The Effectiveness of Personal Data Assistants in Improving Daily Function of Adults with Mild Traumatic Brain Injury

Connie Lee Budiwarman

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THE EFFECTIVENESS OF PERSONAL DATA ASSISTANTS IN IMPROVING DAILY FUNCTION OF ADULTS WITH MILD TRAUMATIC BRAIN INJURY

by

Connie Lee Budiwarman

A Thesis
Submitted to the
Faculty of The Graduate College
in partial fulfillment of the
requirements for the
Degree of Master of Science
Department of Occupational Therapy

Western Michigan University
Kalamazoo, Michigan
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Connie Lee Budiwarman
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Connie Lee Budiwarman, M.S.
Western Michigan University, 2004

This study evaluated the effectiveness of using Personal Data Assistants to help with memory and/or organizational difficulties with adult patients who had survived mild Traumatic Brain Injury. Utilizing an AB single subject design method with a training period, one subject ultimately completed the study. The study demonstrated mixed results. Through the use of daily record sheets, the subject reported improvement in three areas of daily function but reported negative improvement in three areas of daily function. This study suggests, but does not completely support, the potential use of Personal Data Assistants with patients with Traumatic Brain Injury.
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INTRODUCTION

Traumatic brain injury (TBI) is defined by the National Head Injury Foundation as “an insult to the brain, not of a degenerative or congenital nature but caused by an external force, that may produce a diminished or altered state of consciousness, which results in impairment of cognitive abilities, physical functioning, and emotional functioning.” (Reed, 2001, p. 503).

According to the Brain Injury Association (2001), “every 15 seconds in America, a person sustains a TBI. Each year, over 373,000 of the two million Americans who sustain a TBI are hospitalized, about 56,000 die, and another 100,000 are permanently disabled.” Seventy percent of brain injuries result in mild brain injury, 20% in moderate to severe, and 10% are fatal (Reed, 2001).

Mild brain injuries are also known as “concussion.” There is only a brief or momentary loss of consciousness, if any. For some, symptoms of mild TBI may improve over 1-3 months. For others with mild TBI, cognitive symptoms may persist for indefinite periods of time. Moderate brain injury is one that results in a loss of consciousness usually lasting only minutes or a few hours followed by a few days or weeks of confusion. Brain contusions or hematomas may accompany moderate TBI’s. Persons sustaining a moderate brain injury will usually have cognitive and behavior impairments that can last for many months. However, with treatment, some individuals are sometimes able to make a nearly complete recovery. Severe brain injury almost always results in prolonged unconsciousness or coma lasting days, weeks or even longer. Such persons often have brain contusions, hematomas or damage to the nerve fibers or axons, and some may have suffered from anoxia. Although persons who sustain a severe
TBI can make significant improvements in the first year after injury and can continue to improve at a slower pace for many years, they will often be left with some permanent physical, behavioral and/or cognitive impairments (Brain Injury Association, 2001).

Impairments that may occur to one who has suffered TBI are generally in the following realms: physical, cognitive, visual, perceptual, psychosocial, and behavioral (Gutman, 2001).

Cognitive deficits in the patient with TBI are always evident to varying degrees. The most common deficits are listed below:

1. **Decreased attention and concentration**—impaired ability to maintain an activity without distractibility; impaired ability to concentrate for a length of time and to filter out distractions from the surrounding environment.

2. **Impaired memory**—most frequently observed cognitive deficit in the patient with TBI; can range from inability to recall several words just heard (immediate memory), to forgetting what was for breakfast (short term memory), to having lost memory of events that occurred years before the injury (long term memory).

3. **Impaired initiation and termination of activities**—impaired ability to start and end activities. Perseveration may develop, in which one cannot end the neurological motor pattern started for a specific activity (i.e. one continues task of brushing teeth for minutes without stopping due lack of insight of what to do next).

4. **Decreased safety awareness and poor judgment**—impaired insight of limitations, as well as impulsivity, or the inability to consider consequences before acting.

5. **Impaired executive functions**—self-regulating and control functions that direct and organize behavior (Gutman, 2001). Specific component areas include

When one sustains a mild TBI, he or she may be left to deal with some or all of the above named cognitive deficits. Any combination of cognitive effects would cause impaired function with the individual’s independence in daily function (Radomski, 2002).

Daily function is doing the things that one does in his or her daily life. Daily function, also called occupational function, includes activities of daily living, work, and play or leisure activities (Crepeau, 1998). The following are examples of daily function: self care, going to work or school, caring for family, household maintenance, and hobbies that one may have. When one sustains a TBI and has subsequent cognitive deficits, he/she may have difficulty in completing daily function activities. For example, he or she may have impaired memory so that medication is forgotten and daily appointments are missed. He or she may have impaired executive functions, as well as impaired initiation and termination ability, so that it is difficult to efficiently plan a meal with several steps to be completed. He or she may have decreased attention and concentration so that ability for new learning may be impaired. As can be seen from these examples, cognitive impairments can easily jeopardize one’s daily function ability (Radomski, 2002).

Anxiety and fatigue are also common effects of mild TBI and also may impact one’s ability to successfully participate in daily function activities. Anxiety, defined by Webster, is “worry, uneasiness, apprehension” (Webster, 1990). Fatigue is defined as “weariness from labor of body or of mind, temporary loss of power to respond after repeated stimulation.” (Webster, 1990).” Though anxiety and fatigue may be common
for any person, it is reported these conditions may be more common for those who have survived an injury and/or have special needs (Melvin, 2000).

There are several ways to treat deficits of TBI. The first is remediation, which addresses performance components. The goal is to change biological, physiological, psychological, or neurological processes to restore or remediate impairments in performance components. For example, if one has short-term memory impairment from a TBI, the remedial approach would be to practice short-term memory tasks in repetition to attempt to fix or strengthen memory skills. It must be noted that remediation is valuable only if it improves the ability to perform desired occupations (i.e. short-term memory exercises must help with short term memory while operating in daily life in order for this approach to be valuable).

The next approach is compensation, which addresses performance areas. This approach teaches someone a different method to do the same thing to help by-pass the difficulty area. For example, for a person who has difficulty with initiation and termination of morning routine activities, a compensatory technique would be to have a caregiver write a detailed plan to be followed, including start and finish times.

Finally, the last approach is adaptation, which also addresses performance areas. Adaptation changes the context in which the activity is occurring, so that the challenging aspect of the activity is removed (Early, 2001). An example of the adaptive approach is to remove all potentially dangerous appliances and utensils from the kitchen for the TBI survivor who has decreased safety awareness and poor judgment. Other adaptive techniques include environmental modifications (i.e. wheelchair ramps, grab bars, etc.), and also adaptation of tools, equipment, and methods. It is important to note here many
people are sensitive to appearances and may reject adaptive equipment because they believe it stigmatizes them. Thus, use of any adaptive technique must be agreeable to the patient and family (Early, 2001).

Personal Data Assistants (PDA's) are pieces of adaptive equipment, also called assistive technology, which is defined as “any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities” (Angelo, 1997, p. 226). PDA’s are possible tools to assist with daily function for survivors of mild TBI who possess any array of cognitive deficits.

PDA’s are defined as “a compact device or mini computer that can store many types of information” (Strait, 2003). Depending on the type and brand, PDA’s can store information such as daily plans, monthly calendars, to-do lists, word documents, money management documents, pager/phone numbers/email addresses. Some even have the capabilities to be a mini-voice recorder as well as alarm system. Information on PDA’s can also be saved on desktops or laptops for backup purposes in case of PDA battery failure. Data can be entered into the PDA from either the PDA itself or personal computer (Strait, 2003).

The focus of this study will be on patients with mild TBI, defined as “physiological disruption of brain function as manifested by at least one of the following: any period of loss of consciousness, any loss of memory for events immediately before or after the accident, any alteration in mental state at the time of the accident, focal neurological deficit that may or may not be transient, initial Glasgow Coma Scale score of 13-15” (Radomski, 2002, p. 857). This study examines the effectiveness of using a
PDA for improving daily function for adults patients with mild TBI. It is hypothesized that a PDA will significantly improve the daily function of adults who have survived from such injury.
LITERATURE REVIEW

Researchers and organizations have completed studies in the area of assistive technology for the cognitive rehabilitation of mild brain injury patients dating back to the 1980's. Harris (1984), in a discussion article, talked of the importance of using external memory devices such as clocks and calendars to facilitate recalls. In their study to be discussed, Kirsch, Levine, Fallon-Kreuger, & Jaros (1987) make mention of other authors who had explored the use of devices such as buzzer systems and digital chronographs to remind patients of appointments or times for self-care procedures.

Kirsch et al. (1987) evaluated the effectiveness of a microcomputer called COGORTH (COGnition ORTHosis) for the completion of everyday activities. The COGORTH is a computerized task guidance system and is designed to program complex tasks that a patient would otherwise be unable to complete unless assisted by another person via instructional modules. This study suggested the potential utility of the microcomputer as a compensatory device via single case study. This study utilized an ABA study design with one subject, and found that use of this microcomputer assisted the subject with her ability to successfully complete the kitchen task of baking cookies (Kirsch et al., 1987). Limitations of this study include lack of broadness of daily function (i.e. only evaluated the task of baking cookies) and the possibility of improvement being due to simple task repetition (and not with computer intervention).

In 1989, Giles & Shore evaluated the effectiveness of an electronic memory aid (called a Psion Organiser) for a memory-impaired adult of normal intelligence and documented its usefulness. The Psion Organiser is small enough to fit into an inside jacket pocket or a handbag, but it has a keyboard large enough for easy data entry. It
includes functions such as time, calculator, diary, alarm, and memo pad. Information is accessed by the *find* command. A single subject, though an ABAC experimental design, demonstrated that this Psion Organiser helped the patient to independently perform functional activities at specific and scheduled times throughout the day. The Psion Organiser is a considerable advance over earlier memory aids, and it may be helpful to other memory-impaired patients (Giles & Shore, 1989). Positive attributes to this study are that the time periods were widely separated (i.e. month apart) to minimize practice effects and to allow a comparable period between all conditions.

NeuroPage is a mnemonic cueing system, developed by neuropsychologist Neil Hersh and engineer Larry Treadgold in 1994 (Wilson, Emslie, Quirk, & Evans, 1999). Since then, this has been a research topic for many researchers. This system utilizes radio-paging technology and involves the patient wearing an ordinary alphanumeric pager. NeuroPage uses an arrangement of microcomputers linked to a conventional computer memory and, by telephone, to a paging company. The scheduling of reminders or cues for each individual are entered into the computer. On the appropriate date and time, the reminder is transmitted to the individual. All the individual needs to learn is to press a button (Wilson et al., 1999). Various researchers (Evans, Emslie, & Wilson, 1998; Wilson et al., 1999; Wilson, Evans, Emslie, & Malinek, 1997) have looked into the usefulness of the NeuroPage with patients with neurological impairments.

Evans et al. (1998) described a single case investigation in which NeuroPage and a checklist was effective in cueing behavior for a 50-year old woman seven years post-CVA. Using a series of ABAB single-case experimental designs, this subject demonstrated a marked improvement on her ability to carry out intended actions at the
appropriate time using the NeuroPage and also a checklist (Evans et al., 1998). It appears
difficult to determine which, the NeuroPage or the checklist, was more effective in
improving her daily performance.

Wilson et al. (1997) used an ABA single case experimental design, and showed
that all of 15 subjects demonstrated significant improvements in task completion using
NeuroPage. The authors of this study were specific to mention the individuality of each
of the 15 subjects, noting that some made dramatic improvements (from total failure to
total success) while others were still in the poor overall performance range (though being
better than in the baseline period). An odds ratio test and subsequent average
improvement factor, showed that each subject benefited significantly from NeuroPage
(Wilson et al., 1997). A positive attribute of this study is that the authors employed a
significantly higher number of subjects than any other previously mentioned study.

Wilson et al. (1999) replicated the study by Wilson et al. of 1997. This time, they
were in the progress of completing a study of 200 people with memory and executive
problems using NeuroPage. This study incorporated a wider range of memory and
executive deficits than in the original study. Their single case report of one subject
indicated that NeuroPage helped this person to live independently by providing cues for
daily activities to be completed. Using an ABAB single-case experimental design over a
period of 16 weeks, the participant demonstrated that on the whole, he was more
successful with the pager than in the baseline phase (Wilson et al., 1999). This study
included patients of more severe degrees of TBI and consequent deficits, and thus implies
that NeuroPage may be effective with a wider range of participants.
Levinson (1997) developed a customized system that addressed executive dysfunction, such as planning and self-monitoring. This device is called The Planning and Execution Assistant and Trainer (PEAT), a type of PDA that uses the Sony Magic Link device and is based on General Magic's Magic Cap operating system. The device is a little larger than a videotape and weighs 1.3 pounds. His approach was to use artificial intelligence (AI) technology to implement executive functioning concepts. This AI planning system allowed users with brain injuries (or their caregivers) to define scripts for activities, such as morning routines or going shopping. The user could add appointments, or make adjustments to the scripts, and the system evaluated the plan for conflicts and modified the plan accordingly. Plan execution was assisted by prompting the user with visual and audible cues at each step of the plan (Levinson, 1997). This system was limited to executive functioning, and is not intended to compensate for other cognitive dysfunction such as memory dysfunction, which may limit its usefulness in addressing the needs of actual survivors (Cole, 1999). This device seems very large in comparison to current-day PDA's. Studies with this PEAT have been unpublished or unable to be found.

In 2000, Van Den Broek, Downes, Johnson, Dayus, and Hilton performed a study with 5 subjects on the effectiveness of using a Voice Organizer to manage prospective memory errors. The Voice Organizer is a hand-held dictaphone-type device, which is trained to recognize the patient's 'individual speech patterns and stores messages dictated by the user. It can be programmed to replay messages at time periods specified orally by the patient. In contrast to aids such as NeuroPage, the Voice Organizer does not require external programming via a paging company and the patient can use the device
autonomously (Van Den Broek et al., 2000). This study employed an ABA experimental design method. This study required that a relative was willing to participate in the study and accompany the patient to all weekly training sessions and assist with the implementation of the experimental tasks. Their study results showed that all subjects (with one exception) benefited from the use of Voice Organizer, indicating the potential usefulness of this external aid for the rehabilitation of prospective memory impairment (Van Den Broek et al., 2000). An attribute of this study is the number of subjects employed. Limitations of this study are that those with significant expressive speech impairment, poor manual dexterity, or visual deficits cannot employ it.

The Institute for Cognitive Prosthetics (ICP) is a program that focuses on restoration of individual’s functioning through technology, enabling them to perform some of their priority everyday activities (Cole & Dehdasti, 1998). Research has been completed by ICP, mostly via single-subject case studies, on the efficacy of assistive technology devices that are all highly individualized and specialized for each patient. Construction of the one-of-a-kind hardware/software system is highly customized to each patient based on the patient’s unique combination of activity priorities, cognitive and physical abilities, and cognitive and physical deficits. “Results have been significant and substantial,” as demonstrated through several key case studies (Cole & Dehdasti, 1998). Though it appears that these specially designed devices have provided success for the patients, the cost must also be considered. Many patients who have survived TBI may not have the financial resources to explore this option of having a device specially designed for them.
As mentioned in the introduction, a person sustains a TBI every 15 seconds in America (Brain Injury Association, 2001). With such statistics, one would assume that significant research and use of assistive technology has been invested into the cognitive rehabilitation of people with TBI. However, as one study by Gamble & Satcher (2002) reports, only thirty (2.6%) of 1,145 people with TBI of a public rehabilitation facility were provided with assistive technology in their rehabilitation. One thousand one hundred and fifteen (1,115) (97.4%) people with TBI were not provided with assistive technology, and demonstrated lower vocational outcomes by the closure of their case with the rehabilitation facility. Of those patients provided with assistive technology, 73.3% had successful vocational outcome compared to only 48.9% successful vocational outcome of those patients not provided with assistive technology (Gamble & Satcher, 2002). This study employed data of patients with TBI whose cases were closed from October 1992 through September 2000 in a public rehabilitation facility in a southeastern state. Analysis of previously collected data was performed with no contact required with the patients themselves. This study by Gamble & Satcher suggests that assistive technology is a useful resource when serving patients with TBI, and should be more actively sought for use in cognitive rehabilitation.

The literature reviewed reveals that research has been completed on assistive technology devices ranging from simple to complex, however there is room for further research to be completed in the field. Previous studies mentioned have evaluated devices to compensate for poor memory or poor executive functioning skills. Research has yet to be completed on a device that helps compensate for both these deficits. Also, research has yet to be completed on a device weighing only ounces but containing high data
programs. This study examines the effectiveness of using a PDA for improving daily function for adults patients with mild TBI. It is hypothesized that a PDA will significantly improve the daily function of adults who have survived from such injury.
METHODS

Participants

For this study, three subjects were initially selected for the study. Selection criteria to be included in the study are as follows:

1. Defined incident fulfilling at least one diagnosis requirement of mild TBI
2. Any adult ranging from age 18-60 (employment age)
3. Defined incident must be beyond 18 months (time period in which spontaneous recovery can be medically expected)
4. Adequate visual and motor skills to see and operate the PDA
5. Adequate attention span and focus
6. Substantial memory and new learning ability
7. Self-awareness of daily function

Three subjects voiced interest in the study, met for the initial interview, signed consent forms, and began participation in the study. Due to varying reasons and personal circumstances and in differing stages of the study, two subjects dropped from the study. One subject completed the study, and these results will be the only data discussed.

Procedures

Subjects were located by contacting local rehabilitation clinics, psychologists, disabled student services at a local university, and other personal contacts for potential subjects (see Appendix A). Subjects were qualified for this study through an initial phone conversation and subsequent in-person interview. Consent documents were signed once the subjects agreed to participate in the study (see Appendix B). Demographic information was also collected (see Appendix C). A generalized script was followed in
the initial interview and in each subsequent treatment session (see Appendix D). During the training period, the training protocol was followed in teaching the different functions of the PDA (see Appendix E). Subjects identified 3-5 difficulties in daily function from a list of several options with blanks to add difficulties, if needed (see Appendix F). These 3-5 difficulties were measured throughout the study, without and with use of the PDA.

Instrument

The PDA employed in the study is the Palm Zire 21, priced around $125.00 each. It is a commercially available device that is available at most technology and/or office stores. It provides 8 MB of memory, 4.4” X 2.9” size, and weighs 3.8 oz. It offers features such as keyboard or pen entry, calculator, calendar, address book, date book, expense list, spreadsheet, word processor (note pad and memo pad), world clock, and to-do list. This PDA is able to address both memory as well as executive function deficits. This PDA includes a rechargeable battery that needs to be charged approximately every one to two weeks, depending on the amount of usage. It can be hooked up to the personal computer via a cable to the USB port. This communication from the PDA to a computer allows for back-up of data as well as the convenient data entry via computer keyboard (which is larger, and possibly more comfortable and quicker to enter data).

As mentioned in the introduction, many people are sensitive to appearances and may reject adaptive equipment or assistive technology because they believe it stigmatizes them. In order for one to use adaptive equipment or assistive technology, it is important that the equipment be agreeable to the patient and family (Early, 2001). It should be noted that the PDA that is employed in this study is readily available in stores and is a "normal" device that is used by the general population. Therefore, due to the increasing
usage of this technology by all people, any patient using a PDA in public may not feel stigmatized by the use of this device.

**Design**

This study employed an AB single subject design method with a training period. The single subject design allows for each subject to serve as his/her own control. Since mild TBI has so many variations, it is important that each subject’s data be analyzed in light of his or her specific difficulties. Phase A was the baseline period, lasting four sessions while phase B was with the treatment, also lasting four sessions. The training period lasted as long as required for the subject to feel comfortable with the PDA (between two-four weeks). Total study time lasted approximately fourteen weeks, with ½ hour to 1 and ½ hour sessions per week in a location of subject’s convenience.

Subjects were asked to complete a daily record sheet through Phase A and Phase B of this study (see Appendix F). The daily record sheet was a quantitative way for the subject to mark level of difficulty with the identified problem area in daily function. The subject was to report on each problem area using the following scale:

1. 1 (no problem)=no difficulty at all
2. 2 (slight problem)=problem in this area occurred on 1 incident or less
3. 3 (moderate problem)=problem in this area occurred on 2-3 incidents
4. 4 (severe problem)=had difficulty with this area 4 times or more
5. N/A if this difficulty did not affect the subject at all that day

During Phase A, baseline of daily function with current organization and/or memory devices was obtained for three weeks. The weekly treatment sessions during Phase A mostly involved trading completed daily record sheets for the previous week for
uncompleted daily record sheets for the coming week. Aside from informal conversation, a generalized script was also followed which included the following questions:

- How has your daily performance been this last week?
- Were you able to record your daily function everyday this last week? If not, why not?
- Do you feel any change in stress levels this week?

The training period was a time when the PDA was introduced to the subject. The first couple sessions of the training period was spent teaching and learning the basic operations of the PDA (i.e. turning on and off the PDA, re-charging the battery, learning the specialized script, operating the basic functions such address/phone book, to-do list, etc.). Each session began with a review of what had been learned the previous week, as well as answering any questions that may have arose. The last couple sessions of the training period was learning the more advanced functions of the PDA (alarm clock, calendar, money management). The subject kept the PDA during the week, and was encouraged to use it throughout the day.

Once the subject verbalized and demonstrated a working knowledge of the PDA use, Phase B began. During Phase B, the subject was asked to once again complete daily record sheets for a period of three weeks. This time, the subject was asked to rate the problem area on the daily record sheet while incorporating use of the PDA each day. Each week, the subject traded completed daily record sheets for the previous week for uncompleted daily record sheets for the coming week. Each weekly treatment session during Phase B followed the same generalized script that was used during Phase A, with the addition of the following question:
Do you have any questions regarding use of the PDA?

**Participating Subject**

The subject who completed the study is a 58-year old female named A.L. (these initials are made up to protect the identity of the participating subject). A.L. was three years post accident at the time of the study. She was involved in pedestrian versus car accident, of which she was the pedestrian. Aside from several orthopedic fractures, she was also given the diagnosis of mild TBI. Prior to her accident, she was employed full-time as a claims representative at a local agency. She has not been employed since her accident. She resides with her husband in a house. She identified areas of her daily function as doing house tasks such as meal preparation and house cleaning; self-care; keeping appointments outside the home; and social meetings with her friends and family. Daily occupation remained similar between Phase A and Phase B, aside from a short trip to visit family in Phase A. A.L. reported to be independent in most all areas of daily living, with several cognitive complaints that hinder efficiency and productivity in daily activities. A.L. named the following six areas as the most difficult in her daily function:

1. scheduled appointments (preparing and getting to them on time)
2. medication administration (taking the correct medication/dosage at the correct times)
3. daily organization (getting things done in a time efficient manner)
4. anxiety (high level of this)
5. money management (keeping track of money, paying bills)
6. fatigue (extreme on some days).
Organizational and memory aides used prior to the study included pill organizers and day calendar. A.L. had attempted to use a paper and pen checklist in the past, but had found herself to become overwhelmed with a list greater than three tasks.

A.L. was asked to complete a daily record of her performance in the six problem areas mentioned above. During Phase A and Phase B, she reported on each area from a scale of 1 (no difficulty at all) to 4 (had difficulty with this area four times or more) (see Appendix F).
RESULTS

The following is a table of A.L.’s self-reported performance in each area in which she listed difficulty, with the score for each phase averaged (see Table 1).

Table 1: Self-Reported Performance Data

<table>
<thead>
<tr>
<th>Area of Difficulty</th>
<th>Phase A</th>
<th>Phase B</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scheduled Appointments</td>
<td>1.5</td>
<td>1.31</td>
<td>0.19</td>
</tr>
<tr>
<td>Medication Administration</td>
<td>1.55</td>
<td>1.6</td>
<td>-0.05</td>
</tr>
<tr>
<td>Daily Organization</td>
<td>1.81</td>
<td>2.11</td>
<td>-0.03</td>
</tr>
<tr>
<td>Anxiety Levels</td>
<td>1.98</td>
<td>2.24</td>
<td>-0.26</td>
</tr>
<tr>
<td>Money Management</td>
<td>1.65</td>
<td>1.19</td>
<td>0.46</td>
</tr>
<tr>
<td>Fatigue</td>
<td>2.43</td>
<td>2.24</td>
<td>0.29</td>
</tr>
</tbody>
</table>

According to Table 1, A.L. reported improvement in 3 of the 6 areas noted with use of the PDA. She also reported non-improvement or negative improvement in 3 of the 6 areas noted. The following is a visual graph, presenting the same data in a varied way.
According to Table 1, A.L. reported improvement with use of the PDA in the areas of scheduled appointments, money management, and fatigue. She reported, however, non-improvement and even more difficulty in the areas of medication administration, daily organization, and anxiety levels.

When asked of A.L.'s opinion of the PDA, she mentioned that the PDA is a useful tool for jotting things down (with need for fewer post-it notes and big appointment books). It is convenient and small, and also easy to charge up the battery. She likes that there are different programs to pick and different ways to enter data. It is a continuation of the technology world. A.L. reported to be a very organized person before, and the PDA is a new tool that can be very useful to daily life. A.L. did have some dislikes, too, in regards to the PDA. She felt at times that her life was controlled by it. She felt internal pressure in participating in the study, and an internal pressure to learn the information. She mentioned that it takes some time to learn the "how-to's" on operating the PDA. Without any knowledge of the data results, A.L. reported that the PDA did not seem to help with anxiety or fatigue.
DISCUSSION

The research question of this study is: what is the effectiveness of using a PDA for improving daily function for adult patients with mild TBI? The results of this study partially support the hypothesis that a PDA will improve the daily function of adults who have survived from mild traumatic brain injury.

The study results also partially support literature review results that were discussed in an earlier section. Studies by Kirsch et al. (1987) with the COGORTH, numerous authors (Evans et al., 1998; Wilson et al., 1997; Wilson et al. 1999) with the NeuroPage, and VanDenBroek (2000) with the Voice Organizer all demonstrated the effectiveness and usefulness for the respective assistive technology devices studied. The study that Giles & Shore completed with the Psion Organizer in 1989 seems to be the older model pre-cursor to the PDA. The study by Giles & Shore revealed that this device had been successful in helping the subject to independently perform functional activities at specific and scheduled times throughout the day. In all, each study previously described in the literature review indicate the effectiveness of the studied assistive technology device for the subjects with TBI. This study with the PDA only partially supports the studies that were previously done in that the results are somewhat varied, with the subject demonstrating improvement in three areas, but negative improvement in three areas as well.

The devices that were examined in previous literature ranged from buzzers and microcomputers to a paging system. A PDA is considered an advance over earlier technology devices. It addresses memory and organizational skills, whereas devices previously examined looked at adapting for either memory or organizational skills. To
date, there have been few studies published using a tool as powerful as a PDA. This study may be helpful to build on a growing body of knowledge in this area of assistive technology and the TBI population.

Perhaps A.L. would have noted different progress had the training period been significantly longer, so that she would have more time to be used to using the PDA. A.L.’s training period lasted four weeks, and though she demonstrated and voiced a working knowledge of the functions and data entry of the PDA, may not have been completely comfortable with its use. In discussion, possible reasons for A.L. to report negative improvement in the following three areas may include these:

1) Medication administration—A.L. used a pill organizer for medication management prior to using the PDA. Even with use of the organizer, she reported to have missed medications at times. Nevertheless, it was a tool that she had become used to using. Changing her daily routine to using the PDA may have been too difficult or interfered too much with her previous compensation method.

2) Daily organization—A.L. had been used to using a daily calendar prior to using the PDA. Again, changing her daily routine to using the PDA may have initially complicated her routine more than simplified it.

3) Anxiety—A.L. reported internal pressure of trying to learn and use this new complex device. She was asked to record her performance on a daily basis, making her more aware of her deficits. These all, in turn, may have caused increased anxiety.
LIMITATIONS

The results of A.L.’s use of the PDA can only be suggestive. This study’s limitations include a small sample size of only one subject (and a drop out of two subjects), as well as use of self-recorded data. Although this study may suggest the potential utility of the PDA as a compensatory device, it may be possible that many patients of similar disability will or will not be able to benefit from such interventions. Use of the PDA may be limited only to the mild TBI population due to the pre-requisite skills required. These pre-requisite skills include adequate visual and motor skills, adequate attention span and focus, as well as substantial memory and new learning ability.
IMPLICATIONS FOR FUTURE RESEARCH

Further studies should be completed in this area of research. Studies employing the use of multiple subjects would be beneficial in continuing to qualify the usefulness of a PDA for daily function of adults with mild TBI. It would also be useful to evaluate the effectiveness of a PDA for varied populations (such as university attending students or working employees, etc.).
CONCLUSION

In summary, this study evaluated the effectiveness of using a PDA for improving daily function for adult patients with mild TBI. The hypothesis was that a PDA would significantly improve the daily function of adults who have survived from such injury. Via a single subject case study, results of this study only partially support the hypothesis in that the subject reported improvement in some areas of daily function, but decline in other areas of daily function. As mentioned, the results of this study are suggestive and further studies should follow.
Appendix A
Script for Recruitment

Hello! My name is Connie Budiwarman. I am currently an Occupational Therapist in Allegan Public Schools, and also a graduate student at Western Michigan University finishing my Masters of Science in OT. I am performing a study on the effectiveness of Personal Data Assistants (PDA) (ie. palm pilot, a hand held computer) in improving daily function of adults with mild traumatic brain injury. Mild traumatic brain injury is defined as an incident leading to at least one of the following: any period of loss of consciousness, any loss of memory for events immediately before or after the accident, any alteration in mental state at the time of accident, and focal neurological deficit. If you were taken to the hospital after the accident, initial Glasgow Coma Scale score would be 13-15. **I am seeking to recruit 3 subjects who have survived a mild traumatic brain injury to participate in this study.** This study will be used as my graduate thesis. If you are interested in learning more about my research project, please read on. Reading this script will take only a couple minutes of your time.

**Purpose of this study:**
The primary purpose of this study is to evaluate the effectiveness of PDA’s (ie. palm pilot, a hand held computer) in improving daily function of adults with mild traumatic brain injury.

**How this study is being conducted:**
Once participants have been selected, informed consent will need to be signed before any sessions begin. This study will involve approximately 8 sessions (about 45 minutes each session) over a 3-month period. For the first 3 weeks, you will be asked to daily record your performance in specific areas you have difficulty with, using your current organizational and/or memory devices. Then you will be trained for 2 weeks with use of the PDA. Finally, for the last 3 weeks, you will record your daily performance in those same difficulty areas while using the PDA. You will be asked to keep a daily log of your performance, which will take approximately 5 minutes for completion of each log.

**Confidentiality:**
Your confidentiality will be maintained throughout the entire study. Personal names and identifiers will not be used in the reporting of this study.

Thank you for your willingness to learn more about my study. If you are interested or have any comments or questions, I can be reached at (269)492-7991 or at (269)598-1004. I can also be emailed at connie.lee@wmich.edu. Thank you and have a nice day!
Appendix B
Consent of a Responsible Adult

Western Michigan University, Department of Occupational Therapy
Title of Study: “The Effectiveness of Personal Data Assistants in Improving Daily Function of Adults with Mild Traumatic Brain Injury”
Principal Investigator: Dr. Diane Dirette
Student Investigator: Connie Lee Budiwarman, OTR

You have been invited to participate in a research project entitled “The Effectiveness of Personal Data Assistants in Improving Daily Function of Adults with Mild Traumatic Brain Injury.” This research will look at the effectiveness of using a personal data assistant (ie. palm pilot, a hand held computer) with individuals who have experienced a mild traumatic brain injury. This study is Connie Budiwarman’s graduate thesis project.

You are asked to attend approximately 8, 45-minute sessions over a 3-month period. You will also be asked to keep a log of your daily performance, which will take approximately 5 minutes of your time to complete each log. Each session will be scheduled at your convenience (approximately 1 session per week), and at a location of your convenience.

The initial interview will begin with questions regarding your accident or incident leading to mild traumatic brain injury, your treatment and outcomes, your current functional status, and any devices that you may use to help compensate for deficits you may have. Ongoing sessions will follow a generalized script. Questions will be about your performance over the last week. For the first 3 weeks, you will be asked to daily record your performance in specific areas you have difficulty with, using your current organizational and/or memory devices. Then you will be trained for 2 weeks with use of the PDA. Finally, for the last 3 weeks, you will record your daily performance in those same difficulty areas while using the PDA.

As in all research, there may be unforeseen risks to the participant. Due to the significant time commitment of attending sessions and keeping a daily log, the inconvenience may be a possible risk to you. Another potential risk of your participation in this project is that you may be upset by the content of the sessions, since you will be asked to identify and record on daily function difficulties due to a traumatic and, most likely, emotional experience (your incident leading to TBI).
You will also be asked to disclose personal information, which may cause discomfort and/or embarrassment. Connie has prepared a list of actions to take if you should become upset. She will provide you with a list of crisis counselors should you become significantly upset. Arrangements for a crisis counseling meeting can and will be made upon request.

This project may or may not benefit others. It may benefit the larger society in that it will provide evidence-based data on the effectiveness of PDA’s among the mild TBI population. If using a PDA is effective for patients with mild TBI, a PDA may decrease the amount of frustration the individual may experience due to the injury, as well as maximize the control that this patient has over his/her life. This, in turn, may also reduce the burden on caregivers in helping with the patient’s daily function. One way in which you may benefit from this study is that it will allow you a chance to explore a device that may significantly increase your daily performance in life tasks. You will also have the chance to talk about your accident and recovery, which may clarify the details and help you come to terms with the injury for yourself. This has been proven to be vital in a healthy emotional recovery from any traumatic experience. Another benefit of participating is that you will be able to keep the PDA after the study is completed.

All of the information collected from you is confidential. This means that your name or any identifying information will not be used in the reporting of the thesis project. Your identity will be protected throughout the data collection, meaning that your name or personal identifiers will not be mentioned should I discuss this study with anyone for any purpose and that your data will remain in a confidential folder. All data collected will be available to only Connie and her thesis committee. Upon project completion, this data will be kept for at least three years in a locked file of Dr. Diane Dirette’s office at the Earnest Whitney Building, Department of Occupational Therapy before being destroyed. If data needs to be held longer for professional association or research purposes, it can and will be done so.

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Connie at (269)492-7991 or (269)598-1004 or the committee chair, Dr. Diane Dirette, at (269)387-7260. You may also contact the chair of Human Subjects Institutional
Review Board at (269)387-8293 or the Vice President for Research at (269)387-8298 with any concerns that you may have.

This consent document has been approved for use for one year by the Human Subjects Institutional Review Board (HSIRB) as indicated by the stamped date and signature of the board chair in the upper right corner. Subjects should not sign this document if the corner does not have a stamped date and signature. Do not participate in this study if the stamped date is older than one year.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate. You hereby consent and voluntarily offer to be interviewed as part of this study. You will receive a copy of this consent form to read over at a later time, however this copy does not need to be signed.

_________________________  _______________________
Name (print)                  Date

_________________________
Signature

Consent obtained by:  _______________________
Initials of researcher       Date

Office of the Vice President for Research
240W Walwood Hall
Western Michigan University
Kalamazoo, MI 49008-5456
p: 616.387.8298; f: 616.387.8276

The Graduate College
260W Walwood Hall
Western Michigan University
Kalamazoo, MI 49008-5242
p: 616.387.8212; f: 616.387.8232
Appendix C
Demographic Information

The investigators of this study request the following information, which is relevant to the completion of this study. Personal identifiers will not be used in the write-up to protect the confidentiality of all subjects.

Name: ___________________________ Phone Number: ___________________________

Address: ___________________________

Sex:
□ Male
□ Female

Age: ___________________________

Educational level: ___________________________

Current Occupation: ___________________________

Occupation prior to accident: ___________________________
Appendix D
**Generalized Script**

Initial interview key questions:

- When was your accident? How did it happen?

- What treatments took place? What were the outcomes?

- What is your current functional status? What problems do you currently experience, especially in the area of daily function?

- What organizational and/or memory aids do you currently use, if any?

Ongoing sessions once the study has started will involve a generalized script to be used at use session with each subject. The generalized script is as follows:

- How has your daily performance been this last week?

- Were you able to record your daily function everyday this last week? If not, why not?

- Do you feel any change in stress levels this week?

- Do you have any questions regarding use of the PDA? (once use of PDA has started).
Appendix E
Training Protocol

A training period will be provided for individuals participating in this study. The training period will last for as long as required for the subject to verbalize and demonstrate a working knowledge of the PDA. The following skills are to be taught:

- Specialized script for numbers and letters
- Operating programs of the PDA, which include but are not limited to:
  - Calendar
  - To-do list
  - Calculator
  - Memo pad
  - Alarm clock
  - Address/Phone list
  - Checkbook management
  - Voice recorder

The earlier sessions of the training period will be spent teaching and learning the basic operations of the PDA. This includes turning on and off the PDA, re-charging the battery of the PDA, and operating of the basic functions of the PDA (calendar, to-do list, calculator, memo pad). Also, the specialized script for the PDA will be taught. The subject will be allowed to take the PDA home and is encouraged to use it throughout his/her day.

The later sessions of the training period will be spent clarifying any questions from the previous training sessions. Finally, the subject will be taught to operate the more advanced functions of the PDA (alarm clock, address/phone list, expenses management). Again, the subject will take the PDA home and is encouraged to use it throughout his/her day.

If, for any reason, the subject displays or verbalizes a difficulty of grasping the skills needed to operate the PDA, additional training sessions may be provided until the subject displays and verbalizes a comfort with operating the device.
Daily Record Sheet

Study Title: “The Effectiveness of Personal Data Assistants in Improving Daily Function of Adults with Mild Traumatic Brain Injury”
Student Investigator: Connie Lee Budiwarman

Please complete this record sheet everyday, at the end of the day, as much as you are able and store in the provided folder until our next session. If you have any questions, please do not hesitate to call me at (269)492-7991 or (269)598-1004.

Date: ___________ Time Completed: ______ Day of the Week: ___________

Brief Description of Today’s Schedule:

The record sheet is a way for you to mark difficulties that you may have had during your day.

<table>
<thead>
<tr>
<th>Area of Difficulty</th>
<th>Today's Level of Difficulty (see below for definition of levels)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion of Assignments</td>
<td>1 (no problem) 2 (slight problem) 3 (moderate problem) 4 (severe problem) NA</td>
</tr>
<tr>
<td>Submission of Assignments</td>
<td></td>
</tr>
<tr>
<td>Scheduled Appointments</td>
<td></td>
</tr>
<tr>
<td>Medication Administration</td>
<td></td>
</tr>
<tr>
<td>Daily Organization</td>
<td></td>
</tr>
<tr>
<td>Anxiety Levels</td>
<td></td>
</tr>
<tr>
<td>Money Management</td>
<td></td>
</tr>
<tr>
<td>Use of Stored Information</td>
<td></td>
</tr>
<tr>
<td>Forgetting where things are located</td>
<td></td>
</tr>
</tbody>
</table>

Definition of Levels-- 1 (no problem) = no difficulty at all, 2 (slight problem) = problem in this area occurred on 1 incident or less, 3 (moderate problem) = problem in this area occurred on 2-3 incidents, 4 (severe problem) = had difficulty with this area 4 times or more. Mark N/A if this difficulty does not affect you at all.

Please note any further comments about the PDA and how it may have helped/hindered your day.
Appendix G
Approval Letter From the Human Subjects Institutional Review Board

Date: July 31, 2003

To: Diane Dirette, Principal Investigator
    Connie Lee Budiwarman, Student Investigator for thesis

From: Mary Lagerwey, Chair

Re: HSIRB Project Number 03-07-01

This letter will serve as confirmation that your research project entitled “The Effectiveness of Personal Data Assistants in Improving Daily Function in Adults with Mild Traumatic Brain Injury” has been approved under the full category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may only conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: July 16, 2004
Appendix H
APPLICATION FOR CONTINUING REVIEW or FINAL REPORT FORM

In compliance with Western Michigan University's policy that "the HSIRB's review of research will be conducted at appropriate intervals but not less than once per year," the HSIRB requests the following information:

I. PROJECT INFORMATION

PROJECT TITLE: The Effectiveness of Personal Data Assistants in Improving Daily Function in Adults with Mild Traumatic Brain Injury

HSIRB Project Number: 03-07-01

Previous level of review: ☒ Full Board Review ☐ Expedited Review ☐ Administrative (Exempt) Review

Date of Review Request: 06/01/03 Date of Last Approval: 07/31/03

II. INVESTIGATOR INFORMATION

PRINCIPAL INVESTIGATOR OR ADVISOR

Name: Diane Dirette
Department: OT Mail Stop:
Electronic Mail Address: diane.dirette@wmich.edu

(1) CO-PRINCIPAL OR STUDENT INVESTIGATOR

Name: Connie Budiwarman
Department: OT Mail Stop:
Electronic Mail Address: cbudiwarman@yahoo.com

III. CURRENT STATUS OF RESEARCH PROJECT

Please answer questions 1-4 to determine if this project requires continuing review by the HSIRB.

1. The project is closed to recruitment of new subjects.
   ☐ Yes (Date of last enrollment: ) ☑ No (Project must be reviewed for renewal.)

2. All subjects have completed research related interventions.
   ☐ Yes ☐ Not Applicable ☑ No (Project must be reviewed for renewal.)

3. Long-term follow-up of subjects has been completed.
   ☐ Yes ☐ Not Applicable ☑ No (Project must be reviewed for renewal.)

4. Analysis of data is complete.
   ☐ Yes ☐ Not Applicable ☑ No (Project must be reviewed for renewal.)
   - If you have answered "No" to ANY of the questions above, you must apply for Continuing Review. Please complete numbers 5-12 on page 2. If you need to make changes in your protocol, please submit a separate memo detailing the changes that you are requesting.
   - If you have answered "Yes" or "Not Applicable" to ALL of the above questions, the project may be closed.
   - If your protocol has been open for three years and you still want to collect or analyze data, you must close this protocol by filing a final report using this form and apply for approval of a new protocol using an Application for Initial Review. Please make a Final Report on your project by completing numbers 5-9 on page 2.

IV. ☐ Application for Continuing Review ☑ Final Report

Revised 7/03 WMU HSIRB
HSIRB Project Number: 03-07-01

5. Have there been changes in Principal or Co-Principal Investigators?  □ Yes □ No
   (If yes, provide details on an "Additional Investigators" form available at the HSIRB website: http://www.wmich.edu/researchcompliance/hsic/hsicb_2.html.)

6. Has the approved protocol been modified or added to with respect to:
   □ Procedures  □ Yes □ No
   □ Subjects    □ Yes □ No
   □ Design      □ Yes □ No
   □ Data collection □ Yes □ No

7. Has any instrumentation been modified or added to the protocol?  □ Yes □ No
   (If yes, attach new instrumentation or indicate the modifications made.)

8. Has there been any adverse events that need to be reported to the HSIRB?  □ Yes □ No
   (If yes, provide details on an attached sheet.)

9. Total number of subjects approved in original protocol  □ 3-5 □ 6-

10. Total number of subjects enrolled so far □ 2
    If applicable: Number of subjects in experimental group Number in control group

   • If this is a FINAL REPORT you may stop here and return the form electronically
   • If this is an APPLICATION FOR CONTINUING REVIEW continue with numbers 10-12 below.

11. Estimated number of subjects yet to be enrolled □

12. Verification of Consent Procedure: Provide copies of the consent documents signed by the last two subjects enrolled in the project. Cover the signature in such a way that the name is not clear but there is evidence of signature. If subjects are not required to sign the consent document, provide a copy of the most current consent document being used.

13. If you are continuing to recruit subjects for this project, please remember to include a clean original of the consent documents to receive a renewed approval stamp.

Approved by the HSIRB:

Principal Investigator/Faculty Advisor Signature  Date

Co-Principal or Student Investigator Signature  Date

HSIRB Chair Signature  Date

Western Michigan University
Human Subject Institutional Review Board - Mail Stop 6456

Revised 7/03  WMU HSIRB
REFERENCES


