preferred the keyboard-based Pocket PC and had made frequent use of other memory strategies prior to the trial. Opposite results were found for infrequent users.

The only extant study that examines a simplified add-on software for Palm OS devices trained forty-four community-dwelling “older adults” (age range 56-89, mean age 72, SD 7.08) to operate add-on programs designed to simplify medication management and to survey participants, along with standard Palm organizer functions (Sterns, 2005). The participants were not characterized as cognitively impaired. Researchers trained participants for three days, then tested them on how well they could operate the software, finding that all participants could demonstrate independence in using “the basic features of each of the standard programs and were able to use the applications designed for medication reminding and gathering survey data.” 25% demonstrated independence in using all functions on which they were trained.

Though this study does not specifically focus on individuals with cognitive impairment, the researchers note that older adults may face barriers to the use of handheld computers that may be similar to those faced by individuals with cognitive impairment – including “sensory changes, slowed information processing, demands on working memory, and limited attentional resources.” (The researchers do not say whether their participants face such barriers.) This study is unique in testing a training intervention intended to overcome barriers to the use of off-the-shelf PDAs. It does not explore whether participants continued

to use the devices after training or whether they found the devices helpful in their everyday lives.

Research Lags Behind Development

As these studies show, rigorous research into the use of computers as cognitive aids lags behind product development. It is hoped that further trials will be attempted to clarify the usefulness of desktop and handheld computers as ATC. At this point, we know very little about whether handheld computers may be useful tools to compensate for cognitive deficits. We do not know what software may best serve which populations or what training protocols may best enable individuals with varying degrees of cognitive impairment to use these devices.

Though promising efforts have been made to develop disability-specific software for handheld computers, very little is known about the possible effectiveness of this software or of off-the-shelf tools, particularly as combined with a proper training protocol or with adjunctive therapies. Most research so far is anecdotal in nature, based on case studies and subjective reports. More rigorous studies are needed to determine whether functional performance in everyday tasks may be influenced by these devices.

The Future of Computers and Cognitive Rehabilitation:

Ongoing Research

Theoretical Basis

The evolution of computer technology continues at a rapid pace.

Cognitive rehabilitation research teams are investigating innovative uses of Global Positioning Satellite (GPS) systems, wireless links between patients and caregivers, and situational problem-solving algorithms to provide way-finding maps in urban communities, interactive off-site job coaching and robotic nursing assistance. The theory of “distributed cognition” drives these investigations, drawing from literature in computer science and rehabilitation fields.

Distributed cognition theory assumes that the mind’s capabilities can be expanded through the use of media and technology. A universal example is the use of reading and writing to address the limitations of human memory. Tools of this nature allow more difficult tasks to be achieved by “distributing the demands between individuals, their tools, and their co-workers and/or caregivers” (Fischer, 2003). This model closely follows rehabilitation theory, which seeks to improve functional performance through modalities that compensate for disability (Seidel, 1998), and theory derived from the older profession of occupational therapy, which links physical abilities, environmental affordances and task demands in an interrelated chain of human behaviors and therapeutic options (Trombly, 2002).

Distributed Cognition Experiments

Distributed cognition theory leads to a variety of fascinating research efforts, intended to improve the functional independence of individuals with cognitive disability. The Mobility-for-All project at the University of Colorado is investigating the use of GPS-equipped cell phones and encoded navigation maps in bus stops and on buses to assist individuals with cognitive disability in using public transportation (Fischer, 2003).

Another team at the same university is developing a Memory Aiding Prompting System (MAPS), which seeks to combine key elements of cognitive prosthetic systems previously discussed in this chapter. MAPS software, residing on a desktop personal computer, stores reminder alarms, step-by-step visual task cues, directional maps and other information, which is fed through wireless Internet to a Pocket PC to help individuals with cognitive impairment perform individualized tasks in the community. The Pocket PC wirelessly returns information back to the desktop computer concerning the individual's location, performance of tasks and other needs. A Panic Button on the Pocket PC allows the system to phone a human caregiver when necessary (Carmien, 2002) (Carmien, Gorman, DePaula, & Kintsch, 2003) (Carmien, 2004). Though still in development, the MAPS system suggests promising uses of emerging computer technologies in the cognitive rehabilitation field.

Similar projects are under development at Leipzig University, Germany, where a mobile extensible memory aid system (MEMOS) (that links desktop

computer-based prompting software to a wirelessly equipped PDA) has been tested (Carmien, 2004), and at the University of Michigan, where a home-based system of electronic sensors (Independent Lifestyle Assistant (ILSA) (Pollack, 2002a) is linked to a personal computer software (Autominder), to provide customized activity prompts that can be automatically updated and changed based on the behavior of persons in the home (Pollack et al., 2002a) (Pollack et al., 2002b). The Autominder system has also been tested on a roving robotic platform as part of a "Robot-Nurse" project. This multi-university effort aims to create an autonomous mobile robot that can reside "in the home of an individual, and provide him or her with reminders about daily plans" (Pollack, 2002b).

The COACH system (an acronym for Cognitive Orthosis for Assisting Activities in the Community and Home), under development at the University of Toronto, Canada, uses "a personal computer and a single video camera to unobtrusively track a user during an [activity] and provide pre-recorded verbal prompts when necessary" to help the user complete the activity successfully (Mihailidis, Barbenel, & Fernie, 2004). This system was tested using a rigorous withdrawal type ABAB single subject methodology with ten individuals who have moderate to severe dementia. The study sought to determine whether the prototype could decrease their independence on caregivers when washing their hands. The results were promising, showing that the device operated with very little error, and that subjects completed from 10% to 45% more hand-washing steps without supervision when using COACH. These results were statistically significant at a 99% confidence level. The COACH study is the only ecologically

valid research extant on any interactive monitoring-and-response cognitive aid, and stands as a model of the type of research that is needed to show whether these complex technologies may be useful in clinic and community settings. COACH is still a prototype, however, and is not available for use by practicing cognitive rehabilitation clinicians.

Potential versus Realization: What's a Clinician to Do?

As this chapter has attempted to describe, though much promising development is underway to provide advanced "assistive technology for cognition" products, only a few are currently available to rehabilitation practitioners, and most have been poorly researched. The large gap between potential and realization makes for difficult decisions in the cognitive rehabilitation field, where useful therapies are needed now to help the growing population of individuals with cognitive disability. Added to this problem is the rapid evolution of computer technologies, which require continual updating of applied research efforts, in order to provide the best assistive technology available for clients. Cognitive rehabilitation researchers have fallen woefully behind in this endeavor, as evidenced by the lack of any published study on the use of off-the-shelf Palm or Pocket PC handheld computers as cognitive aids, despite their ubiquity in consumer culture.

Clearly, ecologically valid research into the efficacy of electronic cognitive aids is greatly needed. The authors of an extensive review of cognitive rehabilitation tools recommend that:

As the portability of ATC devices increases, it will become increasingly important for research programs to identify the factors that promote or hinder the effective use of ATC systems across the range of community settings in which they will be used and, most critically, to develop research programs that actually test new interventions within those community settings (LoPresti et al., 2004).

Additionally, research is needed on the use of inexpensive, off-the-shelf products that may serve as useful aids to independence for individuals with cognitive disability who cannot afford more exotic, multi-modal interventions or who do not need the level of assistance they provide. Certainly, until the projects devoted to distributed cognition technologies can develop marketable products and provide evidence that they work in the field, rehabilitation practitioners must rely on the tools available. In this case, those tools may be the PDAs and electronic organizers available at office supply stores.

Often-cited complaints against PDAs, however, are the complexity of their screen interfaces and software, and the difficulties individuals with cognitive disability face in learning to use new technologies (W. J. Lynch, 1992) (Levine, Horstmann, & Kirsch, 1992) (O'Connell, Mateer, & Kerns, 2003). Instructional design theory and lessons learned from research into diffusion of innovations can inform training decisions to make handheld computers more user-friendly and useful for individuals with cognitive impairment.

Towards an Assistive Technology Training Model for Individuals with Cognitive Disability

Instructional Design Approach: Theoretical Basis

Most instructional design models are based on General Systems Theory (GST), which, as applied to instruction, posits four primary activities: (1) determining what is to be taught; (2) determining how it is to be taught; (3) conducting a trial and revision (known as “formative evaluation”); and (4) assessing whether learning was achieved (known as “summative evaluation”) (Seels, 1995).

Within this overarching model exist many instructional design variants, but all focus on achieving improved functional performance of a training task by a trainee. In order to achieve that goal, instructional designers first conduct a needs analysis, seeking to assess: (1) the elements of functional performance required (goal analysis), (2) the inherent capabilities and skills of learners (entry behaviors), (3) the environmental affordances and constraints available within a particular performance context (environmental assessment), and (4) the tools needed for training and task performance (Mager, 1997). Typically, the generation of performance goals and the development of instructional design and assessment measures follow the needs analysis process. Assessment may be ongoing (formative) during instruction or occur at the completion of instruction (summative), and in many cases both assessment measures are recommended. With a few special considerations, this instructional design model may prove useful in developing a training protocol for computers used as ATC. In order to

train individuals with cognitive impairment to use any assistive technology, special attention must be paid to entry behaviors and environmental considerations. An assessment of basic computer literacy is important, of course, to determine an individual's comfort level with desktop and handheld platforms.

Additionally, individuals may have developed quite sophisticated repertoires of compensatory strategies to cope with cognitive difficulties, and learning how and whether these strategies have been helpful may provide insight into ways that the ATC intervention may best be implemented. At the same time, many individuals will have come to depend on caregivers or other support personnel to manage the demands of everyday life, and it is important to recognize their role and incorporate their assistance in making the assistive technology intervention successful.

Cognitive impairment may involve difficulties with attention, sensory processing, concentration, memory and the learning of new material, which requires the instructional designer to utilize instructional strategies that compensate for these difficulties. Individuals with cognitive impairment may also have difficulty transferring learning from one setting or situation to another, so training within the learner's actual practice context and environment can be crucial (Parente & Herrmann, 1996).

Sohlberg and Mateer (1989) have reported on a method used to train individuals with cognitive impairment to manage a daily memory log. Repetition of instruction, repetitive role-play to demonstrate use of the memory log and to assess how well the individual has learned each step, and "community training

allowing further notebook practice in naturalistic settings” were seen to compensate for cognitive difficulties in many patients. One might consider adding the provision of training materials in verbal, written and iconic formats, in addition to hands-on practice with the assistive technology tool, in order to capitalize upon preserved strengths in a particular learning style (Dunn & Griggs, 2000).

Formative assessment may be conducted through review of hands-on practice with the assistive technology device, by logging actual usage over time, and by questioning the user and/or caregiver about possible difficulties in using the device. If the training goal is to improve functional performance in everyday life tasks (which is the case with most assistive technology implementations), then it may be helpful to utilize standardized assessment measures that examine this construct.

An instructional designer must bear in mind, however, that every individual with cognitive impairment forms a “universe of one”, with individualized strengths and weaknesses that require personalized adaptation of the training model. Formative assessment and flexibility in training are essential components of any work with these individuals.

At this time there is no training model in place for computer-based assistive technology. These considerations, founded in instructional design theory, may provide waypoints in the development of such a model.

Lessons Learned from "Diffusion of Innovations" Theory

The use of assistive technology typically requires an individual with a disability to learn first how to operate a new and unfamiliar piece of equipment, in order to improve functional performance in everyday life tasks. Research into the "diffusion of innovations" process has shown that individuals are more likely to adopt a new technology if they can be shown that it: (1) is compatible with their needs and values, (2) is not too different from the technology they use now, (3) is not too complex, (4) is available for trial before committing to its use, and (5) is used by other individuals in the community (Rogers, 2005). These considerations may be crucial, when one considers that one-third of all assistive technology devices are abandoned (Scherer, 1996).

The personality characteristics of an individual may play a role in adoption of an assistive technology as well. Successful adopters have been characterized as: (1) desirous of change in what they can do, (2) self-disciplined, (3) proud to use the device, and (4) willing to use the tool in everyday routines (Kintsch & DePaula, 2003). The role of assistive technology provider may be significant too. These change agents must be willing to invest time in training, to facilitate a collaborative rather than directive process in helping a user incorporate the device into his or her everyday routine, and offer follow-along support as needed when difficulties arise (Kintsch & DePaula, 2003; O'Connell et al., 2003). All of these considerations play a role in the success or failure of any assistive technology intervention, and should be accounted for in research methodology and in the development of a clinical practice model.

The Need for a Clinical Practice Model that can Flex with the Evolution of Technological Innovations

Change is the only constant in the world of technology, and clinicians need practice models that are not chained to particular devices in order to adapt their work to ongoing technological innovation. As this discussion has shown, a clinical practice that seeks to flex with change must be based on: (1) a professional grounding in rehabilitation; (2) a sound analysis of an individual client's strengths and weaknesses, and the environmental and task context in which the client lives; (3) an understanding of instructional design principles founded on professional practice, learning theory and lessons learned from "diffusion of innovations" research; and (4) an awareness of relevant, ecologically valid research into technologies that may be appropriate for each individual client. These characteristics, while daunting, may lead to development of assessment and training protocols that are client-centered, outcomes-based and focused on process rather than device, allowing these protocols to flex with technological innovation.

Assistive Technology for Cognition for Individuals with Multiple Sclerosis

As the literature review in this chapter explains, there is a growing body of research and development investigating the use of computer-based assistive technology for cognition, but there are many gaps in that research, which make it difficult for a clinician to know how to proceed. The literature in most cases is "device-specific", and most of the devices under consideration are either

outmoded, no longer available, or attached to large university-based research projects and not yet released to the public. Most of the research cited in this chapter describes anecdotal or subjective outcomes based on clinic-situated case studies that are not ecologically valid.

Clinicians and their clients need interventions that are available, affordable, readily implemented, and shown to be successful in real home and community settings. The technology they use must be simple to operate, durable and easy to maintain. Assessment and training interventions must be based on "best practice" models that have been shown effective with individuals who have cognitive disability. At this point, the literature fails to provide direction in these areas.

With these considerations in mind, the research project proposed herein seeks to address four glaring shortcomings in the literature: (1) no reported research on assistive technology interventions for individuals with cognitive impairment related to multiple sclerosis; (2) no reported research on inexpensive, consumer-based PDAs as cognitive aids, despite their popularity for over a decade as organization tools in the general population; (3) a paucity of ecologically valid research on the use of any assistive technology for cognition with any population; and (4) a need for research that utilizes an assessment and training protocol based on sound academic theory. Chapter Three describes the proposed research and its methodology.

CHAPTER THREE

RESEARCH METHODOLOGY

Introduction

The purpose of this study is to evaluate whether individuals with cognitive impairment related to multiple sclerosis, who are trained in the use of handheld computers as cognitive aids, can learn to operate them and in doing so regain functional independence in everyday tasks. This section includes pertinent information regarding the statistical analysis of the outcome data and descriptions of the study's participants, measures, and procedures.

Approval

The Human Investigations Committee for the Health Sciences of the University of Virginia approved this study and the Informed Consent form. A copy of the approval letter and the Informed Consent form is included in the Appendix.

Design Rationale

As outlined in Chapter Two, the usefulness of cognitive rehabilitation continues to spark lively debate, and clinicians repeatedly call for “more evidence-based work to further define and tailor cost-effective cognitive rehabilitation interventions” (Ricker, 1998) and to “develop research programs that actually test new interventions within community settings” (LoPresti et al., 2004). The authors of an influential meta-analysis of cognitive rehabilitation research recommended that clinical practice:

“should reflect meaningful improvements and functional outcomes such as the use of compensatory strategies to accomplish real-life demands, performance on everyday activities in the person’s home or community, changes in level of productivity, and measures of subjective well-being” (Cicerone et al., 2000).

This study is designed to follow those guidelines. The study design incorporates recommended practices from instructional design and physical rehabilitation theory, including:

- (1) a home-based intervention, intended to maximize transfer of learning to the participant’s environment;
- (2) the use of a consumer-level PDA as a compensatory cognitive aid, to minimize social stigma associated with using an assistive technology;
- (3) a training protocol that addresses various learning style strengths, by including verbal instruction, written instruction, hands-on demonstration and supervised practice;

(4) use of a step-wise training method that builds on learning through repetition of teaching and practice, coupled with graduated new challenges;

(5) a focus on using the PDA to address a participant's self-generated goals in home and community settings; and

(6) updated design elements based on formative evaluations conducted during a previous pilot study.

As noted below, the assessment tools used in this study measured: (1) behavioral memory, (2) change in functional performance of everyday tasks and satisfaction with functional performance at four time-points, (3) change in level of handicap at four time points, (4) actual usage of the device during everyday activities, and (5) participants' subjective experiences in the study. These measures have been chosen to focus on ecologically valid change associated with the intervention.

By incorporating these design elements, the study was intended to answer the recommendations for cognitive rehabilitation research made by the research panels just quoted, while providing a valid compensatory treatment for cognitive disability related to multiple sclerosis.

Study Design

This mixed methods repeated measures study utilizes an A-B-C design, where A represents an 8-week non-treatment phase, B represents a 4-week

treatment phase in which a PDA is introduced and training in its use is provided, and C represents an 8-week post-training phase in which participants are asked to use their PDAs to assist in managing everyday life tasks. Another way of describing this design is as a one-group pre-test post-test model with a double pre-test and a double post-test (Shadish, Cook, & Campbell, 2002).

Because the study concerns the measurement of performance trends over time, this repeated measures design is especially appropriate. This design allows for comparison of participant change on the study's assessment measures during non-treatment, with-treatment and post-treatment periods. Additionally, by adding tests on either end of the intervention, the plausibility of threats to validity based on maturation, instrumentation and regression is reduced (Myers, 1966a). The second pre-test, which allows a measurement of functional change during an 8-week pre-treatment period, constitutes a "dry-run" to clarify the biases that might exist in estimating the effect of treatment (Shadish et al., 2002), while the second post-test provides an opportunity to examine whether there is a "carryover effect" in improved functional performance by participants using the handheld computer independently once the training period ends (Myers, 1966a).

Determination of Variables

The main dependent variable in this study is "functional independence in everyday tasks." An "everyday task" might be defined as any activity an individual may wish or need to perform as a part of his/her daily life, and may

include basic activities of daily living such as eating, bathing and dressing, instrumental activities of daily living, such as housekeeping, money management and shopping, and the complex interactions involved in community, school and job settings. Leisure and social activities are important adjunctive everyday tasks. "Functional independence" is a term used by rehabilitation practitioners to denote the ability to perform a particular task without human assistance. Because everyday tasks vary widely among different individuals, this study utilizes a functional independence measurement tool, the Canadian Occupational Performance Measure" (COPM) that allows for such variety. The COPM asks each participant to self-identify areas of functional disability, which can then be addressed by a rehabilitative intervention.

Other pertinent dependent variables include "level of handicap" and "behavioral memory". "Level of handicap" is a construct that looks at functional independence from a different perspective, examining how much impact a disabling condition has on engagement in everyday occupational and social activities, and how much caregiver support is required by the participant. The primary assessment tool used to measure this construct in the current study, the Craig Handicap Assessment and Rating Technique (CHART), offers a list of generic everyday tasks addressing areas of functional activity. These include: (1) self-care, (2) physical mobility, (3) cognition, (4) occupation, (5) social relations

and (6) economic resources.¹ The tool requires a participant to circle choices on Likert-scaled questions that list how much human assistance the participant needs to complete various tasks in each category. Level of handicap is an important indicator of the success of any rehabilitative intervention, in that caregiver burden can be enormous among families beset by multiple sclerosis, and any treatment that offers relief from this burden is always welcome.

Behavioral memory is a construct that can be measured on a standardized test, and re-measured post treatment. It includes elements of prospective memory, immediate and delayed recall, concentration, divided attention, auditory and visual memory and time/place orientation. Each of these cognitive functions is key to success in everyday task performance, and the assessment tool used in this study, the Rivermead Behavioral Memory Test - Extended (RBMT-E), is designed to simulate the function of behavioral memory in everyday activities. For instance, a task on the RBMT-E asks the participant to watch where the test giver places a pair of objects within the testing room, then later requires the participant to recover those objects when an alarm sounds, thus testing delayed recall and prospective memory in a task that simulates everyday activity.

The independent variables in this study are (1) introduction of a PDA to an individual with cognitive impairment related to multiple sclerosis, (2) a specific training program intended to teach the individual to use the PDA as a cognitive aid and (3) routine use of the PDA by this individual in everyday life tasks over a

¹ This study will not include the "economic resources" sub-test. This sub-test asks participants to provide an estimate of household income and an estimate of annual medical costs. The investigator feels that these questions are unnecessarily intrusive and not particularly useful for this study's purposes.

period of four weeks after the training is completed. The Functional Assessment Tool for Cognitive Assistive Technology (FATCAT) will be used to measure retention of training, routine use of the PDA during the post-training period and qualitative measures of participant satisfaction with the intervention.

Participants

Selection

This study was designed to recruit twenty individuals with cognitive impairment related to multiple sclerosis. Participants were not selected for age or gender, though M.S. typically does not occur in individuals under age 18 and attacks more females than males. All participants were required to have functional cognitive impairment as measured on the assessment instruments used in the study.² Additionally, participants needed to be community dwelling, to have functional corrected vision and to have eye-hand coordination sufficient to manipulate a portable computer interface using a stylus. They also needed to demonstrate the capacity to respond to an electronic audio, visual or vibration reminder alarm. Participants were recruited with fliers provided to the University of Virginia's multiple sclerosis clinic in Charlottesville and with an ad in the *M.S. Newsletter* of the Blue Ridge Multiple Sclerosis Society. All participants were

² Participants self-identified as having cognitive impairment, rated the relative importance of their cognitive impairment to their other M.S. related difficulties on the study's demographic sheet, and listed functional difficulties on the COPM. The CHART assessment includes a cognitive sub-test (see Appendix H) and the RBMT-E provides a profile score that rates level of cognitive impairment as compared to a control group (see Appendix G).

volunteers. Participants were allowed to keep the PDAs provided during the study. This was their only compensation.

Twenty-one individuals who met study criteria applied to participate in the study, and all were accepted and signed consents. One person dropped out prior to the intervention phase, because her responsibilities changed at home, and she did not feel that she would be able to commit her time to participating in the project. Information from this individual's initial assessment has not been included in analyzing the study results. The other twenty participants completed the study. Their characteristics were as follows (see Appendix C):

Sixteen participants were women, four were men, a gender ratio that is slightly higher than the gender frequency of M.S. incidence in the general population.³ Their ages ranged from 37-73 (median 50). Only one participant was African-American; the rest were Caucasian.⁴ Only two (aged 69 and 73) were past retirement age, yet all but one had retired from full-time jobs. Those below age 65 said that M.S. symptoms had forced early retirement. During the course of the study, the only individual who held a full-time job was fired.⁵ Three participants continued to hold part-time employment in home-based businesses.

³ In the general population, it is estimated that the female to male ratio for individuals with M.S. is 2.5:1 (Burks and Johnson, 2000).

⁴ M.S. racial prevalence in the U.S. has been most recently estimated as 51% Caucasian, 26% African-American and 23% all other races/ethnicities (Noonan, Kathman, & White, 2002).

⁵ This participant's employer had previously refused requests for accommodations related to her cognitive difficulties (a less distracting work environment, for instance) and cited lack of organization and forgetfulness as two reasons for discharging her during the pre-treatment period of this study.

Fifteen participants were married (13) or lived with significant others (2), three were single, one was divorced and one was widowed. Date of diagnosis with M.S. ranged from 1965 to 2003 (median date 1994). Thirteen participants had relapsing-remitting M.S., three had primary progressive M.S., three had secondary progressive M.S. and one had chronic progressive M.S.⁶ Twelve participants were taking a prescribed, injected, immuno-modulatory medication, eight were not.

Participants were asked to rank how much common M.S. symptoms affected their performance of everyday tasks. As shown in Table 1, all ranked cognitive problems as either their most important (11 participants) or second most important (9 participants) symptom.

⁶ Disease type population distribution in the U.S. is estimated at 85% relapsing-remitting, 15% secondary progressive and 5% primary or chronic progressive (Burks and Johnson, 2000).

Table 1
Self-Ranking of M.S. Symptom Importance

| Symptom | Most important | 2 nd most important | 3 rd most important | 4 th most important |
|-----------|----------------|--------------------------------------|-----------------------------------|--------------------------------------|
| Fatigue | 7 | 11 | 2 | 0 |
| Cognition | 11 | 9 | 0 | 0 |
| Pain | 0 | 0 | 8 | 11 |
| Mobility | 2 | 0 | 10 | 8 |
| Other | 0 | 0 | 0 | 1 (depression) |

Note: Total number of participants ranked in each category.

The demographic sheet also asked participants to list cognitive strategies or aids that they currently used. Table 2 lists these strategies and aids, along with the sum of participants using each one.

Table 2

Cognitive Strategies or Aids Used Prior to the Study

| Strategies or Aids | Users |
|-----------------------|-------|
| Sticky notes | 7 |
| Pocket calendar | 7 |
| Wall calendar | 6 |
| Lists | 3 |
| Write things down | 3 |
| Have people remind me | 3 |
| Pill organizer | 2 |
| Computer | 1 |
| Kitchen timer | 1 |
| PDA ^a | 1 |

Notes: Table shows number of participants using each strategy (some participants listed more than one).

^a Participant no longer uses this device, because it has a monochrome screen that "is too hard to read" and she "never got the hang of using it".

The demographic sheet also asked participants to list their competence in using computer equipment. All participants had a home computer and all but one knew how to use it to compose and print documents, send e-mail and browse the Internet. Five managed digital photographs on the computer. One participant also knew how to create basic web pages.

Description of the Setting

All assessment and training interventions were conducted in the homes of the participants.

Measures

Assessment tools include:

Demographic Survey Tool. This instrument (as noted above) captures demographic information about each participant, including age, race, type of M.S., year diagnosed, primary medications, relative severity of cognitive impairment in relation to other M.S. symptoms, occupation and presence of caregiver.

Rivermead Behavioral Memory Test – Extended (RBMT-E). A widely used test of everyday memory, the RBMT-E “was developed to detect impairment of everyday memory functioning and to monitor change following treatment for memory difficulties” (B. Wilson, Cockburn, & Baddelay, 1991). The test includes items assessing orientation, immediate and delayed recall, prospective

and sequential memory, visual and auditory memory, and name/face recognition. The RBMT-E provides a raw score (range 0-157) and a standardized profile score (range 0-48). The profile score is necessary to properly weight sub-test scores that may vary widely on the raw score rating. This allows for comparison across items of the test. The RBMT-E is often used as a correlative test for validity of other cognitive assessments. Convergent validity has been demonstrated with the WAIS and Warrington tests of intellectual functioning (Cockburn, Wilson, Baddelay, & Hiorns, 1990), and validity, parallel form, and inter-rater reliability were proven to be high in a test matching 176 individuals with brain injury to 118 control subjects (B. Wilson, et al., 1989). Example item: Face recognition: 10 post card-sized black and white photographs of various faces are shown. A second item is conducted. 20 photographs are shown, including those previously shown and additional photographs. Score is kept on recognizing photographs initially shown.

Canadian Occupational Performance Measure (COPM) A semi-structured interview assessment, the COPM is used across disability categories by occupational therapists. Test-retest reliability has been rated at 0.89, and internal consistency at 0.71 (Bosch, 1995). Researchers have demonstrated criterion validity in comparison with "spontaneous client-identified problems" and construct validity in comparison with the Satisfaction with Performance Scaled Questionnaire (SPSQ) and the Reintegration to Normal Living and Life Satisfaction Scale (McColl, Paterson, Davies, Doubt, & Law, 2000). A pair of

studies support convergent and divergent validity of the COPM (Dedding, Cardol, Eyssen, Dekker, & Beelen, 2004) (Polgar & Barlow, 2002).

The COPM is a unique client-centered instrument, in that it allows a participant to determine his/her own areas of need, providing information that cannot be obtained with other standardized health measurements. Each participant self-determines five areas of disability in everyday life tasks, rating performance and satisfaction on a 1 to 10 scale. Scores are averaged by the rater. On follow-up, the participant reviews these items and self-determines his/her current rating after treatment. Average scores on initial and follow-up assessments may then be compared.

Craig Handicap Assessment and Reporting Technique (CHART). This interview tool assesses handicap across areas of everyday function. Items focus on objectively observable behaviors that are unlikely to be open to subjective interpretation. Based on the World Health Organization's model of handicap, the CHART investigates levels of human assistance required for the six WHO domains: (1) physical independence, (2) cognitive independence, (3) mobility, (4) occupation, (5) social integration and (6) economic self-sufficiency. In each category possible scores range from 0 to 100. A non-disabled individual would be expected to score 100 on each of the subscales. Scores can be calculated for subscales or averaged for a total score. Five studies support the CHART as a reliable and valid instrument for measuring level of handicap (Segal & Schall, 1995a) (Dijkers, 1991) (Hall, Dijkers, Whiteneck, Brooks, & Krause, 1998) (Segal & Schall, 1995b) (Whiteneck, Charlifue, Gerhart, Overholser, &

Richardson, 1992). Example item: How much time is someone in your home to assist you with activities that require remembering, decision making, or judgment? ☐ Someone else is always with me to observe or supervise. ☐ Someone else is always around, but they only check on me now and then. ☐ Sometimes I am left alone for an hour or two. ☐ Sometimes I am left alone for most of the day. ☐ I have been left alone all day and night, but someone checks in on me. ☐ I am left alone without anyone checking on me.

Functional Assessment Tool for Cognitive Assistive Technology

(FATCAT). I designed the FATCAT as a post-treatment Likert-scaled questionnaire to assess participant satisfaction with the intervention, and as a checklist for assessment of how well participants could demonstrate use of a PDA's functions, and how many entries participants logged on their handheld computers. As such the tool examines retention of training, everyday use of the PDA, and likelihood of participants continuing to utilize the device after the study's conclusion. Short answer questions allowed me to glean qualitative information regarding participants' satisfaction with the intervention. Reliability and validity measures for this new instrument have not been established.

Materials

I provided the participants with Palm Zire 31 personal digital assistants (PDA's). As noted above, I downloaded "Palm Desktop" backup software to the participants' home computers. All verbal and demonstration instruction was supported by written material offering step-by-step guidelines for each PDA function. I provided these guidelines to each participant in notebook form.

Procedures

Initial Assessment

I assessed the 21 volunteers for participation in the study during an interview in each volunteer's home. During this interview, each volunteer signed a consent form and completed a demographic information checklist. I conducted assessment instruments, including the RBMT-E, the COPM and the CHART, examining whether the volunteers met the entrance criteria described earlier in this chapter. As noted, all 21 volunteers met entry criteria. One volunteer dropped out during the pre-treatment phase and her assessment information was not included in the study analysis.

Non-Treatment Phase

For a period of eight weeks following enrollment in the study, participants received no intervention. At the end of this period, I scheduled a follow-up assessment visit during which the COPM and CHART were again conducted. I compared scores on these tests with initial assessment scores to determine whether there had been a significant mean change in everyday task performance and handicap during the non-treatment phase.

Training Phase

Following re-test, I provided each participant with a Palm Zire 31 PDA for use during the study and installed Palm Desktop software on the participant's home computer. Palm Desktop software allowed users to enter calendar, contact, memo and other information using the computer keyboard, downloading this information to the PDA via a USB-link. The software also allowed each user to back-up handheld information to his/her home computer for safe-keeping.

Training in the use of a PDA was conducted during two one-hour home visits scheduled over no more than a one-week period, at the participant's convenience. Participants were trained to make calendar entries, to create alarm reminders, to enter address book information, to use the "Palm Notes" electronic sticky note program, and to operate the Tasks (to do list) program, as these are the handheld tools designed to assist users with memory and organization tasks.

Participants were also trained to operate these programs using the Palm Desktop interface, and to conduct a "hot-sync" information transfer between their home computers and their PDAs. I then asked participants to use the devices at their own discretion to help manage everyday activities. I encouraged them to transcribe information from other organization tools -- such as day minder notebooks, address books and sticky notes -- to the PDA, in order to consolidate this information in one handy location.

Though all participants were cognitively impaired, their cognitive skills and functional needs varied. As noted below, I provided all participants with a multi-modal training intervention intended to capitalize on preserved cognitive strengths, though it is possible that some participants did not need so much reinforcement in order to learn how to use a PDA. Participants rated their functional difficulties on the COPM, which allowed me to adapt their training to their individual needs. Participants who noted difficulty in taking medications on schedule, for instance, were instructed to schedule reminder alarms for their medication routine. Those who forgot passwords and phone numbers were encouraged to add them into the appropriate PDA programs, while those who noted difficulty with multi-tasking were encouraged to schedule activities in the PDA's Task program.

Because short-term memory, retention and new learning ability are often compromised in individuals with cognitive impairment, training was conducted using four modalities: (1) verbal instruction, (2) hands-on demonstration, (3) written instructions and (4) supervised trial. Participants were asked to

demonstrate successful performance of each task, and written materials were provided to supplement verbal training. On subsequent visits, review of initially trained materials preceded training of new material. I asked participants to demonstrate independent performance of previously trained tasks, and examined their PDAs for information entered as homework in previous sessions. Review and repetition of training was implemented throughout the training sessions to assure competence in using the PDA as a memory and organization tool.

Following the initial two training sessions, I scheduled one-hour follow-up home visits weekly for two weeks, to reinforce training and trouble-shoot any difficulties that might arise. During each visit, I asked participants to demonstrate successful performance of information entry tasks on the PDA, and recorded this information on a data sheet. I also recorded how many entries for each of the Palm programs had been entered in the past week and provided additional training as needed.

On the second follow-up visit, I again conducted COPM and CHART assessment measures.

Post-Training Phase

After the second follow-up visit, I did not contact participants for a period of eight weeks. This period constituted the post-training phase of the intervention, during which participants were asked to continue using their PDAs to help manage everyday life tasks. During this phase, participants were free to contact me via telephone or email for help with the devices, if necessary. At the

end of the eight-week period, I returned for a final assessment visit. During this visit, all initial assessment instruments were conducted again (RBMT-E, COPM and CHART) and a fourth instrument, the Functional Assessment Tool for Cognitive Assistive Technology (FATCAT) was conducted. This visit concluded the participants' involvement in the study. They were allowed to keep the devices used. Table 3 shows the timetable for assessment measures conducted during the study.

Table 3

Timetable for Assessments

| Time | Intervention |
|-------------|--|
| Week One | Consent and Initial Assessment (Demographic Survey Form, RBMT-E, COPM, CHART, demographic sheet) |
| Week Nine | Pre-Training Assessment (COPM, CHART) |
| Week Twelve | Post-Training Assessment (COPM, CHART) |
| Week Twenty | Post-Intervention Assessment (RBMT-E, COPM, CHART, FATCAT) |

Statistical Analysis

The three primary assessment tools used in the study – the RBMT-E, COPM and CHART – provide scores that can be compared across successive administrations, in order to test the study hypotheses. This data was entered into SPSS v. 11 for Mac statistical analysis software and the following calculations were conducted:

RBMT-E: A mean of all scores from participants was calculated for each of the two administrations of this test and a paired samples t-test (significance $p < .05$) was used to assess change on this test before and after treatment. It was hypothesized that there would be no statistically significant change in RBMT-E scores, since the intervention did not impact organic thinking skills, but rather

sought to impact functional performance through compensation for impaired thinking skills. Utilized in this way, change in scores on the RBMT-E serves as a “non-equivalent dependent variable,” which may reduce threats to internal validity (Shadish et al., 2002).

COPM: A mean of all scores from participants was calculated for each of the four administrations of this test, and a repeated-measures ANOVA (significance $p < .05$) was used to compare change on this tool across test administrations. Mauchley’s chi-square derived test was used to determine whether the assumption of sphericity had been violated, and, if so, provided a corrected F-statistic.⁷ It was hypothesized that there would be a statistically significant change recorded on the main ANOVA. It was hypothesized that additional corrected t-tests would show no statistically significant change in COPM scores during the non-treatment phase of the study, but a significant change in COPM scores during the training phase, which would carry over during the post-training phase.

CHART: A mean of all scores from participants was calculated for each of the four administrations of this test, and a repeated-measures ANOVA (significance $p < .05$) was used to compare change on this tool across test administrations. As with the COPM scores, Mauchley’s test was used to determine whether the assumption of sphericity had been violated, and, if so, a

⁷ In repeated measures design, there is a necessary relationship between scores in different treatment conditions (since the same participants are taking the tests successively). In calculating a repeated measures ANOVA, we must assume that the relationship between pairs of experimental conditions is similar. This is known as the “assumption of sphericity”.

corrected F-statistic was used. If the main ANOVA showed a significant difference in scores across administrations, two-tailed t-tests were conducted among mean CHART scores on the four assessment levels, in order to examine where functional change occurred during the study. It was hypothesized that there would be a statistically significant change in the corrected main ANOVA ($p < .05$) across test administrations, that subsequent corrected t-tests would show no statistically significant change in scores during the pre-treatment period, but a significant change during the training period that would carryover during the post-training phase.

Because the CHART records sub-scores on changes in function related to physical independence, cognitive independence, mobility, occupation, social integration and economic status, mean changes were measured within these categories and paired t-test calculations comparing pre-training and post-training levels were made on each category of sub-score in order to determine which sub-scores, if any, showed significant change during the study. This procedure was intended to allow a more focused analysis of the factors most impacted by the intervention.

FATCAT: This tool records both quantitative and qualitative data. The most salient quantitative data was expected to be the record of each participant's actual weekly use of the PDA, as measured by examining weekly data entries on the device's calendar/alarm software. Participants who entered weekly data into the programs on which they were trained could be said to have learned how to use those programs independently. This information was expected to inform

discussion of the study's Hypotheses One, Two and Three and serve as a measure of treatment fidelity.⁸ Treatment fidelity was also measured on the FATCAT by the recording of how well participants demonstrated use of the PDA, as trained, on post-treatment assessment.

Additional FATCAT data was analyzed using qualitative analysis procedures, in order to determine the satisfaction of participants with the training intervention, their sense of the PDA's usefulness as a cognitive aid, whether they expected to continue using the PDA after the study ended, and what additional capabilities or affordances they would have liked the PDA to have. These data contributed to an examination of the study's strengths and limitations, and to a discussion of future research possibilities.

Organization of the Remainder of the Paper

This chapter has explained the methods used in this quasi-experimental study to determine whether individuals with cognitive impairment related to multiple sclerosis can learn to use handheld computers as assistive technology and whether such devices can improve their functional performance in everyday tasks. Chapter Four will provide a report of the statistical findings from this study and

⁸ "Treatment fidelity" refers to methodological strategies used to monitor and enhance the reliability and validity of behavioral interventions. In this study, participants who used the handheld computers as trained provided evidence that the training worked for them, and that the behavioral intervention was useful, thus supporting treatment fidelity.

an analysis of those findings. Chapter Five will provide a summarizing discussion, conclusions and implications drawn from the study.

CHAPTER FOUR

RESULTS

The primary purposes of this study were to determine if individuals with cognitive impairment related to multiple sclerosis could be trained to use a handheld computer, if they could use this device to improve their functional performance of everyday life tasks, and if they could sustain use of the device for this purpose long-term. Specifically, this was evaluated using a repeated-measures design across four time points, using assessment tools that included the Canadian Occupational Performance Measure (COPM) and the Craig Handicap Assessment and Rating Technique (CHART). Additionally, a non-equivalent dependent variable, behavioral memory, was assessed using the Rivermead Behavioral Memory Test – Extended (RBMT-E), with scores compared from initial and final visits. A qualitative research tool, the Functional Assessment Tool for Cognitive Assistive Technology (FATCAT) was utilized to capture information about actual usage of a handheld computer, life events, and qualitative information concerning participant perceptions about the study.

Twenty volunteer participants completed all study procedures. A table of demographic measures for each participant is listed in Appendix C. Statistical analyses of study measures used to test the study questions are described in the following sections.

Learning to Operate a Handheld Computer

The study's first hypothesis is that "individuals with cognitive impairment related to multiple sclerosis can learn to independently operate calendar, notepad, memo and contact functions on a handheld computer." This hypothesis was tested by providing each participant with a PDA, training him/her in its use as described in Chapter 3, and by asking each participant to demonstrate independent operation of the device after the training was completed. Table 4 provides the results of this assessment measured one and two weeks after initial training (during the follow-up phase of training).

As Table 4 shows, all participants demonstrated the ability to independently make calendar entries, set alarms and repeating event reminders, and enter contacts and memos on their PDAs one week after the completion of training. Two weeks after the completion of training, these tasks could be performed by all participants either independently (18-20 participants), after a single verbal cue (0-1 participants) or after a demonstration by me (1 participant).

Participants had the most trouble remembering how to operate the Note Pad alarm feature, which, as Appendix I shows, was not frequently used. Nevertheless, fifteen participants were able to independently demonstrate this feature one week after training was completed and sixteen were able to do so two weeks after training. This finding suggests a need for more thorough training in the use of the Note Pad alarm or a lack of interest by participants in using that

feature, in that it can be inferred that repetition of use reinforced participants' performance with more frequently utilized programs.

As Table 4 shows, however, the training intervention was a success, as assessed by the ability of participants to demonstrate most features on the PDA independently two weeks after the completion of training.

Table 4

Ability of Participants to Perform PDA tasks one week and two weeks after completion of training

| Task | Independent | | Verbal Cue | | Demonstration | |
|----------------------------|-------------|---------|------------|---------|---------------|---------|
| | 1 week | 2 weeks | 1 week | 2 weeks | 1 week | 2 weeks |
| Calendar entry | 20 | 19 | 0 | 1 | 0 | 0 |
| Set calendar alarm | 20 | 18 | 0 | 2 | 0 | 0 |
| Set repeating event | 20 | 18 | 0 | 2 | 0 | 0 |
| Enter note | 19 | 20 | 1 | 0 | 0 | 0 |
| Set note alarm | 15 | 16 | 3 | 3 | 2 | 1 |
| Enter contact | 20 | 20 | 0 | 0 | 0 | 0 |
| Enter memo | 20 | 19 | 0 | 0 | 0 | 1 |
| Hot-sync to pc | 20 | 19 | 0 | 1 | 0 | 0 |
| Desktop calendar entry | 19 | 19 | 0 | 0 | 1 | 1 |
| Set desktop calendar alarm | 19 | 20 | 1 | 0 | 0 | 0 |
| Enter contact on desktop | 20 | 19 | 0 | 1 | 0 | 0 |

Notes: On each demonstration task, participants were rated: (1) independent, (2) requiring a verbal cue from trainer in order to perform task, or (3) requiring a hands-on demonstration by trainer in order to perform task. The table offers the total number of participants demonstrating performance at each level.

Long-Term Learning Retention

The study sought to determine whether training in the use of PDA would be retained long-term. In order to test this question, participants were asked to use their devices at their own discretion for eight weeks after training ended, and then were asked to demonstrate how to operate the device at the end of that period. Table 5 provides the results of this assessment.

As Table 5 shows, 95% of participants were able to demonstrate independent entry of Calendar, Contact and Memo messages, 90% independently entered Notes and downloaded ("Hot-sync") data to their home computer, and 85% independently set reminder alarms, repeating calendar events and Palm desktop Calendar alarms eight weeks after the completion of training. One participant required a demonstration by me to perform most functions.⁹

The second hypothesis is further supported by an accounting of actual handheld computer usage during the eight weeks following the training intervention (see Appendix I). Mean usage of most programs on which the participants had been trained increased week-to-week (and mean usage of all programs increased from Week One to Week Eight), showing that participants were using their devices more frequently as time went on. Table 6 provides descriptive statistics for participant use of PDAs during the eighth week after training.

⁹ This participant's retention of learning stands in contrast to the others, and as such deserves discussion in that he may represent a low-level cohort that does not respond to the intervention. His case is discussed more fully in Chapter Five.

Table 5

Ability of Participants to Perform PDA Tasks Eight Weeks after Completion of Training

| Task | Independent | Verbal Cue | Demonstration |
|----------------------------|-------------|------------|---------------|
| Calendar entry | 19 | 0 | 1 |
| Set calendar alarm | 17 | 2 | 1 |
| Set repeating event | 17 | 2 | 1 |
| Enter note | 18 | 2 | 0 |
| Set note alarm | 10 | 8 | 2 |
| Enter contact | 19 | 1 | 0 |
| Enter memo | 19 | 0 | 1 |
| Hot-sync to computer | 18 | 2 | 0 |
| Open Palm desktop | 19 | 1 | 0 |
| Desktop calendar entry | 19 | 1 | 0 |
| Set desktop calendar alarm | 17 | 2 | 1 |
| Enter contact on desktop | 19 | 0 | 1 |

Notes: On each demonstration task, participants were rated: (1) independent, (2) requiring a verbal cue from trainer in order to perform task, or (3) requiring a hands-on demonstration by trainer in order to perform task. The table offers the total number of participants demonstrating performance at each level.

Table 6

Participant Entries on Handheld Software, Week 8

| Program | N | Range | Min. | Max. | Mean | St. Dev. |
|----------------|----|-------|------|------|-------|----------|
| Reminder alarm | 20 | 187 | 3 | 190 | 35.05 | 40.94 |
| Calendar | 20 | 215 | 3 | 218 | 39.80 | 45.78 |
| Notepad | 20 | 16 | 0 | 16 | 2.55 | 3.80 |
| Contacts | 20 | 81 | 8 | 89 | 36.35 | 22.54 |
| Memos | 20 | 20 | 0 | 20 | 2.00 | 4.36 |

As Table 6 shows, during the eighth week after training, mean entries for the various features on which participants had been trained were as follows: reminder alarm (35.05), Calendar (39.80), Contacts (36.35), Notepad (2.55) and Memo (2). Participant usage ranged widely (one participant averaged 27 reminder alarms per day, while another entered only three during the whole week), but all participants made Calendar, alarm reminder and Contact entries during that week, thus demonstrating retention of training. The Notepad and Memo functions were used less often during Week Eight. Discussion of FATCAT short answer findings in Appendix K further explores why this may have occurred.

Further support for retention of training comes from participant responses to FATCAT 5-point Likert-scaled questions asked eight weeks after the training

intervention (see Appendix J), in which participants strongly supported the statements, "I find the handheld computer simple to use" (4.80), "I am able to use the handheld computer without any help from another person" (4.75), "I found that I was able to respond to reminder alarms almost every time one rang" (4.15) and "I received enough training to use the device effectively for my purposes" (4.95).

Further support for retention of learning is provided by participant responses to the short answers section of the FATCAT (summarized in Appendix K). Five participants listed "ease of use" as their favorite feature of the PDAs, and most participants expressed surprise that such a brief training intervention and such a small device could impact their lives so powerfully. Nineteen participants wrote that they had made the PDAs part of their daily lives and planned to continue using them after the study ended. Three wrote variants on this response: "I don't know how I ever lived without it!"

Functional Performance Change Using a PDA

The study sought to determine whether using a handheld computer could improve participants' functional independence in performing everyday life tasks. The COPM and the FATCAT were used to address this question. The COPM, which tracks an individual's change in functional performance and satisfaction with functional performance across an intervention, was conducted at the four

time points for assessment in this study, and the FATCAT was conducted on final assessment.

On the COPM each study participant self-identified five functional deficits related to cognitive impairment that – upon examination -- fit twelve broad categories. As Appendix D shows, within those categories 55% of participants identified medication management, appointment management and remembering important events, 45% identified multi-tasking and dealing with distractions, 35% identified multi-step tasks and following through on plans, 30% identified staying focused on a project and remembering names and faces, 25% identified managing frustration and not losing things, and one participant (5%) identified performing routine self-care tasks as among their most important functional deficits.

As described in Chapter Three, participants score performance and satisfaction with performance on a 1-10 scale for each deficit they describe, and these scores are averaged in calculating total COPM performance and satisfaction with performance scores for each participant. In this way, the COPM provides two scores: (1) a functional performance score and (2) a satisfaction with performance score. These scores were generated at all four time points of the study. Table 7 provides descriptive statistics for the COPM performance scores. Table 8 provides descriptive statistics for the COPM satisfaction with performance scores. Table 9 presents the software-generated analysis of the repeated measures ANOVA for the COPM performance scores, and Table 10 presents the software-generated analysis of the repeated measures ANOVA for the COPM satisfaction with performance scores. Tables 9 and 10 include

calculations of significant change in overall scores with sphericity assumed, and as adjusted for violations of sphericity.

Table 11 provides paired t-test calculations for the COPM performance scores, corrected with the conservative Bonferroni adjustment. Table 12 provides paired t-test calculations for the COPM satisfaction with performance scores, corrected with the conservative Bonferroni adjustment.

Figure 1 shows a graphic representation of COPM performance score change across four levels of testing. Figure 2 shows a graphic representation of COPM satisfaction with performance score change across four levels of testing.

Table 7

COPM Performance Scores Descriptive Statistics

| COPM | Mean | Standard deviation | N |
|----------------------------|-------|--------------------|----|
| Performance Scores | | | |
| 8-weeks pre-training test | 3.272 | 1.434 | 20 |
| Pre-Training Test | 3.410 | 1.469 | 20 |
| Post-Training Test | 7.417 | 1.634 | 20 |
| 8-weeks post-training test | 7.077 | 1.695 | 20 |

Notes: COPM scores scaled 1-10 (1 = very poor performance, 10 = excellent performance)

Table 8

COPM Satisfaction with Performance Scores Descriptive Statistics

| COPM | Mean | Standard deviation | N |
|----------------------------|-------|--------------------|----|
| Satisfaction Scores | | | |
| 8-weeks pre-training test | 2.717 | 1.509 | 20 |
| Pre-Training Test | 2.860 | 1.433 | 20 |
| Post-Training Test | 7.295 | 1.749 | 20 |
| 8-weeks post-training test | 7.032 | 1.771 | 20 |

Notes: COPM scores scaled 1-10 (1 = very unsatisfied, 10 = very satisfied)

Table 9

Overall Repeated Measures ANOVA of COPM Performance Scores

| COPM | Type III Sum of Squares | Df | Mean Square | F | Observed Power ^a |
|--------------|-------------------------------|--------|----------------|-----------|--------------------------------|
| Sphericity | 306.521 | 3 | 102.174 | 96.023*** | 1.00 |
| assumed | | | | | |
| Greenhouse- | 306.521 | 1.113 | 275.426 | 96.023*** | 1.00 |
| Geisser | | | | | |
| Huyn-Feldt | 306.521 | 1.113 | 270.648 | 96.023*** | 1.00 |
| Lower-bound | 306.521 | 1.000 | 306.521 | 96.023*** | 1.00 |
| Error (COPM) | | | | | |
| Sphericity | 60.651 | 57 | 1.064 | | |
| assumed | | | | | |
| Greenhouse- | 60.651 | 21.145 | 2.868 | | |
| Geisser | | | | | |
| Huyn-Feldt | 60.651 | 21.518 | 2.819 | | |
| Lower-bound | 60.651 | 19.000 | 3.192 | | |

Notes:

^a Computed using alpha = .05

Adjustments for violation of sphericity: Greenhouse-Geisser and Huyn-Feldt

*** Significant at $p < .001$

Table 10

Overall Repeated Measures ANOVA of COPM Satisfaction with Performance Scores

| COPM Satisfaction | Type III Sum of Squares | Df | Mean Square | F | Observed Power ^a |
|----------------------------|-------------------------|--------|-------------|------------|-----------------------------|
| Sphericity assumed | 383.705 | 3 | 127.902 | 104.916*** | 1.00 |
| Greenhouse-Geisser | 383.705 | 1.118 | 343.156 | 104.916*** | 1.00 |
| Huyn-Feldt | 383.705 | 1.139 | 336.947 | 104.916*** | 1.00 |
| Lower-bound Error (COPM-S) | 383.705 | 1.000 | 383.705 | 104.916*** | 1.00 |
| Sphericity assumed | 69.488 | 57 | 1.219 | | |
| Greenhouse-Geisser | 69.488 | 21.245 | 3.271 | | |
| Huyn-Feldt | 69.488 | 21.637 | 3.212 | | |
| Lower-bound | 69.488 | 19.000 | 3.657 | | |

Notes:

^a Computed using alpha = .05

Adjustments for violations of sphericity: Greenhouse-Geisser and Huyn-Feldt

*** Significant at $p < .001$

Table 11

Pairwise t-tests for four levels of COPM Performance scores

| COPM | COPM | Mean difference | Standard error |
|------|------|-----------------|----------------|
| 1 | 2 | -.137 | .109 |
| | 3 | -4.145*** | .398 |
| | 4 | -.3.805*** | .399 |
| 2 | 1 | .137 | .109 |
| | 3 | -4.008*** | .390 |
| | 4 | -3.668*** | .389 |
| 3 | 1 | 4.145*** | .398 |
| | 2 | 4.008*** | .390 |
| | 4 | .340*** | .071 |
| 4 | 1 | 3.805*** | .399 |
| | 2 | 3.668*** | .389 |
| | 3 | -.340*** | .071 |

Notes: Scores based on estimated marginal means with Bonferroni adjustment for multiple comparisons.

*** significant at $p < .001$

Table 12

Pairwise t-tests for four levels of COPM satisfaction scores

| COPM | COPM | Mean difference | Standard error |
|------|------|-----------------|----------------|
| 1 | 2 | -.143 | .127 |
| | 3 | -4.578*** | .430 |
| | 4 | -.4315*** | .437 |
| 2 | 1 | .143 | .127 |
| | 3 | -4.435*** | .408 |
| | 4 | -4.173*** | .411 |
| 3 | 1 | 4.578*** | .430 |
| | 2 | 4.435*** | .408 |
| | 4 | .262*** | .068 |
| 4 | 1 | 4.315*** | .437 |
| | 2 | 4.173*** | .411 |
| | 3 | -.262*** | .068 |

Notes: Scores based on estimated marginal means with Bonferroni adjustment for multiple comparisons.

Level 1 = 8 weeks pre-training

Level 2 = Immediately pre-training

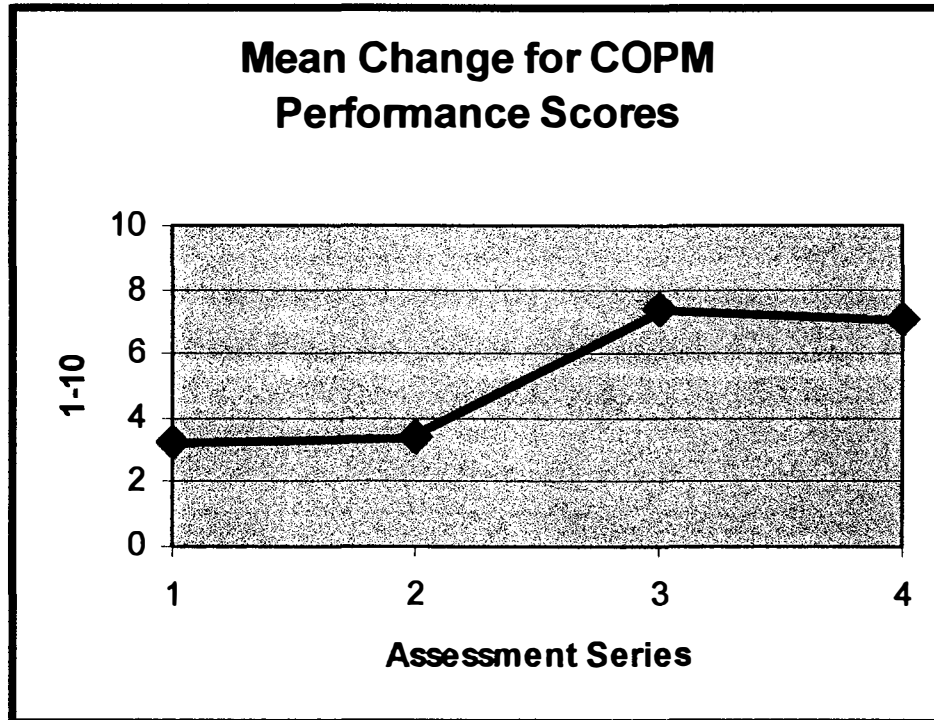
Level 3 = Post-training

Level 4 = 8 weeks post-training

*** significant at $p < .001$

Figure 1

COPM Performance Score Change

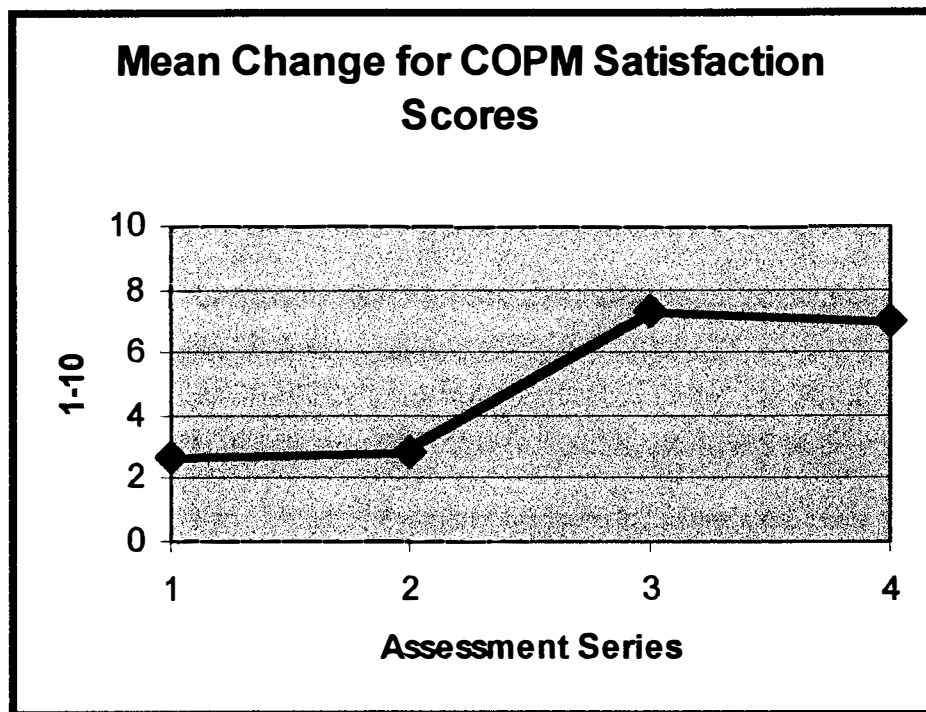


Horizontal Axis Key:

- 1: Initial scores, 8 weeks prior to training initiation.
- 2: Score immediately prior to training initiation.
- 3: Score at end of three-week training period.
- 4: Score eight weeks after completion of training.

Figure 2

COPM Mean Change on Satisfaction with Performance Scores



Horizontal Axis Key:

- 1: Test 8-weeks prior to training.
- 2: Test immediately prior to training.
- 3: Test immediately post-training.
- 4: Test 8-weeks post-training

As Tables 9 and 10 detail, the repeated-measures ANOVA tests for COPM Performance and Satisfaction with Performance mean scores deliver overall significant results ($F = 96.02$, $p < .001$ for performance score, $F = 104.92$, $p < .001$ for satisfaction with performance scores) (though these findings cannot be trusted without first testing for sphericity. In repeated measures ANOVA, scores at different levels cannot be assumed to be independent, since they come from the same subjects. In order to accept an F-test in repeated-measures design, it is necessary to test for sphericity.¹⁰ SPSS provides Mauchley's test of sphericity, which shows that in both the COPM performance calculation and the COPM satisfaction with performance calculation sphericity is violated. Tables 9 and 10, however, provide the results of calculations that show a significant overall change ($p < .001$) for both the COPM Performance and Satisfaction with Performance mean scores when Greenhouse-Geisser ($F = 96.02$, $p < .001$ for performance score, $F = 104.92$, $p < .001$ for satisfaction with performance scores) and Huyn-Feldt ($F = 96.02$, $p < .001$ for performance scores and $F = 104.916$, $p < .001$) corrections for violation of sphericity are calculated. It may be assumed, then, that an overall statistically significant change occurred across test administrations for both the COPM performance scores and the COPM satisfaction with performance scores.

In order to determine where specific change occurred, however, it was necessary to calculate paired measure t-tests for all possible pair-wise

¹⁰ Sphericity is tested by calculating the difference between pairs of scores in all combinations of the treatment levels, and then calculating the variance of these differences. Sphericity is met when these variances are roughly equal (Field, 2004).

comparisons on both the COPM performance mean scores and COPM satisfaction with performance mean scores. Because sphericity was violated in the overall repeated-measures ANOVA calculation, it was necessary to conduct a Bonferroni manipulation¹¹ in order to control for Type I and II errors. The results of this calculation are provided in Tables 11 and 12. These results show that a significant increase in mean scores occurred between pre-tests and post-tests for both the COPM performance (Mean Difference = 4.008, $SE = .390$, $p < .001$) and satisfaction with performance scores (Mean Difference = 4.435, $SE = .408$, $p < .001$) but that no significant change occurred during the initial non-treatment period for either performance scores (Mean Difference = .137, $SE = .109$, $p > .05$) or satisfaction with performance scores (Mean Difference = .143, $SE = .127$, $p > .05$). Additionally, there was a significant decrease in scores between post-treatment and 8-weeks post-treatment scores on both the performance scores (Mean Difference = .340, $SE = .017$, $p < .01$) and satisfaction with performance scores (Mean Difference = .262, $SE = .068$, $p < .01$), though these scores remained significantly higher than scores from both pre-treatment conditions on both performance (Condition One vs. Condition Four: Mean Difference = 3.805, $SE = .399$, $p < .001$; Condition Two vs. Condition Four: Mean Difference = 3.668, $SE = .389$, $p < .001$) and satisfaction with performance measures (Condition One vs. Condition Four: Mean Difference = 4.315, $SE = .437$,

¹¹ The Bonferroni adjustment controls for family-wise error rate in this way: adjust the tested alpha level by dividing the alpha sought (in this case, .05) by the number of comparisons being made (Field, 2004). Testing pair-wise comparisons across four levels requires six t-tests, so the Bonferroni adjustment for the COPM performance and COPM satisfaction with performance scores requires an adjusted alpha of $.05/6 = .008$.

$p < .001$; Condition Two vs. Condition Four: Mean Difference = 4.173, $SE = .411$, $p < .001$).

As these results indicate, the intervention is strongly related to improvement on both functional performance and satisfaction with performance on those activities that participants saw as their most difficult to perform.

Looking back at the sub-categories of performance difficulty cited by participants, a paired sample t-test comparing pre-treatment and post-treatment performance scores on the COPM for each category (see Appendix E) reveals statistically significant improvement in all categories, except frustration management and self-care.¹² The greatest areas of improvement were medication management (*Mchange* of 5.00 on a 1-10 scale), not losing things (*Mchange* = 4.80), remembering important events (*Mchange* = 4.54) and managing appointments (*Mchange* = 4.36). These may be the functional difficulties most readily addressed by the use of a handheld computer as a cognitive aid. Users were specifically trained to enter reminder alarms for medication, important events and appointments. It is less clear how a PDA may help individuals "not lose things", though answers to the FATCAT short-answer questions suggest an answer.

The FATCAT shows that participants strongly agreed with the Likert-5-point scaled questions, "Using a handheld computer has helped me improve performance in at least one area of my daily life" (4.75) and "I would like to continue using this device" (4.90). In keeping with the functional difficulties

¹² Self-care was not calculated, since only one participant selected it.

described in their COPM responses, participants strongly agreed with FATCAT questions, "I primarily use the device as a reminder system for things I need to do" (4.80), "I primarily use the device as a calendar" (4.05) and "I found that I was able to respond to reminder alarms almost every time one rang" (4.15). By the same token, participants strongly disagreed with the statement, "Using this device is just a waste of time" (1.00).

Answers to the FATCAT short answer questions offer qualitative support for the COPM's findings of improvement in performance and satisfaction (see Appendix K). The five primary themes that emerged from analysis of these answers include: (1) gratitude, (2) medication management, (3) improved organization, (4) improved self-control and (5) feature-specific suggestions. Participants overwhelmingly expressed appreciation for being included in the study, because of the way it had impacted their lives. As one wrote, "Thank you so much for giving me back my memory, even if it is now located in a somewhat different place!" Eleven participants commented on using the reminder alarm to help with medication management, which they felt improved their health. Nineteen commented on how the PDA had helped them organize everyday activities, making them feel more in control of their lives, and nine made recommendations for device adaptations that suggested thoughtful day-to-day use. It is possible that feeling healthier and more organized contributed to improved performance and a sense of self-efficacy in areas of day-to-day life beyond those captured by the study data. This possibility deserves a closer examination. Its implications will be discussed in Chapter Five.

These findings show a strong relationship between the intervention and improved performance (and satisfaction with performance) in conducting everyday life tasks, as compared to a pre-training period, further suggesting that functional gains can be maintained over time.

Change in Functional Handicap Using a PDA

Functional handicap, as discussed in Chapter Three, is a construct that measures how much a particular disabling condition impacts functional performance, with a special emphasis on levels of caregiver support needed in everyday life tasks. The CHART and FATCAT were used to measure change in functional handicap, following the same procedure used in measuring change in functional performance, conducting the CHART at the study's four assessment time points and the FATCAT on final assessment.

Table 13 provides descriptive statistics for the CHART scores. Table 14 presents the software-generated analysis of the repeated measures ANOVA for the CHART scores, including calculations of significant change in overall scores with sphericity assumed, and as adjusted for violations of sphericity. Table 15 provides paired t-test calculations for the CHART scores, corrected with the conservative Bonferroni adjustment. Figure 3 provides a graphic representation of CHART score change across four levels of testing.

Table 13

CHART Descriptive Statistics

| Test Level | Mean | Standard Deviation | N |
|-----------------------|--------|--------------------|----|
| 8-weeks pre-training | 78.125 | 12.138 | 20 |
| Pre-training | 77.185 | 12.613 | 20 |
| Post-training | 85.015 | 12.220 | 20 |
| 8-weeks post-training | 84.645 | 12.150 | 20 |

Notes: CHART scores on 1-100 scale (100 = fully independent)

Table 14

Overall Repeated-Measures ANOVA of CHART scores

| CHART | Type III Sum of Squares | Df | Mean Square | F | Observed Power ^a |
|------------------------------|-------------------------------|--------|----------------|-----------|--------------------------------|
| Sphericity assumed | 1039.817 | 3 | 346.606 | 37.499*** | 1.000 |
| Greenhouse- Geisser | 1039.817 | 1.343 | 774.306 | 37.499*** | 1.000 |
| Huyn-Feldt | 1039.817 | 1.408 | 738.600 | 37.499*** | 1.000 |
| Lower-bound Error (CHART) | 1039.817 | 1.000 | 1039.817 | 37.499*** | 1.000 |
| Sphericity assumed | 526.853 | 57 | 9.243 | | |
| Greenhouse- Geisser | 526.853 | 25.515 | 20.649 | | |
| Huyn-Feldt | 526.853 | 26.749 | 19.696 | | |
| Lower-bound | 526.853 | 19.000 | 27.729 | | |

Notes: Table shows Greenhouse-Geisser and Huyn-Feldt adjustments for violation of sphericity.

^a Computed using alpha = .05

*** Significant at $p < .001$

Table 15

Pairwise t-tests of CHART scores

| CHART | CHART | Mean Difference | Standard Error |
|-------|-------|-----------------|-------------------|
| 1 | 2 | .940 | .607 |
| | 3 | -6.890*** | 1.244 |
| | 4 | -6.520*** | 1.206 |
| 2 | 1 | -.940 | .607 |
| | 3 | -7.830*** | 1.044 |
| | 4 | -7.460*** | .999 |
| 3 | 1 | 6.890*** | 1.244 |
| | 2 | 7.830*** | 1.044 |
| | 4 | .370 | .296 |
| 4 | 1 | 6.520*** | 1.206 |
| | 2 | 7.460*** | .999 |
| | 3 | -.370 | .296 |

Notes: Scores corrected with Bonferroni adjustment.

Level 1 = 8 weeks pre-training

Level 2 = Pre-training

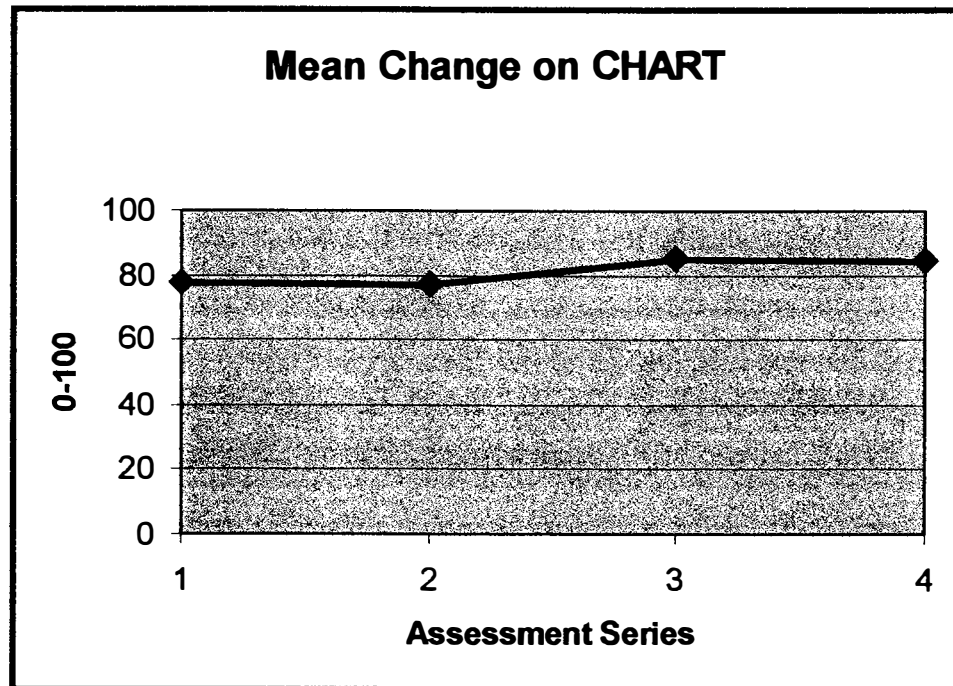
Level 3 = Post-training

Level 4 = 8 weeks post-training

*** significant at $p < .001$

Figure 3

CHART Mean Change across four levels



Horizontal Axis Key:

- 1: 8-weeks pre-training
- 2: Immediately pre-training
- 3: At completion of training
- 4: 8-weeks post-training

As the tables and figures detail, the repeated-measures ANOVA tests for the CHART mean scores deliver overall significant results ($F = 346.61, p < .001$), though these findings cannot be trusted without first testing for sphericity. In repeated measures ANOVA, scores at different levels cannot be assumed to be independent, since they come from the same subjects. In order to accept an F-test in repeated-measures design, it is necessary to test for sphericity.¹³ SPSS provides Mauchley's test of sphericity, which shows that sphericity is violated in the CHART calculation. Table 14, however, provides the results of calculations that show a significant overall change for the CHART mean scores when Greenhouse-Geisser ($F = 37.499, p < .001$) and Huyn-Feldt ($F = 37.499, p < .001$) corrections for violation of sphericity are calculated. It may be assumed, then, that an overall statistically significant change occurred across test administrations for the CHART scores.

In order to determine where actual change occurred, however, it was necessary to calculate paired measure t-tests for all possible pair-wise comparisons on the CHART mean scores. Because sphericity was violated in the overall repeated-measures ANOVA calculation, it was necessary to conduct a Bonferroni manipulation¹⁴ in order to control for Type I and II errors. The results

¹³ Sphericity is tested by calculating the difference between pairs of scores in all combinations of the treatment levels, and then calculating the variance of these differences. Sphericity is met when these variances are roughly equal (Field, 2004).

¹⁴ The Bonferroni adjustment controls for family-wise error rate in this way: adjust the tested alpha level by dividing the alpha sought (in this case, .05) by the number of comparisons being made (Field, 2004). Testing pair-wise comparisons

of this calculation are provided in Table 15. These results show that a significant increase in mean scores occurred between pre-tests and post-tests for the CHART scores (Mean Difference = 7.830, SE = 1.04, $p < .001$), but that no significant change occurred during the initial non-treatment period (Mean Difference = .940, SE = .607, $p > .05$) or for the period from post-test to the 8-weeks after training post-test (Mean Difference = .370, SE = .296, $p > .05$).

The statistical findings for the CHART scores correspond to those for the COPM, showing a significant improvement in functional independence (and a corresponding reduction in handicap) with treatment, as compared to the pre-training period. CHART scores were maintained more strongly in the post-training period (no significant change) than were the COPM scores.

A secondary analysis was conducted on the CHART sub-category scores, to see which were most impacted by the intervention. As Appendix H shows, a paired-sample t-test comparing sub-category scores from pre-training and post-training periods reveals statistically significant improvements in the sub-categories of: (1) mobility (mean 4.40 increase on a 100-point scale); (2) cognition (mean 16.40 increase); (3) social (mean 5.90 increase); and (4) occupation (mean 10.30 increase). Physical ability sub-scores fell slightly during this period, though not significantly (mean 3.00 decrease).

These findings agree with the previously discussed FATCAT results that show participants perceived a reduction in handicap, not just in cognitive

across four levels requires six t-tests, so the Bonferroni adjustment for the CHART scores requires an adjusted alpha of $.05/6 = .008$.

functioning, but across wide areas of their daily lives (Appendices J and K). FATCAT data suggests that taking medications regularly and becoming more organized in performing other tasks helped participants function more successfully in general. The implications of this finding will be further discussed in Chapter Five.

The study's repeated measure design, with tests added on either end of the intervention (in this case the tests 8-weeks prior to training and 8-weeks after training), was intended to reduce the plausibility of threats to validity based on maturation, instrumentation and regression. The results of the tests examining functional change during the eight-week pre-treatment and post-treatment periods strongly suggest that there is a relationship between the intervention and increased functional independence.

No Change in Behavioral Memory Using a PDA

In Chapter Two it was hypothesized that individuals with cognitive impairment related to multiple sclerosis "will not show an improvement in behavioral memory on a standardized test (the RBMT-E) after treatment (in that the intervention is compensatory and does not purport to address brain function directly)". This hypothesis was designed to test the external validity of the intervention by measuring the non-equivalent dependent variable "behavioral memory". If RBMT-E scores changed significantly during the study period, then some phenomenon other than the intervention may have played an important role in any perceived change in functional performance and handicap. Conversely, a

finding of no significant change in RBMT-E scores would strengthen the relationship between intervention and results as measured by the other study tests (Shadish et al., 2002). This is because the tests would show that participants functionally improved even though their organic thinking skills did not. This is exactly what a compensatory intervention such as the current study was intended to achieve.

As described in Chapter Three, the RBMT-E was administered at two time-points, initial assessment and final assessment (20 weeks apart). The RBMT-E returns two results, a raw score total for each participant and a profile score.¹⁵ Table 16 shows the descriptive statistics for the RBMT-E. Table 17 shows the results of a t-test comparing the two sets of results. Raw participant scores for the RBMT-E are provided in Appendix F. A comparison of participant profile scores with scores from a control group is provided in Appendix G.

¹⁵ The profile score is intended to reconcile raw scores on Version One and Version Two of the test. Version One was tested on initial assessment and Version Two on final assessment.

Table 16

RBMT-E Descriptive Statistics

| Score Set | Mean | N | Std. Deviation | Std. Error Mean |
|-----------------------|--------|----|-------------------|--------------------|
| Initial Raw Score | 86.350 | 20 | 19.263 | 4.307 |
| Initial Profile Score | 20.750 | 20 | 8.052 | 5.401 |
| Final Raw Score | 85.925 | 20 | 24.154 | 1.800 |
| Final Profile Score | 20.650 | 20 | 8.381 | 1.874 |

Notes: Raw Score possible range = 0-157. Profile Score possible range = 0-48

Table 17

Paired Sample t-test Results for RBMT-E

| Compar- ison | Mean | Std. Deviation | Std. Error Mean | T | Df |
|-------------------------------|------|-------------------|-----------------------|-------------------|----|
| Raw scores compared | .425 | 14.691 | 3.285 | .129 ^a | 19 |
| Profile scores compared | .100 | 3.447 | .7708 | .130 ^a | 19 |

Notes:

^a Not significant at $p < .05$

The paired-sample t-test results in Table 17 show that there is no significant difference between participant mean scores from the initial RBMT-E administration to the second RBMT-E administration (Raw Scores: $t = .129$, $p > .05$; Profile Scores: $t = .130$, $p > .05$). As noted, this result improves the validity of findings on the COPM and CHART, that there is a significant relationship between the intervention and improvements in functional performance, satisfaction with performance and handicap.

Related Findings: Life Events During the Study

Multiple Sclerosis (as discussed in Chapter One) is a degenerative neurological disease with symptoms that may fluctuate over time. Other life stressors may impact M.S. symptoms, just as such stressors may impact an individual's performance of everyday life tasks. This study was conducted over a twenty week period, and it was assumed that participants would experience life events during that period that might impact their health and their participation in the study. For this reason, a FATCAT question asked participants to list any life events that may have occurred during the study period. Descriptives for this question are shown in Table 19.

Table 19

FATCAT Descriptive Statistics

| Question | Yes | No | Total |
|--------------------|----------------|----|-------|
| Medication Change? | 5 ^a | 15 | 20 |
| M.S. Exacerbation? | 7 ^b | 13 | 20 |
| Other Life Event? | 8 ^c | 12 | 20 |

Notes: Participant responses to life event checklist.

^a Three participants required steroid infusion for M.S. exacerbation. One was placed on antidepressant medication. One received treatment for an unspecified "inflammation".

^b Four participants described the exacerbation as being of moderate intensity, with primary symptoms including fatigue and cognitive changes for which no additional treatment was sought. Three participants required outpatient steroid infusion for more significant exacerbations.

^c Two participants reported that their spouses were diagnosed with a life-threatening illness, two reported significant bouts of major depression (one required a one-week hospitalization, the other included suicidal ideation, both resolved), one participant required physical therapy for a back injury, one participant moved, one moved her parents into her house, and one participant lost her full-time job.

As Table 19 shows, during the study participants experienced a number of significant life events: 35% suffered an M.S. exacerbation during the 20-week study period, 40% suffered another significant life event and 25% required a medication change. Despite such difficulties, these individuals persevered in completing the study. Several commented on the FATCAT (Appendix K) that the intervention helped them cope with their difficulties and one credited the PDA with saving her life. This information provides further qualitative support for the study results, suggesting that the intervention can be worthwhile even for individuals who are undergoing significant life stressors.

Summary

This chapter has presented the results of pertinent quantitative and qualitative data collected and analyzed during the study. The results strongly suggest that individuals with cognitive impairment related to multiple sclerosis can learn to use handheld computers, that they retain this learning over time, and that using such a device in everyday life tasks improves functional performance and satisfaction, while reducing handicap. These results will be further discussed in Chapter Five, where implications for research and practice will be examined.

CHAPTER FIVE

DISCUSSION

The primary aims of this investigation were to determine whether individuals with cognitive impairment related to multiple sclerosis could learn how to operate a PDA and use such a device to improve functional performance in everyday life tasks. The findings indicate that a brief, multi-modal training intervention is sufficient for this population to learn how to use handheld computers, that they retain their learning eight weeks after the training is completed and continue to use their devices at that juncture. Those trained demonstrate statistically significant improved functional performance in everyday life tasks at the conclusion of training, and continue to demonstrate significantly improved functional performance eight weeks after the training intervention.

In light of these findings, the following discussion will consider the implications of the results reported in Chapter Four. First, the main and supplemental analyses will be discussed in reference to possible explanations of the findings and their convergence or divergence with previous literature. Next, clinical, theoretical and research implications of the study will be discussed. Finally, limitations of the study will be reviewed and study conclusions will be drawn with regard to future research directions.

Participants Can Learn to Use a PDA

This study shows that individuals with cognitive impairment related to multiple sclerosis can learn to use a consumer PDA. This finding extends the results of previous case studies examining individuals with cognitive impairment from acquired brain injury, who were able to respond to reminder alarms on an early-generation handheld computer (the Psion Organizer) (though caregivers programmed their reminder devices) (Giles & Shore, 1989; Kim et al., 1999) and a research project that provided the Psion Organizer to twelve brain injury outpatients, nine of whom found it useful as a memory aid and seven of whom said they would continue to use the device after the trial ended (Kim et al., 2000).

Only one other study describes the elements of a training intervention with handheld computers for individuals with cognitive impairment, and that study used a simplified-interface design for its participants (Wright, et al., 2001). That study found that participants were able to use a Pocket PC after training, and as such the current study may be seen as confirming its results. The current study, however, is the first to use an unmodified Palm PDA as a cognitive aid. It is also the first to utilize any sort of cognitive aid for individuals with multiple sclerosis. Its findings support a multi-modal home-based training intervention and the use of off-the-shelf devices, whereas research during the past decade has focused on either caregiver programmed devices (Giles & Shore, 1989; Kim et al., 1999; Gorman et al., 2003; Hart et al., 2002; Kirsch et al., 2004; Mihailidis et al., 2004;

Wade & Troy, 2001; B. Wilson et al., 1997; B. A. Wilson et al., 2001; B. A. Wilson, Scott, & al., 2003) or simplified add-on software (Davies et al., 2002b; Levinson, 1997; Wright et al., 2001), primarily with individuals who have acquired brain injury or mental retardation, and primarily tested in clinical settings.

This study suggests that research focused on simplifying handheld devices for individuals with cognitive impairment may not be the only productive path for cognitive rehabilitation investigators. It also suggests that reliance on caregivers to program cognitive aids may not always be necessary. In this study, a brief, participant-centered and multi-modal training intervention provided enough training for individuals to make use of inexpensive, readily-available consumer PDAs without caregiver supervision. Because this study focused on individuals with multiple sclerosis, however, it is important to conduct further research to see if such a training approach transfers to individuals with other cognitively-debilitating conditions.

Participants Retain Learning Long-Term

Retention of training is a key element of any assistive technology intervention that aims for ecological validity, in that individuals must be able to use the devices on their own once training is completed if the devices are to serve ongoing needs in their everyday lives.

The results of this study support and extend the findings of the only research to have examined cognitive aids over time in the community, a pair of English studies, which used the Neuropage service as a reminder system for individuals with acquired brain injury (B. A. Wilson et al., 2001; B. A. Wilson, Scott, & al., 2003) and a study which compared two simplified reminder systems loaded onto Pocket PCs and used by volunteers with acquired brain injury (Wright et al., 2001).

The English studies relied on caregivers to program the devices, but most participants responded to a phone survey that they found the devices useful and wished to continue using them. In the modified-Pocket PC study, participants who had received two training sessions remembered how to use the devices for the two-month duration of the study and found them useful as cognitive aids.

The current study concurs with these findings and further suggests that individuals with cognitive impairment related to M.S. can make use of unmodified Palm PDAs as cognitive aids without caregiver involvement. Other literature on assistive technology for cognition has not considered retention of training, though it is clear from the current study that a training intervention may be all that many individuals with cognitive impairment need to make use of a consumer PDA.

PDA's Increase Functional Performance

The ultimate test of any physical rehabilitation intervention is whether it improves functional performance in everyday life. Previous case studies have shown that various reminder systems helped individuals with cognitive disability access community activities more independently (Gorman et al., 2003), adhere to assigned tasks (Giles & Shore, 1989) and attend inpatient therapy on time (Kim et al., 1999). Treatment-survey studies have found an early-generation handheld computer (Kim et al., 2000), a pager (Kirsch et al., 2004; B. A. Wilson et al., 2001; B. A. Wilson, Scott, & al., 2003), a portable voice recorder (Hart et al., 2002) and a cell phone (Wade & Troy, 2001) helped people with cognitive disability remember to perform assigned tasks. As the only extant research to measure functional change with a behavioral rating scale (in fact, two scales, the COPM and CHART), this study confirms the efficacy of handheld computers as cognitive aids and points the way to work that may further clarify the benefits that may be expected from these devices.

For instance, in examining the current findings, it is clear that the relationship between change in everyday functional performance and an increased sense of self-efficacy deserves further study. FATCAT short answer respondents (see Appendix K) overwhelmingly described the intervention as helping them feel more organized, more "in control" and better able to face life's challenges. Social Cognitive Theory -- a framework designed to examine relationships of this nature -- holds that human behavior is continually impacted by cognitive and

environmental influences (Bandura, 1986). Applied to instructional design practice, this theory suggests that instructional experiences that have practical applications in an individual's life lead to increased motivation and confidence and improved functional performance, which in turn leads to a greater sense of self-efficacy. The reciprocal nature of this relationship may help explain this study's findings, in which participants showed functional gains, improved confidence and strong motivation to continue the cycle (as one participant wrote of the intervention, "It has been tremendous for my state of mind. I do too much, but this thing makes me feel like I can do more!") Future investigators may wish to formally explore this relationship, in order to improve and extend the efficacy of their cognitive rehabilitation efforts.

PDA's versus Low-Tech Cognitive Aids

The study results, as described in Chapter Four, show that there was no significant change in functional performance, satisfaction with performance or handicap during an eight-week pre-training period. Of note, however, all participants stated on initial evaluation that they were already using some sort of cognitive aid or organizational strategy to help manage their cognitive impairment. As Table 2 shows, ten tools were used, the most prevalent being sticky notes and pocket calendars. Yet the study intervention significantly improved participants' performance above their function when using these tools, suggesting that PDAs may be more effective than traditional, low-tech cognitive

aids. This finding supports previous work showing improved adherence to task prompts when using a handheld computer, as compared to written reminders (Davies et al., 2002b; Giles & Shore, 1989).

It is possible that some combination of cognitive aids might further improve functional performance, and that this combination might best be tailored to the cognitive status and functional needs of particular individuals. On the FATCAT, participants in this study described condensing the information on their collections of sticky notes, business cards and calendar reminders onto their handheld devices, saying this made them feel more organized. The PDA, in these cases, substituted for their previous strategies, while adding a reminder alarm function and other features that improved upon those strategies.

Cognitive Levels: Are there People Who Cannot Benefit?

Cognitive impairment is a broad and fluid construct, so it is unlikely that there is any one-size-fits-all intervention that can address the needs of every individual in the cognitive disability population. Among the current study's participants, examination of RBMT-E scores (see Appendix G) reveals that 35% of participants (7) were categorized as having "impaired memory", 55-60% (11 on first test, 12 on second) had "poor memory" and 5-10% (2 on first test, 1 on second) had "average memory". No participants on either test had either "good memory" or "exceptionally good memory". These findings correspond to the

self-assessment of participants, all of whom described deficits in functional cognition that impacted everyday life tasks.¹⁶ RBMT-E scores delineate differences in behavioral memory status among the participants, and though there are not enough subjects to make further comparisons of performance change as related to RBMT-E categories, discussion of the one participant who was not able to learn how to use a PDA may shed light on the difficulties inherent in designing cognitive rehabilitation interventions.

This individual scored in the "impaired memory" category on the RBMT-E. A former insurance claims adjuster, he had lost his job four years prior to the study, because of cognitive impairment related to his progressive form of M.S. and a psychiatric illness. On initial assessment, he was the only participant who could not demonstrate independent desktop computer use (e-mail, basic word processing, web-surfing), and during the study, he had the least success in retaining PDA training. One week prior to the final assessment, he suffered a serious M.S. exacerbation, which required three steroid infusions, and on final assessment, he appeared drowsy and somewhat confused. He was unable to demonstrate independent operation of any PDA function, and his caregiver said that he had not been using the PDA, except to play Solitaire. On examination, the PDA showed few entries during the post-training period. As previously noted, his caregiver said that she saw the potential for such a device, but wished he had tried it earlier in his life, when his cognitive skills were less impaired.

¹⁶ As previously noted, of the eighteen participants who were not yet of retirement age, seventeen stated that they had lost their jobs because of M.S.-related symptoms, including cognitive impairment, and the eighteenth lost her job for these reasons during the pre-training period of the study.

This individual may represent a cohort of people with more severe cognitive impairment who require a more intensive intervention (perhaps focused on a combination of cognitive aids, caregiver support and environmental management) than the current intervention provided. More research is needed to delineate exactly who can benefit from cognitive rehabilitation efforts utilizing handheld computers and other rehabilitation strategies.

Clinical Relevance

The findings of this study in context with past research have significant implications for the provision of rehabilitation therapy to individuals with cognitive impairment related to multiple sclerosis. Taken as a whole, the results of this study indicate that provision of a consumer PDA, coupled with a functional assessment and a brief training intervention, can significantly improve the everyday task performance, self-efficacy and organization of individuals with cognitive impairment related to multiple sclerosis. This is the first time that any intervention for this population has shown such positive results. Based on these findings, occupational therapists, speech and language pathologists, neuropsychologists and cognitive rehabilitation counselors may be well-advised to consider adding assistive technology for cognition interventions to their treatment arsenal.

Assessment Considerations

In considering whether to implement such a treatment, clinicians must recognize that all elements of the intervention may be important for treatment success. As with any assistive technology, clinicians must take the time to learn how to operate the devices proficiently, particularly those features that may impact cognitive performance,¹⁷ since they will need to train their clients and provide trouble-shooting assistance. In assessing clients, it is important to recognize that this intervention is not designed to remediate cognitive function, but rather to compensate for cognitive impairment by improving functional performance of everyday tasks. As such, assessment can best be focused on functional performance deficits rather than on tests of cognitive capacity. The tools used in this study, the COPM and CHART, provide useful information about a client's performance needs, but other tools may serve the same purpose.

Training Considerations

In carrying out a training intervention, clinicians are advised to consider the importance of instructional design principles and the lessons from diffusion of innovations theorists discussed in Chapter Two. Training that recognizes these principles can play to a client's preserved cognitive skill, overcome trepidation

¹⁷ In this study, participants found the reminder alarm and calendar features to be most helpful, but each of the device's standard features were successfully utilized by many participants.

about learning a new technology, incorporate practices that have been shown to work with individuals who have cognitive impairment, and assure a more successful learning experience. General strategies to consider include: (1) provision of consistent verbal, written, iconic and hands-on instruction; (2) repetition and reinforcement of learning; (3) application of the intervention to individualized functional performance goals¹⁸; (4) graded instruction that starts with a general introduction to the device and proceeds toward more specific training goals as proficiency is gained; and (5) on-going follow-along, as needed, to accommodate the device to each individual's needs.

Cost Considerations

In the current health care climate, cost and time considerations are important. The cost of a Palm Zire 31 PDA, as used in this study, is currently \$128. A similar device, the Palm Zire 21, costs \$100. This intervention, as implemented in the current study, may include a 90-minute functional assessment interview (including the tools used in this study), two 90-minute home-based training interventions and a pair of weekly 60-minute follow-up visits, for a total of 6.5 hours of therapy. Additional time might be necessary, of course, for travel to client homes and for bookkeeping. Because this intervention involves assistive

¹⁸ In this study, I used the COPM as a self-assessment measure of functional performance difficulties and tailored PDA training to each participant's individual needs, as noted in Chapter Three.

technology, it behooves the practitioner to make him/herself available at any time to trouble-shoot technical difficulties.¹⁹

Multiple Impairment Considerations

It is important for clinicians to recognize that this intervention is not appropriate for individuals with sensorimotor deficits that make operation of a PDA problematic. Study participants needed to demonstrate functional corrected visual acuity, hearing and dexterity in order to operate a PDA. Many individuals with multiple sclerosis have deficits in one or more of these areas, making use of a PDA difficult. There are, however, a wide variety of adaptive tools available to compensate for these impairments, some of which come installed on PDAs. For instance, screen brightness, font size and alarm volume can be adjusted, while some participants with impaired dexterity may prefer to enter information on their home computers using a full-sized keyboard, then download (hot-sync) information to the handheld device, rather than using stylus input on the device screen.

¹⁹ During this study, the investigator made a total of three additional trips to participant's homes during the post-training period. Two trips were necessary to trouble-shoot connection difficulties between the participant's handheld computer and home pc. The third was necessary to re-set an inoperable device (a simple one-step procedure). One device broke down altogether, because of a screen failure when exposed to extreme heat, and was replaced by mail. Participants exchanged a total of twenty-three e-mails with the investigator, requesting additional information or trouble-shooting advice. Using e-mail for these problems was effective and saved time, involving no more than 10 minutes for each exchange.

*Severe Cognitive Impairment
And Motivational Considerations*

A clinician must also recognize that some clients may not have the cognitive skill or interest necessary to learn how to use such a device. As previously discussed, in this study only one participant failed to master the device, but this individual may represent a cohort of clients who may require a different level of intervention. Further research is necessary to explore situations of this nature. That said, this study shows that individuals with a wide range of cognitive disability can learn to use assistive technology for cognition independently to improve their lives.

*Considerations Regarding
Familiarity with Computers*

As previously discussed, though only one study participant had ever used a PDA before (unsuccessfully), all owned home computers and all but one were able to demonstrate common computer usage (web-surfing, basic word processing and e-mail). Diffusion of innovations theory holds that adoption of a new technology occurs more readily when individuals are introduced to a technology that is not "too different" from technology they already use. By the logic of this theory, because PDAs are similar to desktop computers, adoption for the study

participants was easier.²⁰ Clinicians may find that some individuals who are not already computer users resist adoption of a PDA or have difficulty in learning how to use it. Further research with this population is indicated.

Considerations for the Future

Though further research is necessary to confirm and extend these findings, the results strongly suggest that interventions of this nature work, and as computers become more compact and more powerful in the years to come, and as researchers develop more disability-specific software and wireless extensions for them, therapists must consider their burgeoning importance as assistive technology for the rapidly growing cognitive disability population.

Treatment with Other Cognitive Disability Groups

Finally, though this study focused on cognitive impairment related to multiple sclerosis, therapists may find that its clinical implications extend to other diagnostic categories that have a cognitive disability component, particularly acquired brain injury and mental retardation, the categories investigated by most previous assistive technology for cognition researchers. Additionally, this study's

²⁰ Conversely, the one participant who did not learn to use the PDA successfully was also the one who could not demonstrate desktop computer skills. Though many other issues played into his difficulties in managing the PDA (as discussed elsewhere in this chapter), difficulty in using a desktop computer may have predicted problems in learning to use a PDA.

findings may be seen to support and extend that work to the multiple sclerosis population.

Cognitive impairment is a burgeoning disability category worldwide. As previously noted, at least 20 million Americans suffer with this condition, and with the aging of the world's population over the next several decades, the problem is expected to attain epidemic proportions. It is imperative for researchers and clinicians to develop and implement effective rehabilitative therapies to address the functional disability caused by cognitive impairment. This study offers evidence for one fruitful approach to the problem.

Theoretical and Research Implications

The Relationship between Instruction and Device

One of the theoretical aims of this study was to explore the practical application of instructional design theory and diffusion of innovations theory in an assistive technology context. Future work in this area may fruitfully examine the relative importance of instruction and device in the intervention, particularly concerning the question, "how much instruction is needed, and how should instruction be adapted, for individuals with varying levels of cognitive disability in order for them to learn how to use a handheld computer as a behavioral tool?" It is apparent from this research that instructional design and diffusion of innovations theories can inform physical rehabilitation theory in training individuals who have cognitive disability. This relationship needs to be explored

more fully. For instance, only one study participant had ever used a PDA before, yet all but one knew how to use desktop computers. Training the participants to use a PDA involved a direct application of diffusion of innovations theory in instructional design (as outlined in Chapter Three), which may prove useful as a framework for other assistive technology approaches.

The Issue of Self-Efficacy

In analyzing the study's qualitative results, the issue of "self-efficacy" emerged (see Appendix K). Many participants described growing more self-assured in performing everyday tasks, which led them to rely on their PDAs in pursuing more challenging activities. Bandura's Social Cognitive Theory provides a frame of reference for this phenomenon that is worthy of research in the field of physical rehabilitation, where motivation is seen as a key to functional independence.

Prior work in the area of assistive technology for cognition has focused almost entirely on disability-specific software or caregiver-programmed devices, but this study found that individuals with widely varying levels of cognitive ability related to M.S. can learn how to operate consumer PDAs and benefit from their use as organizational tools without caregiver involvement. If PDA use improves self-efficacy, then the intervention's impact may extend beyond the data collected in this study, leading to interventions that more fully integrate self-

efficacy concepts in helping individuals improve their lives. Future research is needed to explore this unexpected, yet promising, finding.

Ecological Validity

Another unique feature of this study, within the field of computer-assisted cognitive rehabilitation research, was its methodology, which focused on measuring the intervention's effect on functional performance in everyday life tasks over time in the community. This "ecologically valid" method is recommended to other researchers as a guide to developing interventions that have practical utility.

Future Directions

As computers become more compact and powerful, their use as cognitive aids can be expected to grow. Future researchers may find this study useful as a baseline for determining how effective basic PDA functions may be in helping individuals with cognitive impairment perform everyday life tasks, and expand upon these findings in developing task-specific software and adaptive training interventions. Researchers may ask, for instance, if it is possible to develop a handheld computer that adapts itself to the needs of a specific user or that performs its own training intervention for users.

Current rehabilitation research in robotics, global positioning satellite way-finding, wireless technology and wearable computing, as outlined in Chapter Two, may lead to revolutionary practical applications for individuals with cognitive disability. It is important for all researchers to recognize, however, that new assistive technologies are often abandoned by users. Again, training interventions that include lessons from instructional design and diffusion of innovations theories may broaden their adoption by individuals with disability, just as ecologically valid methodologies may verify which technologies are likely to be adopted by end users. Clearly, the use of computers as assistive technology is a promising new research domain, which has only begun to bear fruit in studies such as this.

Limitations

Due to the complex nature of this study and its several assessment instruments, this study was not without limitations. These limitations are presented so that they may be considered and addressed in future investigations of assistive technology for cognition.

Sampling Limitations

Participants were selected from volunteers who responded to a flier posted at the University of Virginia M.S. clinic or an ad posted in the *Blue Ridge M.S.*

Society Newsletter. As such, the sample is neither randomized nor representative of the M.S. population as a whole. As discussed in Chapter Three, the sample's gender and racial balance does not match the general U.S. population of people with M.S. Additionally, by design, participants needed to demonstrate intact corrected vision, hearing and dexterity, which further limits the study's applicability within the population of individuals with cognitive impairment related to M.S. It is possible that many individuals within central Virginia who might have qualified for the study either did not read one of the ads or did not choose to respond. Due to these sampling restrictions, the results may not be generalizable to a geographic region, to other ethnicities, across genders or to M.S. patients with complex sensorimotor impairment. Future researchers may wish to utilize a randomized controlled-trial model with a larger sample that is more inclusive in order to better generalize.

Instrument Limitations

The two assessments used to measure functional change in the study (COPM and CHART) rely on self-report, which in turn relies on respondents understanding the questions asked and responding truthfully and accurately. I sought to minimize self-report bias by including records of actual device use, demonstration of competence in using the device and qualitative questions focused on the participants' perceptions about the intervention (captured on FATCAT).

Another limitation related to the instruments is the assumption that they measure what they purport to measure. Although the COPM, CHART and RBMT-E used in this study exhibit appropriate levels of validity and reliability, the FATCAT survey designed for the study has not been calibrated. It is important to be cautious in drawing conclusions from this tool. Future researchers may wish to develop software that tracks actual usage of a PDA in real time to more accurately capture how individuals use their devices day-to-day. They may also wish to develop instruments that better delineate the specific functional performance areas most impacted by the intervention and further explore qualitative directions discovered by this research.

Because the primary quantitative functional measures used in this study (COPM and CHART) were based on self-assessment by participants, it is possible that participants artificially inflated post-training scores based on a Hawthorne effect. Measuring actual device use and asking for demonstration of device use after training was intended to mediate this effect.

Procedure Limitations

Because participants self-identified functional performance deficits, which were then addressed in training with the PDA, not all participants received training in exactly the same way. Though all followed the assessment and training protocol and received training in basic PDA functions, emphasis varied

based on my estimate of each participant's needs and ability level. Three participants, for instance, received an additional home visit to trouble-shoot PDA difficulties.²² Another was provided with a new PDA when hers broke.²³ This approach is consistent with an ecologically valid therapeutic intervention, but caution is advised in interpreting the results based on this training variability.

Summary and Conclusion

The results of this study empirically support the predictions made in Chapter One, that individuals with cognitive impairment related to multiple sclerosis can learn to use off-the-shelf handheld computers as assistive technology and improve their independence in performing everyday activities by doing so. The study is the first reported research in the field of assistive technology for cognition to measure functional change in community settings over time, and as such offers an ecologically valid extension of prior research in this area. Additionally, the study is the first to utilize widely-available, off-the-shelf Palm PDAs within the context of a home-based training intervention, an approach that suggests directions for further investigations into brief, inexpensive and readily

²² The investigator also received and responded to a total of 23 emails requesting additional PDA information during the post-training phase of the study.

²³ This participant placed her device near a wood stove and found that the heat discolored the computer screen. The investigator sent her a new device, with a reminder not to expose it to undue heat or cold.

available cognitive rehabilitation therapies. Finally, this is the first rehabilitation study of any kind to demonstrate success in treating cognitive impairment related to multiple sclerosis. It is hoped that its results will lead to more effective treatment methods for this intractable and debilitating condition.

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APPENDICES

APPENDIX A

Human Investigations Committee Protocol and Consent Form

Appendix A:1

Human Investigations Committee Protocol

Handheld Computers as Cognitive Aids for Individuals
with Thinking Skills Impairment related to Multiple Sclerosis

Background:

Cognitive rehabilitation therapists have long used external memory aids to help patients manage thinking skills impairments. The same devices that assist people without disabilities in organizing their day-to-day tasks - calendars, alarm clocks, shopping lists, scheduling notebooks, etc. - can be readily adapted so that individuals with cognitive impairments may remember to take their medications, sequence routine activities (such as dressing and cooking), find their way in the community and manage behavioral challenges. Typically, these adaptations have involved analyzing activities, simplifying the device interface, investing some time in training and enlisting caregivers to reinforce use of each strategy (Parente & Hermann, 1998).

Since their emergence in the mid-1990s, handheld computers have incorporated task management capabilities, and their appeal to the average consumer is apparent at any upscale coffee shop or business meeting. The rehabilitation community has made halting efforts at including these devices in cognitive treatment regimes, but despite their apparent potential to increase functional independence among individuals with cognitive impairment, so far little research has been completed to show how they may best be used with various diagnostic groups. A trial of palmtop devices with 12 brain injured patients at Spaulding Rehabilitation Hospital showed that, despite continued prospective memory impairments, after introduction of the devices functional ability improved (Kim, et al., 2000). A study conducted with 12 patients with mental retardation supported the use of handheld devices in time and task management activities (Davies, Stock & Wehmeyer, 2002). Similar small studies have been published in the fields of dementia, developmental disabilities and psychiatry, all pointing to the benefits inherent in portable, multi-functional task management applications for cognitively impaired users. A web-search of current rehabilitation trials shows several larger studies underway, but these studies are ongoing and no results have yet been published. The investigator of this proposed study is currently conducting research on the use of portable computers by individuals with autism or acquired brain injury. No research has been reported on the use of portable computers as cognitive aids for individuals with Multiple Sclerosis.

As research continues, the development of portable computer technology outraces our ability to keep up. Combination devices - incorporating cell phones, electronic organizers, pagers and global positioning satellite trackers - expand the opportunities available for cognitive rehabilitation therapists, and each day

seems to bring new products with new features at lower costs to a growing market. Rehabilitation-focused engineering teams, such as Denver, Colorado's AbleLinkTech (www.ablelinktech.net), Palo Alto, CA's Brain-Aid (www.brainaid.com), and Palm Beach, FL's Cognitive Systems, Inc. (www.cosys.com), have developed handheld devices and/or handheld-based software specifically designed for cognitively impaired patients. This adds a new challenge for rehabilitation research teams, who must scramble to keep up with all that technology offers even as they attempt to conduct their studies.

Clearly, the ever increasing power and decreasing size of portable computers offer new opportunities for their use with a wide range of disability populations. This study builds on a pilot study of four participants conducted at the University of Virginia in Spring 2005 by this investigator, which was the first to examine the efficacy of handheld computers with individuals who have cognitive impairment related to Multiple Sclerosis.

Hypothesis to be Tested:

The hypothesis for this study is that individuals who have functional cognitive impairment related to Multiple Sclerosis can measurably improve their functional independence in everyday activities by utilizing the task management features of a handheld computer, which they have been trained to use for that purpose.

The outcome measures used will include:

- Canadian Occupational Performance Measure (COPM). The COPM is a person-centered semi-structured interview, which examines areas of dysfunction in everyday activity and interests. Participants self-select up to five activity areas in which they would like to improve their function, rating current performance and satisfaction on a 1-10 scale. Following the intervention period, the interview is conducted again, resulting in a comparison of ability and satisfaction scores before and after. The COPM is widely used by occupational therapists across disability groups and has been used for several years by the investigator in a community reentry program for adults with brain injury (Law, Baum & Dunn, 2001).
- Craig Hospital Assessment and Reporting Technique – Revised (CHART-R). The CHART-R is a widely used checklist for determining levels of supervision required for self-care, social activities, cognitive performance and community accessibility. It may be completed by participant or caregiver and will be administered before and after intervention for comparison purposes.

- Rivermead Behavioral Memory Test (RBMT). The RBMT is a standardized multi-task assessment tool that examines functional memory in retrospective and prospective tasks. It is recognized as a sensitive measure of actual memory performance in real world environments and is in wide use by psychologists and cognitive rehabilitation therapists (Wilson, 1989).
- Functional Assessment Tool for Cognitive Assistive Technology (FATCAT). The FATCAT is a questionnaire designed by the investigator and intended to measure competency in using a handheld computer and participant satisfaction with the treatment intervention. Interviewees will be asked to score each question on a 1-5 scale (Segal & Schall, 1995).

Human Participants:

Number: At UVA: 20 At other sites: 0

Ages. All ages will be admitted. Multiple Sclerosis typically does not strike individuals until their late teens, however, so it is not expected that any children will be enrolled.

Sex. We are not selecting for sex.

Race. We are not selecting for race.

The investigator anticipates initially screening 20-30 individuals. From that group, we anticipate at least twenty individuals will meet selection criteria and elect to participate in the intervention. It is expected that no more than two participants will withdraw or dropout during the study. Statistically significant results are expected from this sample.

Because this study will recruit patients with cognitive impairment, we have incorporated several safeguards to protect their rights:

- Protocol information will be provided to all participants in written form and verbally.
- All admitted participants will sign a consent form and a designated family member or legal guardian will also sign a consent form.
- All participants and caregivers will be given one week to consider the information prior to assent and consent.
- The investigator will be available via phone and email throughout the study to answer any questions related to the protocol.

Inclusion/Exclusion Criteria

Criteria for inclusion:

Any individual with a confirmed diagnosis of Multiple Sclerosis may apply to participate in the study. In order to participate, participants must demonstrate functional cognitive impairment on the study's initial assessment measures. Participants must have a live-in family member or caregiver who is willing to participate in the study, as described in the consent criteria. Participants must have corrected functional vision that allows them to read text and/or graphic materials on a handheld computer screen. Participants must have eye-hand coordination adequate to manipulate the buttons on a portable computer screen. Participants must be able to demonstrate the ability to respond to an auditory or vibrating reminder alarm on a handheld computer. Participants must be community-dwelling and agree to live in the Commonwealth of Virginia for the duration of the study.

Criteria for exclusion:

Participants who do not meet inclusion criteria will be excluded.

Restrictions (if any) on use of other drugs or treatments. NA

Recruitment

How will participants be recruited? (check all that apply)

- ☒ Posters/Flyers
- ☐ Television
- ☐ Radio
- ☒ Newspaper Ads
- ☐ Internet
- ☐ Medical Record/ Database Review. NOTE- potential participants will be contacted after obtaining the approval of their attending physician and HIC approval of method of contacting potential participants (i.e. letter)
- ☐ Medical Record/ Database Review. NOTE- participants will not be contacted
- ☒ Referrals from other health care professionals ☐ Discuss protocol with patients of PI or sub-investigators during a standard clinical visit

Study participants will be recruited with fliers posted at the James Q. Miller Multiple Sclerosis Clinic of the University of Virginia and at other central Virginia neurology offices. Additionally, an ad will be published in the quarterly newsletter of the Multiple Sclerosis Society for western Virginia. Potential participants will be able to apply via email or telephone directly to the investigator.

Each potential participant will be visited by the investigator in his/her home or at a nearby location of his/her choosing. At this time, consent materials will be provided verbally and in writing to each potential participant and his/her caregiver. Three forms will be in place to gain appropriate consent:

- (1) Project Participant Consent Form, to be signed by potential participants,
- (2) Caregiver Consent Form, to be signed by a designated caregiver who will be providing support to the project participant during the project, and
- (3) Legal Guardian Consent Form, to be signed by the participant's legal guardian, if the participant has one.

Potential participants and designated caregivers or legal guardians will be given one week to review these materials, during which time the investigator will be available by phone and email to answer questions. At the end of one week, the investigator will meet potential participants and designated caregivers or legal guardians again, and any additional questions will be answered. If they decide to participate in the study, they will then sign the consent forms and an appointment for a one-hour initial assessment visit will be scheduled.

Only those potential participants who meet enrollment criteria will be accepted into the study. This will be explained clearly both verbally and in the consent form.

Do you plan to enroll any of your own patients, staff, employees or sub-investigators listed on this protocol? No

Biomedical Research:

Once a candidate who meets initial criteria has signed a consent form and a designated caregiver or legal guardian has signed a consent form, the investigator will conduct an initial assessment at the candidate's home (or at another nearby location of the candidate's choosing), utilizing the assessment tools noted above (COPM, CHART-R, RBMT and CUTA), and including an interview with a designated family caregiver, in order to determine whether a particular candidate may benefit from the project. Those candidates deemed appropriate will be enrolled and a second assessment visit will be

scheduled for eight weeks later. (Measures for the first and second assessment visits will be compared to determine whether any functional cognitive change has occurred during the pre-training period. These measures will also be compared with any change measured during the post-training period in order to help determine the possible efficacy of treatment.)

After the second assessment visit, the investigator will schedule three home training visits of one hour each, to be conducted in no more than a ten-day period. During this time, the investigator will provide a handheld computer to the participant, assist in downloading associated software on his/her computer (if he/she has one), and train the participant and caregiver in how to use the device as a memory and organizational aid. Following the initial training visits, the investigator will schedule weekly one-hour visits for three weeks to reinforce training and troubleshoot difficulties. The investigator will write progress notes for each of these visits, tracking progress with the intervention and any issues that may arise during training. This information, stripped of identifiers, will be used to analyze training efforts across participants.

At the end of this period, the participant will be asked to continue using the device to assist in everyday life tasks for a period of eight weeks. Following this period, the investigator will return for a post-treatment assessment visit, during which re-tests will be conducted using the same assessment tools used in the initial assessment. On this visit, the investigator will also conduct the FATCAT measure, which examines competence in and satisfaction with the use of a handheld computer. This visit will conclude the participant's involvement in the study. He/she will be allowed to keep the handheld device provided. This will be the only compensation provided to the participant.

What treatments, normally used, will be omitted for the study? None

What details of the study are best kept secret from the participants?

Participants will not be apprised of intervention progress with other study participants during the study.

Taping/Photography

Will participants be recorded on audiotape? No

Will participants be photographed or recorded on videotape? No

Study Design:

Biomedical

What kind of controls will be used?

This design incorporates an 8-week pre-treatment period, a 4-week training period during which a participant will be taught to use a handheld computer, and an 8-week post-training period during which the participant will be asked to continue using a handheld computer to help manage everyday tasks. Comparisons of functional cognitive change will be made between pre-training and post-training periods. Individual participants will in this way serve as their own controls.

This protocol examines

Single-blind, double-blind, other: No blinding

If randomized, how? Not randomized

Plans for statistical analysis:

- 1) For the quantitative outcome instruments (COPM, CHART-R, RBMT, FATCAT), paired-t-tests will be conducted to measure differences in mean outcomes scores before and after the intervention.
- 2) For the *progress notes*, content analysis procedures will be used to summarize written comments and to identify recurring themes.

Risk/ Benefit Analysis:

It is generally estimated that 45-65% of Multiple Sclerosis patients suffer cognitive impairment (Peyser, et al., 1980, McIntosh-Michaelis, Roberts, & Wilkinson, 1991). Thousands of individuals with cognitive impairment from Multiple Sclerosis go without professional treatment today, because of a lack of therapeutic resources, payer restrictions and/or remote location from service centers. Cognitive problems force many people with M.S. to leave their jobs. Additionally, caregivers suffer under tremendous strain in supervising and managing cognitive-behavioral challenges on a day-to-day basis. The research and development described in this proposal is designed to empower cognitively impaired individuals to function more independently, using task management features built into a handheld computer. The project also provides support training for family caregivers. This intervention is expected to be extremely cost-effective, easily individualized and potentially transferable to other cognitively impaired disability groups. Risk to participants, as outlined below, is minimal. We believe the potential benefits of this work outweigh those risks.

For the participant, there is little to no medical risk from participating in this non-invasive study. All equipment utilized by the participant during the study is neither inherently dangerous (e.g. heavy) nor electrically dangerous (beyond the risk of any battery-operated consumer device). There is a potential psychological risk to participation in this study, in that the intervention may not succeed in improving functional performance by participants. Some participants may find working with electronic portable computers daunting and impractical for their needs. Additionally, the several visits and phone calls by the project director may prove inconvenient for some participants.

To help manage these risks, each participant and his/her identified caregiver will be carefully educated on how to safely manage daily life tasks using a portable computer within study guidelines, and additionally trained in how to safely operate said device. Throughout the study, the investigator will be available via phone and email to address practical issues that may arise through use of the device. The investigator will make every effort to schedule visits at convenient times for participants and caregivers. The risk that the intervention may not help a particular individual will be detailed both verbally and in written consent forms. Confidentiality will be assured through use of a consent protocol within the guidelines of the UVA HSC HIC.

Risk-Benefit Ratio

This study provides potential benefits outlined in the previous section. It poses minimal risk of breach of Protected Health Information that will be minimized by following institutional and federal confidentiality regulations. The risk-benefit ratio is acceptable.

Data and Safety Monitoring Plan

Monitoring and aggregate review will be performed by the investigator and HIC through annual review. No serious problems are anticipated but should they occur while the participant is in the protocol they will be reported to the HIC according to HIC policies. Any unanticipated problem or serious and unexpected adverse events will require re-evaluation of the risk of the study.

1. What risks are anticipated secondary to the intervention or participation in this protocol?

No secondary risks beyond those discussed in the risk-benefit ratio section of this form are anticipated

2. When will reporting of problems/events begin?

☒ After subject signs consent
☐ After subject begins study intervention
☐ Other (specify)

3. Problems/events occurring in each subject will be reported to the HIC until:

☐ Subject completes participation in the protocol
☐ End of intervention
☐ 30 days post intervention
☒ Subject completes intervention and follow up period of protocol
☐ Other: (specify)

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**Principal Investigator
(Print)**

**Principal Investigator
(Signature)**

Date

**Department Chair or Appointee
(Print)**

**Department Chair or Appointee
(Signature)**

Date

Please note that if the PI or any sub-investigator is also the Department Chair, that person cannot sign as the Department Chair. The PI's supervisor (e.g. Dean or his designee) will need to sign on the second line. The same individuals must also sign the Investigator's Agreement.

Appendix A: 2

Consent Form

CONSENT OF AN ADULT TO BE IN A RESEARCH STUDY

Participant's Name _____

Medical Record # _____

Summary

The most important things to remember about this study are:

- (1) This study is being conducted to determine whether handheld computers may be useful as cognitive aids for people with Multiple Sclerosis who have a functional thinking skills impairment.
- (2) Your participation is entirely voluntary, and you may withdraw from the study at any time without penalty.
- (3) You will not be personally identified as a participant in this study and all personal identifiers will be removed from study materials prior to any publication.

Why is this study being done?

The purpose of this research study is to examine whether handheld computers may be useful as cognitive aids for people with Multiple Sclerosis who have a thinking skills impairment. Twenty people will be enrolled to participate in the study.

Risks:

1. The handheld computer that you will use during this study may not improve your functional independence in performing everyday life tasks.

Benefits:

1. The handheld computer that you will use during this study may improve your functional independence in performing everyday life tasks.
2. You may keep the handheld computer that you will use during the study, whether you find the device useful or not and whether you complete participation in the study or not.

What is an Informed Consent?

You are being asked to be in a research study. The purpose of this form is to give you the information you will need to help you decide if you want to be in this study. Please read this form carefully. Please ask the investigator (Tony Gentry) to answer your questions about anything you do not understand. You may keep a copy of this form to examine and think about before you decide if you want to be in the study. When all your questions have been answered, you can decide if you want to be in this study. If you do decide to be in this study, you will get a copy of this signed form to keep for your records.

Introduction

You are being asked to be in a study of handheld computers as cognitive aids for individuals with Multiple Sclerosis. The purpose of this study is to see if a handheld computer can help M.S. patients manage everyday tasks. You are being asked to be in this study because you have applied to participate, and because you have a cognitive impairment related to Multiple Sclerosis. Up to twenty people will be in this study at UVA. The decision to be in this study is up to you. Your part in the study is expected to last twenty weeks.

Are there some people who should not be in this study?

The person in charge of this study or a member of the study staff will talk with you about the requirements to be in this study. It is important that you are truthful with them about your history. You should not be in this study if you do not meet all the qualifications.

You should not be in this study if:

- you are not being treated for Multiple Sclerosis,
- you do not have a thinking skills or memory impairment,
- you do not have functional corrected vision,
- you cannot manipulate the buttons on a handheld electronic device,
- you do not have a family member or caregiver who is willing to participate in the project with you, or
- if your hearing is severely impaired.

How much time will this study take?

Your participation in the study will take twenty weeks. The investigator will visit your home or another nearby place of your choosing to meet with you a total of ten times (one hour visits) during that period. During the final twelve weeks of the study you will be asked to use the handheld computer on a daily basis to assist you in performing everyday life tasks.

What is involved in this study?

After you and a family member or legal guardian sign your consent forms, the investigator (Tony Gentry) will schedule an assessment visit at your home or at a nearby place of your choosing. On this visit, you will complete a cognitive test, a structured interview about your everyday activities, and checklists that examine how much help you need during the day and how comfortable you are with various electronic devices. This visit is expected to take an hour.

Based on the results of this assessment visit, the investigator will notify you whether you qualify to participate in the study or not. If you do not qualify, you will not be asked to participate in the study.

If you do qualify, the investigator will schedule a second assessment visit eight weeks after your initial assessment. The purpose of this second assessment is to see whether your thinking skills change during this period without treatment. Any change during this period will be compared later with any change experienced during the treatment period.

After the second assessment visit, the investigator will schedule a home visit to begin your work with a handheld computer selected by the investigator. This computer will be a handheld device, the Palm Zire 31 personal organizer. With your permission, the investigator will load software for this device onto your home computer, if you have one. He will then train you and your designated family member to operate the device's reminder and organizational functions, helping you incorporate the device into your everyday life routines. These trainings will take place during three home visits of one hour each, conducted over no more than a ten-day period.

Following this training period, you will be asked to use the device during everyday activities for ten weeks. During the first two weeks of this period, the investigator will schedule one-hour weekly home visits to trouble-shoot any difficulties you may have with the device and to complete your training. During the last eight weeks, you may contact the investigator at any time for assistance in using the device, but he will not otherwise schedule any appointments with you.

At the end of this period, the investigator will schedule a follow-up assessment visit, during which he will conduct the same test, interview and checklists performed on your first visit. He will use the information gathered from these assessments to measure whether the device has helped you better manage everyday life tasks. At that point, your participation in the study is complete. You may keep the device.

The table below shows how the investigator's visits will be scheduled:

| | |
|---------------------|---|
| Initial home visit | Sign consents and conduct initial assessment measures |
| 8-week period | No treatment period |
| Second home visit | Conduct assessment measures and schedule training |
| Over next week | 2 home visits to train participant and caregiver in use of device |
| Over next two weeks | Weekly home visits to complete training |
| Final 8-week period | Participant uses device in everyday life tasks, as trained |

| | |
|------------------|--|
| Final home visit | Investigator conducts final assessment to see if using the device has improved functional performance in everyday life tasks |
|------------------|--|

This study is not meant to find out if you have any other disease or problem. You will be told of research results that are important to your health during the study. No other information will be shared with you until all the people in the study have finished and the information has been studied. At that time you can ask for more information. Results of the study, without any personal identifiers, may be made public through presentations at professional conferences and through publication in professional journals.

What are the risks of being in this study?

Risks and discomforts to you may include inconvenience from the investigator's several visits to your home, the requirement that you undergo training in how to manage the handheld computer, and the risk that the treatment may not benefit you. The investigator recognizes that there may be an element of psychological stress associated with participation in a research protocol or in learning to use a handheld computing device. Please consider this risk as well.

There may be side effects that may happen to you that we don't know about now. You should call the investigator if you have any symptoms or reactions.

Could you be helped by being in this study?

If you are in this study, you may find that using a handheld computer improves your independence in performing everyday life tasks. We do not promise that you will be helped by being in this study.

What are your other choices?

You may choose not to be in this study.

You do not have to be in this study to be treated for your illness or condition. You can receive the usual treatment even if you choose not to be in this study. The usual treatment would include the current treatment you are receiving from your medical team.

Will you be paid for being in this study?

You will not get any money for being in this study. You may keep the handheld computer that is provided to you during the study.

What are the costs of being in this study?

There are no monetary costs for participating in this study. Time costs will include the time that you and your caregiver will spend with the investigator in learning how to use the device, in completing assessment instruments and in using the device in your everyday activities. Total time costs to you are projected to be no more than 30 hours over the twenty-week period of your participation in the project, and may be as little as 15 hours during that period.

What happens if you are hurt during this study?

There are no plans to pay you for lost wages, disability, or discomfort if you suffer any unexpected injury directly resulting from this study. Treatment for an unexpected injury directly resulting from the research study that is not covered by your insurance will be provided free of charge at the University of Virginia. You do not give up legal rights for personal injury by signing this form.

What happens if you change your mind?

You do not have to be in this study if you do not want to be. You may choose to withdraw from this study or to stop the study at any time. You are not required to be in this study in order to receive services normally available to you at the University of Virginia. You will be told about information learned during the study that may be important to you in deciding if you want to continue in this study.

If you do decide to stop the study you will be asked to contact the investigator by phone (804) 840-7226 or by email at log2n@virginia.edu to inform him of your withdrawal. The study researcher may remove you from the study at any time. Some reasons for taking you out of the study would include concerns about your health and safety or if you do not follow instructions.

How will information about you be used and protected?

Federal and state privacy laws govern how UVA can use and share your personal and medical information. We will do everything we can to protect your privacy in this study. However, we will need to share your information with people who may not have to follow the same laws. Some of these people may be allowed to release your information without your permission.

Signing this form:

- gives your health care providers permission to provide information about you to UVA researchers for this study; and
- gives UVA researchers permission to gather, use, and release information about you for this study.

You do not have to sign, but if you do not, you cannot be a part of this study.

If you sign this form, there will be 4 general categories of people who can use and release information about you. They are:

1. People who do the research or manage the study
2. People who oversee the study to make sure it is being done correctly
3. People who pay for the study
4. People who evaluate the study results

What information do we collect for the study?

We may collect any, or all, of the following:

- Personal information such as your name, address, date of birth, and social security number
- All of your medical records and test results (from before, during and after the study) from any of your doctors or other health care providers, including mental health care and substance abuse records, and HIV/AIDS status records
- Records and test results that relate only to this study
- Information we need to bill others for your care

What will be done with this information?

Your information will be used to:

- Track whether the study is being done correctly
- Observe the effects of the study and understand its results
- Report study results to sponsors and government agencies such as the FDA (Food and Drug Administration)
- Publish the study results in medical journals. (This would be done in a way that protects your privacy. No one will be able to find out you were in this study.)

Who will we share your information with?

- The sponsor of the study and groups who work for the sponsor
- Government agencies such as the FDA or other organizations that oversee research at UVA
- People or committees who work to see that research at UVA is safe
- Insurance companies (or others) that may pay for your care
- The company that makes the drug or device we are studying

When can you see your records from this study?

Information we collect about you for this study might be kept in a record that is separate from your medical record. You will not be able to see what is in the separate research record until the end of the study.

How long does this permission last?

This permission to use and release your information does not end unless you cancel it.

What if you sign the form but then decide you don't want your information used and shared?

You can change your mind about letting us use and share your information. To cancel your permission, you would have to send a letter to the researcher listed on this form. If you cancel your permission, you cannot continue to be in the study.

Even if you cancel your permission, we may still need to use *some* information about you. We will still use the information collected about you up until the time you decide to stop being in this study. We need that information to:

- avoid losing study results that have already included your information
- help those who oversee the study

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical record will be able to find out that you are in this study. This is done so your regular doctors will know what drugs or treatment you are getting in this study. If you have other health problems during the study, they will be able to treat you properly.

Contact Information

Please contact the people listed below to:

- Learn more about the study
- Ask about the way the study is done or about treatments
- Report an illness, a research related injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished

Report a concern about the study

Principal Investigator: Tony Gentry

Telephone: 804-840-7226

What if you have a concern about a study?

You may also report a concern about a study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Human Investigation Committee
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-2620
Fax: 434-924-2932

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the HIC Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Conclusion

Please check one of the following:

_____ You agree to be contacted after this study is done for follow up information or to be asked to be in other studies.

_____ You do not agree to be contacted after this study is done for follow up information or to be asked to be in other studies.

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. When you sign below, you are saying you understand the information we gave you about the study and in this form. **If you sign the form it means that you agree to be in the study.**

PARTICIPANT
(SIGNATURE)

PARTICIPANT
(PRINT)

DATE

PERSON OBTAINING CONSENT
(SIGNATURE)

PERSON OBTAINING CONSENT
(PRINT)

DATE

APPENDIX B

Assessment Forms

Appendix B: 1

Canadian Occupational Performance Measure

Appendix B: 2

Craig Handicap Assessment and Rating Technique

Appendix B: 3

Rivermead Behavioral Memory Test – Extended

Appendix B: 4

Demographic Survey Form

UVA M.S. PDA Study – Demographic Survey Form

Name: _____ Age: _____

Marital Status: _____

Multiple Sclerosis Issues:

Year Diagnosed with M.S. _____ Type: _____

Current Primary Medication: _____

Please rank your M.S. symptoms by number, with "1" as the biggest problem and "5" as the least troubling:

___ Fatigue

___ Cognitive and Memory Problems

___ Pain

___ Physical mobility

___ Other _____

Occupational Situation:

Occupation: _____

If retired, what was your previous occupation, and when did you retire?

Use of electronic devices:

Please check products you have and use independently:

___ computer

___ palm pilot

___ Internet search

___ computer games

___ E-mail

___ Instant messaging

___ money management software

___ web design

Appendix B: 5

Functional Assessment Tool for Cognitive Assistive Technology

Functional Assessment Tool for Cognitive Assistive Technology (FATCAT)

Name: _____

Please rate the following statements based on how strongly you agree with them. Circle numbers for ratings as follows:

- 1 = I strongly agree with this statement
- 2 = I disagree with this statement
- 3 = I neither agree nor disagree with this statement
- 4 = I agree with this statement
- 5 = I strongly agree with this statement

1. Using a handheld computer has helped me improve performance in at least one area of my daily activities.
1 2 3 4 5
2. I find the handheld computer simple to use.
1 2 3 4 5
3. The training I received on how to use the handheld computer taught me what I needed to know.
1 2 3 4 5
4. I am able to use the handheld computer without any help from another person.
1 2 3 4 5
5. I primarily use the device as a reminder system for things I need to do.
1 2 3 4 5
6. I primarily use the device as a calendar.
1 2 3 4 5
7. I would like to continue using this device.
1 2 3 4 5
8. Using this device is just a waste of time.

- | | | | | | |
|-----|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 |
| 9. | I misplaced this device at least once. | | | | |
| | 1 | 2 | 3 | 4 | 5 |
| 10. | The device broke down at least once. | | | | |
| | 1 | 2 | 3 | 4 | 5 |
| 11. | I found that I was able to respond to reminder alarms almost every time one rang. | | | | |
| | 1 | 2 | 3 | 4 | 5 |
| 12. | This study was conducted in accordance with the protocol I signed. | | | | |
| | 1 | 2 | 3 | 4 | 5 |

Please briefly answer the following questions:

1. When entering information on the device, which mode did you use most: (1) Palm Desktop on your home computer, (2) stylus or (3) onscreen keyboard on the pda?
2. What do you like best about the device?
3. What do you dislike about the device?
4. What additional features would make this device more useful for you?

5. What feature would you like to change and how would you change it?

6. What feature did you find most useful?

- a. Reminder alarms
- b. Calendar
- c. Portability
- d. Address book
- e. Memo
- f. Note Pad
- g. Other _____

Is there anything else you would like to share about being a part of this project?

FATCAT PDA Data (to be entered by investigator on examination of PDA):

| Week | Reminders | Calendar | Note | Contacts | Memo |
|-------|-----------|----------|------|----------|------|
| One | | | | | |
| Two | | | | | |
| Three | | | | | |
| Four | | | | | |
| Five | | | | | |
| Six | | | | | |
| Seven | | | | | |
| Eight | | | | | |

Uses for Reminders:

Uses for Note Pad:

Uses for Memo:

Other Uses of PDA:

Contacts to Investigator for help during study:

APPENDIX C

PARTICIPANT RAW DATA

PARTICIPANT RAW DEMOGRAPHIC DATA

| Participant | Age | Sex | Race | Marital Status | Year Diagnosed | M.S. type | Employment status |
|-------------|-----|-----|------|-------------------|-------------------|--------------|----------------------|
| 1 | 52 | F | C | Widow | 1987 | SP | PT |
| 2 | 69 | F | C | Married | 1965 | PP | RET |
| 3 | 73 | M | C | Married | 1981 | PP | RET |
| 4 | 47 | F | C | Married | 1997 | RR | PT |
| 5 | 50 | F | AA | Single | 1997 | RR | RET |
| 6 | 45 | F | C | Single | 1998 | RR | RET |
| 7 | 45 | M | C | Married | 1992 | SP | RET |
| 8 | 39 | F | C | Married | 1994 | RR | RET |
| 9 | 51 | F | C | Married | 1987 | RR | RET |
| 10 | 49 | M | C | Married | 2003 | RR | RET |
| 11 | 38 | F | C | Married | 1994 | RR | RET |
| 12 | 52 | F | C | Married | 1994 | RR | RET |
| 13 | 37 | F | C | Married | 1990 | RR | RET |
| 14 | 54 | F | C | Divorced | 1995 | SP | RET |
| 15 | 50 | F | C | Sig. Other | 1976 | RR | RET |
| 16 | 44 | M | C | Single | 2001 | PP | RET |
| 17 | 52 | F | C | Married | 1980 | CP | RET |
| 18 | 56 | F | C | Married | 2001 | RR | RET |
| 19 | 40 | F | C | Married | 2001 | RR | RET |
| 20 | 53 | F | C | Sig. Other | 1983 | RR | PT |

APPENDIX D

COPM DEFICIT CATEGORIES

COPM PERFORMANCE DEFICITS

| Categories of Deficits Identified by Participants | Number of participants identifying this deficit |
|--|---|
| Performing routine ADL (grooming, dressing, etc.) | 1 |
| Keeping track of appointments | 11 |
| Taking medications on schedule | 11 |
| Performing multi-step tasks (cooking, shopping, balancing checkbook, etc.) | 7 |
| Multi-tasking (doing two or more things at the same time) | 9 |
| Following through on plans | 7 |
| Remembering important events | 11 |
| Managing frustration | 5 |
| Staying focused on a project | 6 |
| Remembering names and faces | 6 |
| Not losing keys, other items | 5 |
| Dealing with distractions | 9 |

APPENDIX E

COPM ITEM-BY-ITEM T-TEST

COPM ITEM-BY-ITEM T-TESTS

| Deficit | Mean | Std. Deviation | T | df | Sig. (2-tailed) |
|-------------------|-------|----------------|--------|----|-----------------|
| ADL (a) | | | | | |
| Appointments | -4.36 | 2.46 | -5.882 | 10 | .000 |
| Medications | -5.00 | 2.19 | -7.569 | 10 | .000 |
| Multi-step tasks | -3.43 | 2.82 | -3.217 | 6 | .018 |
| Multi-tasking | -2.55 | 1.58 | -4.822 | 8 | .001 |
| Follow through | -3.14 | 2.03 | -4.085 | 6 | .006 |
| Important events | -4.54 | 2.21 | -6.829 | 10 | .000 |
| Frustration (b) | -2.40 | 2.61 | -2.058 | 4 | .109 |
| Staying focused | -3.67 | 1.63 | -5.50 | 5 | .003 |
| Names/faces | -3.50 | 2.66 | -3.217 | 5 | .024 |
| Not losing things | -4.80 | 1.92 | -5.580 | 4 | .005 |
| Distractions | -4.33 | 2.34 | -5.543 | 8 | .001 |

Notes: T-test comparing COPM item-by-item means from initial assessment and final assessment for each deficit category ($p < .05$)

(a) No t-test, because only one item.

(b) Not significant at .05 p.

APPENDIX F

RBMT-E RAW SCORES

RBMT-E RAW SCORES

| Participant | Raw Pre- test | Profile pre- test | Raw post- test | Profile post-test |
|-------------|------------------|----------------------|-------------------|----------------------|
| 1 | 88 | 25 | 90 | 21 |
| 2 | 96 | 22 | 98.5 | 26 |
| 3 | 54 | 4 | 56 | 4 |
| 4 | 96 | 23 | 101 | 29 |
| 5 | 87 | 25 | 92 | 24 |
| 6 | 100 | 27 | 100 | 27 |
| 7 | 88 | 25 | 100 | 27 |
| 8 | 87 | 21 | 100 | 27 |
| 9 | 113 | 30 | 100 | 27 |
| 10 | 107.5 | 32 | 98.5 | 27 |
| 11 | 88 | 25 | 100.5 | 27 |
| 12 | 84 | 16 | 88 | 17 |
| 13 | 84.5 | 15 | 86 | 15 |
| 14 | 87 | 18 | 68 | 10 |
| 15 | 89 | 26 | 98.5 | 27 |
| 16 | 40 | 6 | 51 | 6 |
| 17 | 71 | 18 | 88 | 17 |
| 18 | 112 | 27 | 98.5 | 26 |
| 19 | 52.5 | 5 | 51 | 5 |
| 20 | 102.5 | 25 | 98.5 | 26 |

Notes: Possible Raw Score Range = 0-157

Possible Profile Score Range = 0-48

APPENDIX G

RBMT-E PROFILE SCORES COMPARED TO CONTROL MEANS

***RBMT-E PROFILE SCORES
COMPARED TO CONTROL MEANS***

| Category | Profile score range | Number of participants in category, first test | Number of participants in category, second test |
|------------------------------|------------------------|---|--|
| Impaired | 0-18 | 7 | 7 |
| Poor memory | 19-27 | 11 | 12 |
| Average memory | 28-36 | 2 | 1 |
| Good memory | 37-42 | 0 | 0 |
| Exceptionally good memory | 43-48 | 0 | 0 |

Notes: Control mean based on the performance of 188 control subjects tested by RBMT-E authors (Wilson, Cockburn et al. 1991).

APPENDIX H

CHART SUB-CATEGORY T-TEST

CHART SUB-CATEGORY T-TESTS

| CHART sub-tests | Mean change | Std. Deviation | Std. Error Mean | T | df | Significance (2-tailed) |
|--------------------|----------------|-------------------|-----------------------|--------|----|----------------------------|
| Physical (a) | 3.000 | 20.617 | 4.610 | .651 | 19 | .523 ^a |
| Mobility | -4.4000 | 5.688 | 1.272 | -3.459 | 19 | .003 |
| Cognition | -16.400 | 11.923 | 2.666 | -6.152 | 19 | .000 |
| Social | -5.900 | 8.837 | 1.976 | -2.986 | 19 | .008 |
| Occupation | -10.300 | 16.348 | 3.656 | -2.818 | 19 | .011 |

Notes: Paired-sample t-test results for sub-categories of CHART compared for pre-training and post-training periods

^a Not significant at $p < .05$.

APPENDIX I

MEAN PDA ENTRIES PER WEEK

MEAN PDA ENTRIES PER WEEK ^a

| Function | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|------------------|-------|-------|-------|-------|-------|-------|-------|-------|
| Calendar Alarm | 17.65 | 21.30 | 22.85 | 26.70 | 28.80 | 29.05 | 30.60 | 35.05 |
| Calendar Entries | 19.40 | 25.35 | 26.20 | 28.95 | 32.35 | 33.15 | 35.20 | 39.80 |
| Note Pad Entries | 2.35 | 2.00 | 2.20 | 2.15 | 2.80 | 1.95 | 2.15 | 2.55 |
| Contacts | 3.05 | 11.05 | 17.90 | 22.25 | 27.80 | 32.50 | 33.55 | 36.35 |
| Memos | .90 | 1.20 | 1.60 | 2.10 | 1.75 | 1.65 | 1.85 | 2.00 |

Notes:

^a Weeks 1-8 Post-Training

APPENDIX J

PARTICIPANT MEAN SCORES ON FATCAT LIKERT-SCALED QUESTIONNAIRE

PARTICIPANT MEAN SCORES ON FATCAT LIKERT-SCALED QUESTIONNAIRE

| Item No. | Question | Mean response |
|----------|--|---------------|
| 1 | Using a handheld computer has helped me improve performance in at least one area of my daily activities. | 4.75 |
| 2 | I find the handheld computer simple to use. | 4.80 |
| 3 | I am able to use the handheld computer without any help from another person. | 4.75 |
| 4 | I primarily use the device as a reminder system for things I need to do. | 4.80 |
| 5 | I primarily use the device as a calendar. | 4.05 |
| 6 | I would like to continue using this device. | 4.90 |
| 7 | Using this device is just a waste of time. | 1.00 |
| 8 | I misplaced this device at least once. | 1.65 |
| 9 | The device broke down at least once. | 1.40 |
| 10 | I found that I was able to respond to reminder alarms almost every time one rang. | 4.15 |
| 11 | I received enough training to use the device effectively for my purposes. | 4.95 |
| 12 | The investigator was responsive to my needs throughout the project. | 5.00 |

Notes: Questionnaire key:

- 1 = I strongly disagree with this statement.
- 2 = I disagree with this statement.
- 3 = I neither agree nor disagree with this statement.
- 4 = I agree with this statement.
- 5 = I strongly agree with this statement.

APPENDIX K

PARTICIPANT PERCEPTIONS:

FATCAT SHORT ANSWERS SUMMARY

FATCAT

Participant Perceptions: Short Answers

The FATCAT includes a short-answer section intended to elicit participant perspectives on the intervention. The following paragraphs present these questions and discussions of participant responses.

Question One: When entering information on the device, which mode did you use most: (1) Palm Desktop on your home computer, (2) stylus or (3) onscreen keyboard on the pda? Participants varied widely in their preferences for interfacing with their PDAs. Ten used the stylus, eight used the onscreen keyboard, one used the Palm Desktop and one used all equally.

Question Two: What do you like best about the device? This question led to quite expansive answers, in one case filling a single-spaced page. All participants found the reminder alarm for calendar events to be useful, and all used other device features as organizational tools as well. As one participant wrote about her device, "I like everything! It has changed my life. It helps me. It enables me to remember to do all I need to do. I put everybody's birthdays in it! It's spoiling me rotten!" Others commented that using the PDA had helped them regain control over their everyday lives. One wrote, "It frees up my mind because I know I have everything recorded and know it will remind me. Peace of mind and confidence. It has been tremendous for my state of mind. I do too much, but this thing

makes me feel like I can do more!" Another commented, "Now, I don't look dumb." Interestingly, "ease of use" was mentioned by five participants as the feature they liked best about the device. Four commented that the device had helped them take their medications more regularly, and that this had made them feel healthier. As one wrote, "I am shocked at how much more organized taking two dumb little pills on schedule makes me feel!!!!!"

Question Three: What do you dislike about the device? Twelve participants wrote, "nothing". Four felt that the stylus was unwieldy and difficult to retrieve from its slot in the device. Two felt that the alarm was annoying ("it's like nagging") and one complained that the device was intolerant to temperature changes.²⁴ One participant found the device too complicated to use successfully without assistance from his wife.²⁵

Question Four: What additional features would make this device more useful for you? Four participants requested a carrying case with a belt clip and received these from the investigator (they were not originally included with the device). Two participants wrote, "nothing". Other additional suggested features included: (1) an extra stylus, (2) a cell phone, (3) a spell-checker, (4) more games, and (5) "a beeper so you could find it if lost" (each feature suggested by a different participant).

²⁵ This participant deserves discussion, as he was the only individual in the study who was not able to successfully learn how to operate the device. Discussion of his case follows in Chapter Five.

Question Five: What feature would you like to change and how would you change it? Only two participants responded to this question. One, who used the photo display software, asked for a way to adjust display contrast on photos individually. Another wanted a cord to connect the stylus to the device, so it would not be dropped.

Question Six: What feature did you find most useful? Select from: (a) reminder alarms, (b) calendar, (c) portability, (d) address book, (e) memo, (f) note pad, (g) Tasks or (h) other. Seven participants chose the reminder alarm, four chose the address book, three wrote "portability", two selected "calendar" and two selected "note pad". Two chose both the reminder alarm and the memo.

Question Seven: What programs or features not listed above did you use? Eighteen participants used the calculator, nine participants played the Solitaire game²⁶, nine used the World Clock feature as an alarm clock and four downloaded digital photographs to the Photo feature. Four participants made use of color-coded categories in their calendars. One used the Money software to record expenditures.

Question Eight: Did you look up additional resources for your device or download programs to it from the Internet? If so, what resources or downloads did you access? One participant cut-and-pasted Internet news articles to the Memo feature of her device, so she could remember to discuss them at lunch with her friends.

²⁶ On final assessment, one participant asked the investigator to remove the Solitaire game from her device, because "I can't stop playing it."

Question Nine: Is there anything else you would like to share about being a part of this project? Several participants commented that they were grateful for being included in the study, and many provided lengthy answers, which pursued a few general themes. These may be summarized as: (1) gratitude, (2) medication management, (3) organization and (4) self-control. Most participants expressed wonder that such a brief training and such a small device could impact their lives so powerfully. As one participant wrote, "the most important thing is having someone understand what I was going through and then find a solution for it. I can't tell you how much that means to me." Another commented, "thank you so much for giving me back my memory, even if it is now located in a somewhat different place! Life has suddenly become so much easier and more pleasant!"

All of the participants take medications of some sort, and eleven commented in their response to this question that the reminder alarm had helped them follow their medication regimes more consistently. As one wrote, "it chimes every morning to get my medicine and I used to forget until my blood pressure was pounding!"

Many participants mentioned that using the PDA had helped them become more organized, reducing the clutter of sticky notes at their desks, and helping them keep track of appointments, addresses, shopping lists and recipes. Feeling more organized led to a new sense of confidence and control for several participants. As one wrote:

I used to be overwhelmed with paper, and I'd forget where I put my notes. Now it's all in one place. My whole attitude has changed. This is so cool. I love being organized! I've learned you don't have to look at the big mess and get depressed. Accomplish the little things! Using the handheld, all of my abilities haven't changed (like getting dressed), but how I feel about it has. I can do things and be organized about it. I feel so good about that.

Though the reminder alarm and calendar functions were the devices' most popular features, all participants made use of other software to help organize their lives. One participant carefully described her myriad uses of the device:

I used to feel disorganized and cluttered. After I started using the PDA, I first got myself on a schedule with medications. I started to feel better! I then started scheduling appointments or events so I wouldn't forget I had to do something. I moved on to note pad. This stopped all the little pieces of paper I would have laying around. The memo was great for planning Christmas dinner and Christmas shopping. The Tasks have been great for meeting deadlines. Last of all I've started to use the Contacts. At first I put names of people I call frequently. Then I added additional categories, and put in names and numbers I had on business cards or scraps of paper. I also enjoyed playing Solitaire. The calendar is better than my rolling walker as an assistant! The expense program is really handy for keeping track of my money. Tasks is my favorite. I love setting the due dates and ticking off my to do list. It reminds me every day until I do it!

Many participants commented that using the PDAs had helped them emotionally. In most cases, they expressed relief at feeling a new sense of control over their day-to-day activities. One participant, however, credited her device with saving her life. She wrote:

Another great use I had – I went through a tremendous depressive state. Suicide kept coming into my mind. I kept notes on my Palm device (betwixt the crying spells). I think this allowed me to vent when I felt worthless. Thank you! You've helped me more than you realize. I am doing fine now!

In responding to the short-answer questions on the FATCAT, nineteen of the twenty participants stated that they enjoyed using their PDAs, had made the devices a part of their everyday lives, and planned to continue using them after the study ended. One participant, however, did not succeed in doing so. His RBMT-E scores were the lowest in the sample, he has multiple medical conditions, including a psychiatric disorder, and he suffered a serious M.S. exacerbation during the project. His significant other said that he enjoyed playing Solitaire on the PDA, but that she had to set alarms for him, and that he responded to them inconsistently. On final assessment, he was drowsy and inattentive, unable to demonstrate the PDA's basic features. This individual stands in sharp contrast to the other participants, all of whom were able to learn how to use the device and made it a part of their everyday lives. As such, he may represent a low-level cohort that would require a more intense training program, a simplified device or an entirely different cognitive intervention (perhaps focused on caregiver-driven supports and environmental management). His caregiver noted that she saw the potential for such a device, but wished "he had tried it earlier."