IS ERRORLESS LEARNING AN EFFECTIVE STRATEGY FOR A PROCEDURAL MEMORY TASK?

AND CLINICAL RESEARCH PORTFOLIO

CLAIRE L. DONAGHEY
Is Errorless Learning an Effective Strategy for a Procedural Memory Task?

& Clinical Research Portfolio

Volume I

(Volume II bound separately)

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Chapter 1: Systematic Literature Review

Head Injury as a Risk Factor for Alzheimer’s disease: A Systematic Review of Epidemiological Studies

Prepared in accordance with the requirements for submission to:
Ageing & Mental Health

(See Appendix 1.1)

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Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology
Abstract

**Objectives.** The association between head injury and Alzheimer’s disease is controversial and somewhat equivocal. This systematic review aimed to determine the link between head injury and Alzheimer’s disease by evaluating the epidemiological literature. **Method.** Case control studies, population cohort studies and autopsy studies that report the clinical risk factors for Alzheimer’s disease and that specifically included head injury as a possible risk factor were identified. The methodological checklists provided by the Scottish Intercollegiate Guideline Network (SIGN) ‘A Guideline Developers’ Handbook’ (SIGN 50, 2001) were used. Checklists for case-control studies and cohort studies were used to determine the quality of studies included in this review. **Results.** A total of 27 studies were found. Of these, 23 were case-control studies and 4 were cohort studies. Of the 27 studies included, 19 supported head injury as a risk factor for Alzheimer’s disease and eight studies did not. Three studies received the highest methodological rating (2++), 20 studies received an average methodological rating (2+) and four studies received the lowest methodological rating (2-). **Conclusions.** This review does not conclusively support the notion that head injury is a risk factor for Alzheimer’s disease. At present, the evidence is not strong enough to fully support the role of head injury in relation to the development of Alzheimer’s disease. Further research is required to clarify the role of previous head injury and the influence of other risk factors such as gender and family history on a previous head injury in relation to the development of Alzheimer’s disease.

**Keywords:** Alzheimer’s disease, Head Injury, Risk, Case-control, Cohort, Review
Introduction

Alzheimer’s disease is the most common neurodegenerative disorder accounting for 50 - 60% of all age-related dementia (Andersen et al., 2006). Specifically, pooled analyses suggest that the prevalence of Alzheimer’s disease rises from approximately 0.5% of the population aged 65 to 69 years to 8% at ages 80 to 85 years and 20% at ages over 90 years (Lobo et al., 2000). Early predictors and the clinical course of the disease have been reasonably well established and attempts at identifying possible risk factors for the development of Alzheimer's disease have been made (McDowell, 2001). Four risk factors for Alzheimer’s have been established: increasing age, the presence of the apolipoproteinE-epsilon4 (APOE 4) allele, familial aggregation of cases, and Down's syndrome (McDowell, 2001). Other studies point towards additional risk factors that may either accelerate or increase vulnerability to develop Alzheimer's disease. Possible risk factors that have been identified are gender (women generally appear at higher risk than men), education, and head injury (McDowell, 2001).

Head injury is the most common cause of death and disability in the Western population for people under the age of 45 (Bruns & Hauser, 2003). Every year head injury affects around 100 to 150 individuals per 100 000 population (Thornhill et al., 2000) and leads to death in 10 – 15% (Bruns & Hauser, 2003). The characteristics of the adult head injury population have proven to be consistent over many studies. Sorenson and Kraus (1991) produced a review of several studies based within the USA. They reported that typically the highest risk of injury is between the ages of 16 and 25 years, declining until late middle age and beginning to increase again about age 60 or 65 years. This pattern of occurrence was
comparable between the two sexes, although it varies in magnitude. The latter point has not always been noted as the incidence ratio between men and women usually ranges between 2:1 and 2.8:1 (Kraus & McArthur, 1996).

The link between head injury and Alzheimer’s disease is controversial. It has now been suggested that not only is head injury the leading cause of death for young adults but is also a risk factor for Alzheimer’s disease. The possibility that a head injury may predispose a person to developing Alzheimer’s disease has significant social and medical implications (Van Den Heuvel, Thornton, & Vink, 2007). It is therefore imperative to identify whether a link between head injury and Alzheimer’s disease exists and whether any preventative measures can be established.

Preliminary studies implicate a possible role for head injury in the development of Alzheimer’s disease. Neurobiological and neuropathological research suggests that this is a plausible association. It is now generally accepted that the development of Alzheimer’s disease is characterised by the presence of neurofibrillary tangles (NFT’s) and neuritic plaques. The leading ‘amyloid cascade hypothesis’ suggests that the accumulation of amyloid-β peptides, which are found primarily within neuritic amyloid plaques, are the primary influence in Alzheimer’s disease (Hardy & Selkoe, 2002). These plaques are neurotoxic. It is likely that symptoms of dementia are due to an excess accumulation of plaques, for smaller densities of plaque have been found in the brains of non-demented people (Tomlinson, Blessed, & Roth, 1970). In addition, the severity of dementia appears to increase with the degree of neurofibrillary tangle formation (Rosenberg, 2000). The
pathology of brains which have sustained a head injury shares certain similarities with the pathology of Alzheimer’s disease. Insight into this potential link has come from the study of boxers with dementia pugilistica or ‘punch-drunk’ syndrome (Gentleman et al., 2004). At the pathological level, neurofibrillary tangles similar to those seen in Alzheimer’s disease can be found in the brains of boxers with this syndrome (Corsellis, Bruton, & Freeman-Browne, 1973). Roberts, Allsop, and Bruton (1990) also demonstrated that Alzheimer-like pathology with diffuse Aβ plaque deposition was found in the brains of boxers suffering from dementia pugilistica. It can be speculated that Aβ deposition resulted from repeated blows to the head over a long period and that such events may also occur in the brains of head injured individuals (Van Den Heuvel et al., 2007). Histopathological studies of individuals who died after suffering a severe head injury demonstrate widespread cerebral Aβ deposition in both short-term and long-term survivors irrespective of age (Roberts et al., 1994; Gentleman et al., 1997). This implies that changes in the brain following a head injury would lead to an increased risk of developing Alzheimer’s disease.

There is accumulating evidence from epidemiological studies supporting head injury as a risk factor for the development of Alzheimer’s disease (Jellinger, Paulus, Wrocklage, & Litvan, 2001). However, the association between head injury and Alzheimer’s disease remains controversial and somewhat equivocal. Mortimer et al. (1991) conducted a meta-analysis investigating the association between head injury and Alzheimer’s disease and provided convincing evidence in support of an association. The association was strongest in those who were male and in those who lacked a positive family history of dementia. A systematic review of the case-control literature was carried twelve years later by Fleminger, Oliver,
Lovestone, Rabe-Hesketh, and Giora (2003). This review included seven case control studies which were included in Mortimer et al.’s meta-analysis and eight additional case control studies. In addition to reviewing the evidence for head injury as a risk factor for Alzheimer’s disease, evidence of a relationship between APOE status and head injury as a risk factor for Alzheimer’s disease was also examined. Similar to the findings of Mortimer et al. (1991), this review concluded that a history of previous head injury was a risk factor for developing Alzheimer's disease although this association was only noted in males. It is important to note, however, that when the studies that had not matched the relationship of the informant to the case and control subject were removed from the analysis, there was a reduction in the odds ratio (OR) to a non-significant level. There was also a reduction in the odds ratio when the eight additional studies not included in Mortimer et al.’s (1991) meta-analysis were analysed separately. Hence, this suggested that head injury was no longer associated with Alzheimer’s disease.

While there appears to be growing evidence from both neuropathological and epidemiological research, the research that has been conducted to date is vulnerable to methodological criticism. Much of the research concerning the association between previous head injury and the development of Alzheimer’s disease has been based on case-control studies which may be subject to potential recall bias. Informants for patients with Alzheimer’s disease may be more motivated to recall a history of head injury if this may in part explain a predisposition towards dementia (Chandra, Philipose, Bell, Lazaroff, & Schoenberg, 1987). Furthermore, case-control samples may not be representative of the general population. Additionally, the varying outcomes documented in the literature may
stem from authors addressing slightly different research questions and placing more or less
weight on the factors under investigation. Hence, it is important to consider these issues
when determining the association between head injury and Alzheimer’s disease.

Research Questions:

Primary research question:

- Does head injury increase the risk of Alzheimer’s disease?

Arising from the primary question are two secondary research questions that pertain to the
causal role of either head injury or Alzheimer’s disease in any association:

- Does Alzheimer’s disease increase the risk of head injury?
- Is the incidence of Alzheimer’s disease more common than expected in a head injury
  population?

Methodology

Inclusion Criteria

This review searched for case control studies, population cohort studies, and autopsy studies
that reported the clinical risk factors for Alzheimer’s disease and that specifically included
head injury as a possible risk factor. The inclusion criteria were developed from a
comprehensive review of the literature and consideration of the criteria used by Fleminger et
al. (2003). Six criteria were identified and used as necessary requirements for inclusion:
(1) Human studies only: The review was interested in clinically relevant factors.

(2) Dementia of the Alzheimer type: Different mechanisms lead to the development of different types of dementias (e.g. vascular dementia, fronto-temporal dementia) (Kramer et al., 2003; Neary, Snowden, & Mann, 2000). This review focuses on one type of dementia to enable a better understanding of risk factors.

(3) Diagnostic criteria for Alzheimer’s disease: This review required that studies used the National Institute of Neurological and Communicative Disorders and Stroke-Alzheimer’s Disease and Related Disorders Association (NINCDS-ADRDA) criteria for probable or possible Alzheimer’s disease (McKhann et al., 1984) or the Diagnostic and Statistical Manual for Mental Disorders (DSM) criteria to make a clinical diagnosis of Alzheimer’s disease.

(4) Head injury with or without loss of consciousness: This review was interested in head injury of any severity. This allows consideration of whether a head injury of a lesser severity may be implicated in the development of Alzheimer’s disease.

(5) Head injury occurred prior to the onset of Alzheimer’s disease: To be a risk factor, head injury must occur before the onset of Alzheimer’s disease.

(6) Participants are aged 16 or older: This review excluded children or adolescents as these two cohorts are too young to assess the risk of Alzheimer’s disease.

Identification of Studies

Searches were undertaken in PsychINFO (1985 – November week 1, 2007), Ovid Medline (1980 – November week 1, 2007), Embase (1980 – 2007, week 46), CINAHL (1982 – November week 2, 2007), Web of Knowledge (1985 – 2007), and Cochrane Database of...
Systematic Reviews (1st Quarter, 2007) using a comprehensive search strategy. The search strategy was divided into three components; component A identified papers relating to "Alzheimer's disease". Component B identified papers relating to "Head Injury" or "Traumatic Brain Injury". These two components were combined using the Boolean operator AND, with component C, which identified papers relating to "Risk Factors". As an indication of quality, the review required that the search strategy retrieved studies identified as major papers from previous systematic reviews. The search strategy was refined if the main studies were not identified. In addition to the electronic search, the reference lists of systematic review articles and papers retrieved through the electronic database search were hand searched to identify any further papers of relevance.

The search process generated 290 studies. A total of 222 papers were excluded on the basis of titles and duplicates. The remaining 68 papers were searched in more detail using the abstract as guidance. On the basis of the abstract, 50 were rejected. Eighteen papers were read in full text form. Of these, 13 met the inclusion criteria. Reference lists of these 13 papers were hand searched in addition to the reference list of the review by Fleminger et al. (2003). As a result, a further 21 papers were read in full text form. Of these 21 papers, a further 14 met the inclusion criteria. A total of 27 papers were included in the systematic review.

Quality Rating Criteria

The methodological checklists provided by the Scottish Intercollegiate Guideline Network (SIGN) ‘A Guideline Developers’ Handbook’ (SIGN 50, 2001) were used. Checklists for
case-control studies and cohort studies were used to determine the quality of studies by assessing aspects of methodology that have been shown to be significant in terms of interpretation of results (SIGN 50, 2001) (See Appendix 1.2 and 1.3). These include participant selection, assessment, confounding, and statistical analysis. Once these areas were assessed, each study was given an overall rating. The ratings assigned to each area were: Well covered; Adequately addressed; Poorly addressed; Not addressed (i.e., not mentioned or indicates that this aspect of study design was ignored); Not reported (i.e., mentioned, but insufficient detail to allow assessment to be made); Not applicable. The SIGN guidelines use the following coding system for the overall rating of the study:

++ All or most of the criteria have been fulfilled (Where they have not been fulfilled the conclusions of the study are thought very unlikely to alter).

+ Some of the criteria have been fulfilled (Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions).

- Few or no criteria fulfilled (The conclusions of the study are thought likely or very likely to alter).

In addition to the code allocated (i.e., ++, +, -), each study was assigned a number (1 to 4) which is associated with the level of evidence offered by the study. Category 1 is the highest level of evidence and relates to meta-analyses, systematic reviews, and randomised control trials. Category 2 considers the level of evidence offered by case-control and cohort designs. Category 3 refers to non-analytic studies, for example, case studies. Category 4 is the lowest level of evidence offered by a study and relates to expert opinion.
Results

Of the 27 studies included, three fulfilled all or most of the criteria, i.e. 2++ (Broe et al., 1990; O’Meara et al., 1997; Plassman et al., 2000), 20 studies fulfilled some of the criteria, i.e. 2+ (Chandra et al., 1987; Ferini-Strambi, Smirne, Garancini, Pinto, & Franceschi, 1990; Forster, Newens, Kay, & Edwardson, 1995; Fratiglioni, Ahlborn, Viitanen, & Winbald, 1993; French et al., 1985; Graves et al., 1990; Henderson et al., 1992; Kondo, Niino, & Shido, 1994; Launer et al., 1999; Li et al., 1992; Lindsay et al., 1994; Mayeux et al., 1993; Mortimer, French, Hutton, & Schuman, 1985; Rasmusson, Brandt, Martin, & Folstein, 1995; Salib & Hillier, 1997; Schofield et al., 1997; Shalat, Seltzer, Pidcock, & Baker, 1987; Suhanov et al., 2006; Tsolaki, Fountoulakis, Chantzi, & Kazis, 1997; van Duijn et al., 1992) and four studies fulfilled few or none of the criteria, i.e. 2- (Amaducci et al., 1986; Gedye, Beattie, Tuokko, Horton, & Korsarek, 1989; Guo et al., 2000; Jellinger et al., 2001). Of the four cohort studies that were included in this review, one fulfilled all or most of the criteria, i.e. 2++ (Plassman et al., 2000), two fulfilled some of the criteria, i.e. 2+ (Launer et al., 1999; Schofield et al., 1997) and one fulfilled few or none of the criteria, i.e. 2- (Guo et al., 2000). In summary, three studies fulfilled all or most of the criteria, twenty studies fulfilled some of the criteria, and four studies fulfilled few or none of the criteria. Table 1 provides an overview of the studies.

Inter-rater reliability between two independent assessors of methodological quality was good to excellent. Overall agreement between the two ratings was 89%. Discrepancies between ratings were discussed and resolved.
Nineteen studies included in this review concluded that head injury is a risk factor for Alzheimer’s disease and eight did not. Of the 19 supporting the association between head injury and Alzheimer’s disease, five (Gedye et al., 1989; Graves et al., 1990; Plassman et al., 2000; Schofield et al., 1997; van Duijn et al., 1992) supported the association in terms of accelerating the onset of initial symptoms in those who already have an increased vulnerability to developing Alzheimer’s disease. Six studies (Guo et al., 2000; Mayeux et al., 1993; O’Meara et al., 1997; Plassman et al., 2000; Schofield et al., 1997; Suhanov et al., 2006) only supported the association between head injury and Alzheimer’s disease if the head injury resulted in loss of consciousness. Additionally, three (Guo et al., 2000; Jellinger et al., 2001; Plassman et al., 2000) studies suggested that the head injury requires to be classified as severe in order for it to be considered a risk factor for Alzheimer’s disease. Interestingly, four studies (Amaducci et al., 1986; Chandra et al., 1987; Lindsay et al., 1994; Shalat et al., 1987) reported that head injury was more common in cases with Alzheimer’s disease than controls but this did not reach statistical significance. Finally, one study (Henderson et al., 1992) supported the association but only for sporadic Alzheimer’s disease rather than familial Alzheimer’s disease.

Of the 27 studies included in this review, seven studies receiving the highest methodological ratings have been selected for a fuller analysis of their methodological strengths and weaknesses. As such, the three papers which received a 2++ rating (Broe et al., 1990; O’Meara et al., 1997; Plassman et al., 2000), two case-control studies which received a 2+..
rating (Fratiglioni et al., 1993; van Duijn et al., 1992) and two cohort studies which received a 2+ rating (Launer et al., 1999; Schofield et al., 1997) are discussed. By doing this, it is hoped an insight into the strengths and weaknesses of the literature can be gained by the reader. The relative strengths and weaknesses of the remaining papers will be documented in the discussion.

High Quality Studies (2++ Criteria)

Broe et al. (1990) conducted a retrospective case-control study in Australia that considered several other clinical and environmental risk factors for Alzheimer’s disease in addition to head injury. They included both early- and late-onset cases. The study took place between March 1986 and February 1989. A risk factor interview was designed specifically for this study and assessed previous health, family history, lifestyle, and occupational or domestic exposures. They identified four risk factors for AD: a history of either dementia (Odds Ratio = 3.64), probable AD (Odds Ratio = 4.27), Down’s syndrome (Odds Ratio = 11.33) in a first-degree relative and little or no physical exercise in the recent (Odds Ratio = 6.25) and more distant past (Odds Ratio = 3.50). Their findings did not support head injury as a risk factor for Alzheimer’s disease. Medical investigations of cases prior to entry into the study were thorough and included an assessment by a neurologist, a clinical examination, a neuropsychological evaluation assessing all cognitive domains and 60% of participants had a CT scan. Broe et al. (1990) gave a clear account of their classification of a significant head injury. In addition, they took account of injuries occurring at any time and for those that occurred 10 years or more prior to their participation in the study. However, medical records were not used to document previous head injury history and relied on informant recall that
may be liable to recall bias.

O’Meara et al. (1997) examined the association between Alzheimer’s disease and head injury and the presence of the APOE-e4 allele. This was a retrospective case-control study. The study took place between 1987 and 1995 in Seattle, Washington. A cognitively intact informant was required for both cases and controls. Cases and controls were matched with regard to their reference age (defined as the patient’s age one year before the case-informant first noticed cognitive or behavioural symptoms which later led to seek medical care). They found an increased risk of Alzheimer’s disease following head injury with loss of consciousness (Odd Ratio = 2.1). Moreover, when they analysed men and women separately, there was a significantly elevated risk for men (Odds Ratio = 4.2) while women showed no increased risk (Odds Ratio = 1.1). APOE-e4 was found to be an independent risk factor for Alzheimer’s disease although there was no interaction between APOE-e4 and head injury. A major strength of this study was that the authors went to great lengths to account for potential confounding (age, sex, education, race, proxy informant type, length of relationship with the proxy) in their design and when analysing their data. Hence, they were able to minimize the risk of bias. A limitation of this study was the absence of confirmation of a head injury using medical records and they did not continually use spouses as informants for both cases and controls.

A retrospective cohort study by Plassman et al. (2000) investigated the risk of developing Alzheimer’s disease and other dementias as a result of a head injury in early adulthood. In addition, they aimed to identify whether there was an interaction between head injury,
APOE-e4 allele, and Alzheimer’s disease or dementia. Participants were World War II US Navy and Marine male veterans who had served in the military during 1944 to 1945 and were hospitalised during their service due to either sustaining a head injury, pneumonia or laceration wounds. Medical records were used to verify head injury exposure classification. The severity of head injuries were rated using a modification of the scale developed by Frankowski, Annegers, and Whitman (1985). This resulted in two cohorts: ‘exposed’ and ‘unexposed’. The results from this study indicate that head injury in early adult life was associated with an increased risk of Alzheimer’s disease (Odds ratio = 2.16) and dementia (Odds Ratio = 2.46), suggesting that head injury is a risk factor for dementia in general. Additionally, this risk increased with severity of the head injury. Upon further analysis, they suggest that sustaining a previous head injury may result in an acceleration of dementia onset. A major strength of this study was the thorough screening and assessments of participants to determine whether they had Alzheimer’s disease, another type of dementia, or were dementia free. Moreover, they compared participants with non-participants to ensure there were no significant differences in terms of risk factors between those who accepted and those who refused to take part in the study. Additionally, Plassman et al. (2000) took into account history of alcohol abuse when determining the association between head injury and Alzheimer’s disease. This was an important factor as life style (habitual alcohol abuse and living alone) following head injury has been shown to increase mortality rates among the head injury population (McMillan & Teasdale, 2007).

Average Quality Studies (2+ Criteria)

Fratiglioni et al. (1993) aimed to determine the relative risk factors for late-onset Alzheimer’s
disease by focusing on genetic, birth, and environmental factors. A structured interview was administered to an informant for both cases and controls. Findings suggest that a family history of dementia is the main risk factor for late-onset Alzheimer’s disease. An association between head injury and Alzheimer’s disease was not found (Relative Risk = 0.3). Possible confounding variables (age, sex, education, informant type, alcohol consumption) were accounted for in their design and subsequent analysis. This minimized the risk of bias. However, they did not use medical records to document previous head injury, instead relying on informants thereby introducing the risk of recall bias.

van Duijn et al. (1992) looked at the association between head injury and Alzheimer’s disease, the time between the head injury and disease onset, and the interaction between head injury and other risk factors (i.e. family history of dementia, sex, and education). The study was population based and took place between January 1980 and July 1987. Cases were patients diagnosed with Alzheimer’s disease prior to January 1980. Controls were randomly selected from the population register of the municipality of the patient at the time of diagnosis and were assigned a ‘reference age’. This was defined as the age of onset of Alzheimer’s disease in the matched case. A structured interview was administered to assess the occurrence and severity of head injury as well as other putative risk factors (i.e. family history of dementia, education) for Alzheimer’s disease. They concluded that head injury may be implicated in Alzheimer’s disease. However, they found a non significant increased risk for those with a history of head injury with loss of consciousness (Odds ratio = 1.3). When the data were analysed separately according to gender, an increased risk was observed only in men (Odds ratio = 2.0). Additionally, an association was proposed between the initial
signs of Alzheimer’s disease and having sustained a head injury within the preceding ten years (Odds ratio = 8.0). However, no association was found between disease onset and a head injury sustained more than 10 years ago (Odds ratio = 0.8). The study benefited from good control of confounding variables (i.e. education, sex, family history of dementia). However, van Duijn et al. (1992) failed to use medical records to document previous head injury.

Launer et al. (1999) completed a pooled analysis of four European population-based prospective studies of individuals 65 years and older (European Studies of Dementia, EURODEM). Launer et al.’s (1999) main objective was to examine the risk of Alzheimer’s disease associated with a family history of dementia, female gender, education, smoking, and head injury. Participants were recruited from studies based in Denmark, France, the Netherlands, and the United Kingdom between 1988 and 1996. Information regarding risk factors was collected from participants using a structured interview during the baseline phase when the entire sample was dementia free. Launer et al. (1999) reported that head injury is not a risk factor for Alzheimer’s disease (Relative Risk = 1.02), however, men were found to have an increased risk (Relative Risk = 1.66). When considering whether the participant had sustained a previous head injury, the authors did not take into account when the injury occurred relative to the onset of Alzheimer’s disease. As such, it is difficult to determine the relationship between head injury and Alzheimer’s disease due to ambiguity of the timing of the head injury and the onset of dementia symptoms. Future studies using this design should document time since injury relative to the onset of initial symptoms as well as incorporating the authors own suggestion of collecting a measure of head injury independent from an
Schofield et al. (1997) investigated the risk of Alzheimer’s disease in people with a history of head injury. All participants were recruited from a longitudinal, community based study in New York City. Almost all participants entered the study between December 1989 and November 1991. Once entered into the study, participants completed a brief cognitive screening examination. Those screened positively (i.e. no evidence for cognitive deficits) and a randomly selected subgroup that scored negatively (26%) were referred to a clinical evaluation team for a comprehensive clinical assessment. This assessment was completed annually. Information regarding history of a head injury was sought on two separate occasions. Initially, a physician attached to the research team assessed the participants’ medical history using a standardised format. Following this, an independent risk factor questionnaire was administered to participants. The authors suggest that head injury may be a risk factor associated with an earlier age at onset of Alzheimer’s disease. This was especially noted for those reporting a head injury with loss of consciousness exceeding five minutes (Relative Risk = 11.2). A strength of this study was the prospective cohort design. However, there were several weaknesses. Previous head injury was not documented using medical records. Instead they relied on information from the participant and a risk factor questionnaire that was administered on only one occasion at the beginning of the study. In addition, disagreements in the history of head injury were noted between the information obtained by the physician and the risk factor questionnaire. This calls into question the reliability of the criteria used to classify a head injury.
Discussion

This review of epidemiological studies of Alzheimer’s disease and the role of head injury as a risk factor brings together a number of case-control and cohort studies of varying quality. The majority of the research is based on case-control studies. This raises a number of issues regarding the reliability and validity of the results due to recall and selection biases. It was hoped that by reviewing case-control and cohort studies separately, a comparison could be drawn between the results offered by the two different study designs. This may offer a better understanding of the role head injury may play in the subsequent development of Alzheimer’s disease.

Fleminger et al. (2003) concluded that head injury was a risk factor for Alzheimer’s disease, although only in males. This conclusion was based on a review of all of the studies included in Mortimer et al.’s (1991) meta-analysis as well as eight additional studies. When Fleminger et al. (2003) performed a separate analysis on those eight studies published after Mortimer et al.’s (1991) meta-analysis, no significant association between head injury and Alzheimer’s disease was found. This finding is of interest although the possible reasons behind it were not explored by the authors. One explanation for this finding would be variability in the quality of the studies included the two meta-analyses. Using the current review’s criteria, it appears that those studies published after 1991 were of higher methodological quality than those before 1991. Four of the studies published before 1991 (Amaducci et al., 1986; Chandra et al., 1987; Graves et al., 1990; Mortimer et al., 1985) suggested that head injury is a risk factor. The methodological quality of these four studies ranged from poor, i.e. 2- (Amaducci et al., 1986) to average, i.e. 2+ (Chandra et al., 1987; Graves et al., 1990; Mortimer et al.,
Two studies (Broe et al., 1990; Ferini-Strambi et al., 1990) of high methodological quality (2++ and 2+ respectively) did not support a relationship between head injury and Alzheimer’s disease. Of those studies published after 1991 (Forster et al., 1995; Fratiglioni et al., 1993; Li et al., 1992; Lindsay et al., 1994; O’Meara et al., 1997; Rasmusson et al., 1995; Tsolaki et al., 1997) three suggest that head injury is a risk factor (Lindsay et al., 1994; O’Meara et al., 1997; Rasmusson et al., 1995) whereas four do not (Forster et al., 1995; Fratiglioni et al., 1993; Li et al., 1992; Tsolaki et al., 1997). Six out of the seven studies carried out since 1991 received an average methodological rating (i.e. 2+) and one (O’Meara et al., 1997) received the highest methodological rating (i.e. 2++). Interestingly, those studies carried out after 1991 not only appear to have a higher methodological quality than earlier studies, but would also suggest that head injury is not significantly associated with the development of Alzheimer’s disease. Therefore, Fleminger et al.’s (2003) conclusions appear questionable as the evidence would suggest that head injury is not a risk factor for Alzheimer’s disease.

Classification of Alzheimer’s disease and Head Injury

The accurate diagnosis of Alzheimer’s disease is a critical issue to consider when investigating the relationship between head injury and subsequent disease onset. While diagnosis cannot be definitively established until post-mortem investigation, only one study used post-mortem evidence (Jellinger et al., 2001). Ten studies used post-mortem evidence for a selection of their cases (Broe et al., 1990; French et al., 1985; Graves et al., 1990; Guo et al., 2000; Mortimer et al., 1985; Plassman et al., 2000; Rasmusson et al., 1995; Schofield et al., 1997; Shalat et al., 1987; van Duijn et al., 1992) to confirm the presence of
neurofibrillary tangles (NFT’s) and neuritic plaques. The remaining sixteen studies (Amaducci et al., 1986; Chandra et al., 1987; Ferini-Strambi et al., 1990; Forster et al., 1995; Fratiglioni et al., 1993; Gedye et al., 1989; Henderson et al., 1992; Kondo et al., 1994; Launer et al., 2000; Li et al., 1992; Lindsay et al., 1994; Mayeux et al., 1993; O’Meara et al., 1997; Salib & Hillier, 1997; Suhanov et al., 2006; Tsolaki et al., 1997) used alternative methods of diagnosis. All of the studies used the NINCDS-ADRDA (McKhann et al., 1984) criteria to diagnose possible or probable Alzheimer’s disease. However, as NINCDS-ADRDA criteria has an estimated specificity of only 0.65 (Salib & Hillier, 1997), a large number of Alzheimer’s disease cases are likely to be misclassified. Clearly, without a definitive diagnosis of Alzheimer’s disease, the association between head injury and Alzheimer’s disease is difficult to establish.

A similar issue arises when confirming a head injury due to the varying operational criteria. Twenty-one studies (Amaducci et al., 1986; Broe et al., 1990; Chandra et al., 1987; Ferini-Strambi et al., 1990; Forster et al., 1995; Fratiglioni et al., 1993; Gedye et al., 1989; Graves et al., 1990; Henderson et al., 1992; Kondo et al., 1994; Launer et al., 2000; Lindsay et al., 1994; Mayeux et al., 1993; Mortimer et al., 1985; O’Meara et al., 1997; Rasmusson et al., 1995; Salib & Hillier, 1997; Schofield et al., 1997; Shalat et al., 1987; Tsolaki et al., 1997; van Duijn et al., 1992) did not corroborate the information obtained from informants with medical records. No study in this review with the exception of Plassman et al. (2000) used standardised criteria to identify or classify a head injury. In addition, the recording of a head injury can be unreliable and routine hospital data can lead to substantial underestimation of the incidence of a head injury (Thornhill et al., 2000). Given that true diagnosis of both head
injury and Alzheimer’s disease can be difficult to establish, research in this area is challenging. As only one study in this review used standardised operational criteria for head injury, it is difficult to generalise the findings to the head injury population. To overcome such issues, future studies should use uniform and well established criteria to identify and classify head injury.

Recall Bias
Recall bias is a further issue which influences the reliability of the information obtained from proxy informants and poses a major concern when interpreting the results obtained from case-control studies. Informants for individuals with Alzheimer’s disease may selectively recall head injuries occurring shortly before the onset of disease symptoms whereas informants for controls may selectively under recall incidences (Chandra, Kokmen, Schoenberg, & Beard, 1989). This possible discrepancy advocates the use of objective measures such as medical records and to consider the influence of this bias whilst analysing the data to overcome this issue. Eleven studies (Adaducci et al., 1986; Broe et al., 1990; Chandra et al., 1987; Fratiglioni et al., 1993; Graves et al., 1990; Mayeux et al., 1993; Mortimer et al., 1985; O’Meara et al., 1997; Rasmusson et al., 1995; Shalat et al., 1987; van Duijn et al., 1992) take into account the influence of recall bias on the reliability of the results obtained whereas eleven studies do not (Ferini-Strambi et al., 1990; Forster et al., 1995; French et al., 1985; Gedye et al., 1989; Henderson et al., 1992; Kondo et al., 1994; Li et al., 1992; Lindsay et al., 1994; Salib & Hillier, 1997; Suhanov et al., 2006; Tsolaki et al., 1997). Those studies that do not consider the effects of recall bias on their outcome have received a lower rating in terms of methodological quality.
Assessing Cognitive Status in Control Groups

Another common theme within the literature relates to the methods employed by case-control studies to assess cognitive status in control participants. Fifteen studies (Amaducci et al., 1986; Broe et al., 1990; Chandra et al., 1987; Ferini-Strambi et al., 1990; Forster et al., 1995; Fratiglioni et al., 1993; Henderson et al., 1992; Li et al., 1992; Lindsay et al., 1994; Mayeux et al., 1993; O’Meara et al., 1997; Rasmusson et al., 1995; Salib & Hillier, 1997; Tsolaki et al., 1997; van Duijn et al., 1992) used a brief screening tool to ascertain the control group’s cognitive status. Screening measures used included the Mini-Mental Status Examination (MMSE; Folstein, Folstein, & McHugh, 1975), the Short Portable Mental Status Questionnaire (Pfeiffer, 1975), and the Blessed Dementia Scale (Blessed, Tomlinson, & Roth, 1968). Four studies in this review (Fratiglioni et al., 1993; Li et al., 1992; Salib & Hillier, 1997, Tsolaki et al., 1997) assigned low MMSE cut-off scores (i.e. 20/30 and 24/30) to their control groups. Setting such a low score calls into question whether these control groups could adequately control for the factors under investigation given the potential for their own cognitive impairments. However, even though the conclusions of Fratiglioni et al. (1993), Li et al. (1992), Salib and Hillier (1997), and Tsolaki et al. (1997) are weakened by such factors, they at least assessed their control groups. Six studies (French et al., 1985; Graves et al., 1990; Kondo et al., 1994; Mortimer et al., 1985; Shalat et al., 1987; Suhanov et al., 2006) did not assess their control groups to determine whether they were cognitively able. Future research would benefit from addressing methodological concerns relating to the cognitive assessment of controls.
Future Research

Future research requires comprehensive prospective cohort studies that ensure that confounding variables are taken into account during the design and the analysis of data. Comparisons should be drawn between cases and controls on important demographic variables and similarities between the two populations should be sought. Control of such variables would in turn increase the validity and generalisability of the findings. Ideally, cohort studies would focus on individuals who have sustained a head injury rather than those who have developed Alzheimer’s disease and administer annual neuropsychological evaluations to document cognitive deterioration. Such studies would provide invaluable information regarding the likelihood of Alzheimer’s disease developing in an individual with a history of a head injury and whether there is a temporal association. A similar design was used by Nemetz et al. (1999). Interestingly, this study did not support head injury being an independent risk factor for Alzheimer’s disease, but suggested that head injury accelerates the time to onset of initial dementia symptoms. Their findings provide support for the idea that head injury is one of several risk factors that accelerates the onset of Alzheimer’s disease in persons, for reasons as yet unknown, susceptible to the disease (Nemetz et al., 1999). Five studies included in this review (Gedye et al., 1989; Graves et al., 1990; Plassman et al., 2000; Schofield et al., 1997; van Duijn et al., 1992) implicated the role of head injury in accelerating the progression of Alzheimer’s disease pathology in those who have an increased vulnerability to the disease or who are already in the presymptomatic phase of the disease. This notion is plausible but requires further epidemiological research.
Conclusion

This review does not conclusively support the notion that head injury is a risk factor for Alzheimer’s disease. At present, the evidence is not strong enough to fully support the role of head injury in relation to the development of Alzheimer’s disease, especially in consideration of the questionable findings of Fleminger et al.’s (2003) review. However, the main findings coming from the literature would suggest that there does appear to be a role for head injury in relation to increased risk but only when other factors such as gender and family history are taken into account.

Undoubtedly, this is a very exciting and important area of research. It is clear from the neuropathological research that there are certain similarities between the pathology of brains that have sustained a head injury and the pathology of Alzheimer’s disease. However, the literature has been unable to provide evidence as to how this presents as head injury being a risk factor for Alzheimer’s disease. Only when epidemiological studies of high quality have been developed and replicated can the link between head injury and the development of Alzheimer’s disease be confirmed.
References


Chapter 2: Major Research Project Paper

Is Errorless Learning an Effective Strategy for a Procedural Memory Task?

Prepared in accordance with the requirements for submission to:
Neuropsychological Rehabilitation

(See Appendix 2.1)

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Abstract

Errorless learning has been demonstrated to be an effective strategy for the cognitive rehabilitation of people with memory impairment. This study aimed to determine whether errorless learning is an effective strategy for teaching a complex procedure. Cognitive impairment has been tentatively linked with outcome after rehabilitation for lower limb amputation. Addressing this impairment may improve outcome. The aim of this study was to determine whether using an errorless learning approach would be beneficial for individuals who are learning how to put on their prosthetic limb. Thirty participants from a prosthetic clinic (WestMARC) were randomly assigned to an intervention (n = 15) or control group (n = 15). Results suggest that errorless learning is beneficial in terms of increasing the number of correct steps recalled from a fitting sequence (Mann-Whitney U = 28; p = 0.000, 2-tailed) compared to the control group. In addition, the errorless learning group made fewer errors during the fitting sequence compared to the control group (Mann-Whitney U = 39; p = 0.002, 2-tailed). The findings suggest that errorless learning is a beneficial approach to use when individuals are learning a procedural memory task.

Keywords: Errorless Learning, Cognitive Rehabilitation, Prosthetic Rehabilitation, Skill Learning
Introduction

Individuals who have undergone lower-limb amputation face many challenges post surgery. Individuals can spend up to two months in hospital. This time involves recovery from surgery and numerous fitting appointments with the prosthetic department. Once they have recovered from surgery and have been fitted with a prosthetic limb, they face a long rehabilitation programme. Rehabilitation takes a structured and supportive approach which gradually becomes less supportive until discharge. Physiotherapy is initially heavily involved in terms of physical and supervision support moving towards using less supportive devices and support such as walking frames and walking sticks to discharge. Individuals going through this rehabilitation programme often abandon the functional use of the limb after discharge (Sockalingam, Condie, & Treweek, 1998).

There is a dearth of research in this area concerning reasons for unsuccessful prosthetic use. However, research has pointed towards a link between cognitive difficulties and prosthetic use. Hanspal and Fisher (1997) reported that achieved prosthetic use was significantly correlated with cognitive ability. This relationship is supported by clinicians working in the field of prosthetic rehabilitation. Local clinicians have observed that difficulties may arise when individuals do not adequately learn how to use their prosthetic limb, which then inhibits future use. As there has been a noted link, albeit not well researched, between cognitive ability and prosthetic limb use, cognitive rehabilitation may be a worthwhile technique to use in terms of focusing on possible cognitive difficulties in order to increase prosthetic limb use.
Cognitive rehabilitation is an approach which is used to help individuals with cognitive impairments work together with healthcare professionals to identify and devise strategies for addressing their difficulties (Wilson, 2002). Cognitive rehabilitation takes a functional approach as its main emphasis is to enhance functioning in everyday contexts and to maximise intact functioning. Cognitive rehabilitation uses compensatory techniques rather than restoration as it focuses on residual resources. Compensatory techniques include enhanced learning such as vanishing cues and errorless learning, mnemonics, environmental modification, and external aids. Previous research has demonstrated that cognitive rehabilitation techniques, specifically, errorless learning is an effective strategy for increasing learning of new material, and useful in addressing everyday memory problems (Clare et al., 2000).

In terms of particular compensatory techniques that are used within cognitive rehabilitation, errorless learning and vanishing cue methods are paradigms that have received much attention in recent years. The main premise behind the use of these techniques is derived from work on the distinction between implicit and explicit memory (Graf & Schacter, 1985). Explicit memory refers to the conscious retrieval of knowledge that is acquired, for example, memory for words, names, and places. Implicit memory refers to knowledge that is not consciously retrieved, for example, memory for skills, habits and subconscious processing (Graf & Schacter, 1985; Schacter & Tulving, 1994). Research concerning amnesic patients has reported that individuals suffering from amnesia usually display impairments on tasks measuring explicit memory whilst implicit memory remains relatively intact (Kuzis et al., 1999). Such observations have led researchers to surmise that implicit learning may be
helpful for explicit memory tasks such as conscious retrieval of information. The errorless learning paradigm works on the principle that errors made during a learning task interfere with the correct responses. As these individuals have difficulty correcting their errors through explicit memory, it is assumed that the errors that are made are consolidated and stored as a result of intact implicit memory (Kessels & de Haan, 2003). As such, it is assumed that learning methods which prevent errors will lead to a more efficient learning than allowing the individual to make errors such as in trial and error learning paradigms. When this technique is used, the individual is given the word rather than allowing them to guess. For example, 'I am thinking of a five letter word beginning with Ho and the word is House'. The vanishing cues technique aims to teach individuals material by means of a faded cueing technique. For example, previous research using this technique presented the definition of the word on the first learning trial, then the first letter of the word on the next trial, then the first and second letter on the third trial, and so on, depending on the amount of information the patient needed to guess the correct word, or until the word as a whole was presented. Once this phase had been completed, the cues were faded. That is, the number of cued letters in the next trials was always one less than the number of letters needed to make a correct response (Kessels & de Haan, 2003).

The evidence base for both compensatory learning techniques, i.e. errorless learning and the vanishing cues method, has been building over the past decade. However, the evidence for the use of vanishing cues is not as strong as using an errorless learning paradigm. Kessels and de Haan (2003) carried out a meta-analysis with the objective to review the treatment effects of errorless learning and the vanishing cues method on people with amnesia. A total
of eleven papers were reviewed (eight used an errorless learning strategy, three used a vanishing cues strategy). The results revealed that amnesic patients benefited more from an errorless learning paradigm. Moreover, it was concluded that material is better learned during an errorless condition, resulting in a higher number of recalled items. (Kessels & de Haan, 2003).

Baddeley and Wilson (1994) compared three groups of 16 participants (amnesic, healthy elderly controls, and healthy younger controls) on a word completion task. They compared two learning conditions, an errorless learning method and an errorful (trial and error) approach. Baddeley and Wilson (1994) used a stem completion task in which the subject is given the first two letters of a five letter word and asked to produce the target word. They generated two lists of five letter words. Amnesic subjects were given lists of five words and controls were given lists of ten words. One list was presented in an 'errorful learning' way and the other in an 'errorless learning' way with the order and condition counterbalanced across subjects. Results from this study illustrated that the errorless condition produced better performances than the errorful condition for all groups, with the greatest benefit for the amnesic group. Baddeley and Wilson (1994) concluded that errorless learning was effective because it capitalised on intact implicit memory skills.

Similarly, Hunkin, Squires, Parkin, and Tidy (1998) conducted a study investigating the effectiveness of errorless and errorful learning methods with memory impaired individuals on list learning of single words. They concluded that errorless learning was more effective when learning new information. In addition, they suggest that the benefits of errorless
learning may be due to the effects of error prevention on residual explicit memory. This suggestion regarding the underlying processes of errorless learning is different to the conclusions made by Baddeley and Wilson (1994). However, regardless of the underlying mechanisms, error prevention whilst learning new material has been shown to be advantageous over other methods allowing errors to be made during learning trials.

Akhar, Moulin, and Bowie (2006) were interested to see if errorless learning was of benefit to individuals with mild cognitive impairment (MCI). Memory impairment in this patient population is deemed not to be as severe as in the early stage of Alzheimer's disease. Akhar et al. (2006) compared 16 people with mild cognitive impairment with 16 older adult controls to learn two lists of ten words in an errorless condition and an errorful condition. The allocation of list to study and the order in which participants received each method were both counterbalanced. In each task there were three learning trials. This study found that errorless learning leads to a significant reduction in new items lost between trials, and also a significant increase in consolidation and acquisition of words. The results from this study demonstrated that errorless learning is an effective rehabilitation strategy for verbal learning in individuals with mild cognitive impairment.

The majority of studies that have been compiled to date concerning errorless learning have used semantic information. That is, they have compared the effectiveness of errorless learning with trial and error learning (i.e. errorful learning) by using word lists or face-name association. The present study intends to look at the effectiveness of errorless learning in relation to procedural information. That is, rather than using a list-learning task,
this study will use a procedural task (i.e. prosthetic limb fitting). There is a dearth of information and research concerning the effectiveness of errorless learning in terms of a procedural memory task. However, Evans et al. (2000) looked at the benefits of errorless learning compared to trial and error learning methods for individuals with acquired memory deficits. They concluded that preventing memory impaired patients from making errors during learning improved learning, but only on tasks in which the retrieval situation facilitated the expression of implicit memory for the learned information (Evans et al., 2000). Additionally, they suggested that the beneficial gain from errorless learning was greater for more severely memory impaired patients.

In addition to the above study, an investigation was completed looking into the benefits of errorless versus trial and error route learning for individuals with an acquired brain injury (Lloyd, 2006). The author recruited 20 participants with moderate to severe acquired brain injury. Participants acquired their brain injury via traumatic brain injury, vascular disorder, or other incidents (brain tumour or removal of cortical cyst). This study revealed that there was a significant difference between the number of errors made under the errorless learning condition compared with the errorful learning condition.

**Rationale**

Following lower-limb amputation, individuals face many challenges post surgery. One challenge is in relation to future successful use of their prosthetic limb. It has been suggested that there is a relationship between prosthetic limb use and cognitive difficulties (Hanspal & Fisher, 1997). Additionally, O’Neill (2008) completed a review regarding cognition and
mobility rehabilitation following lower limb amputation. This review provided further
evidence concerning the link as the author suggested that cognition may be a predictor of
rehabilitation outcome. Anecdotally, local clinicians have highlighted that there are a number
of individuals that experience great difficulty learning how to put on their prosthetic limb in
the appropriate way. If individuals are unable to put on their prosthetic limb, then this
inhibits future prosthetic limb use.

There are gaps in the literature concerning cognitive rehabilitation in relation to cognitive
ability and prosthetic limb use. Although a tentative link has been made between cognitive
ability and prosthetic limb use, it is not yet known whether addressing individuals cognitive
difficulties will increase prosthetic limb use. However, rather than address the notion that
cognitive rehabilitation may increase future prosthetic use, it would be worthwhile to first
determine whether cognitive rehabilitation, in particular errorless learning, is an effective
learning strategy for this patient population. As errorless learning has a growing evidence
base for effective learning of semantic information in amnesic patients (Baddeley & Wilson,
1994; Hunkin et al., 1998), individuals with an acquired brain injury (Evans et al., 2000) and
individuals in the early stages of dementia (Akhtar et al., 2006; Clare, Wilson, Breen, &
Hodges, 1999; Clare et al., 2000) and mixed conclusions regarding route learning (Evans et
al., 2000; Lloyd, 2006), it appears likely that errorless learning may provide additional
benefits to the learning of procedural information. Furthermore, previous research has mainly
focused on list learning information which can not be readily applied to a clinical setting. As
such, there is a need to look at the errorless learning technique in an applied setting.
**Aims and Hypotheses**

The aim of this study was to determine whether cognitive rehabilitation, i.e. an errorless learning paradigm, is an effective strategy to use when individuals are learning how to put on a prosthetic limb.

Main hypotheses:

- Errorless learning will increase the number of correct steps recalled whilst putting on a prosthetic limb
- Errorless learning will reduce the number of errors made whilst putting on a prosthetic limb.

**Methodology**

*Design*

This study utilised a between-subjects design. Participants were randomly assigned to either a control group (treatment as usual), wherein the individual was able to make errors, or an experimental group (i.e. an errorless learning paradigm). The errorless learning paradigm involved the researcher working with the individual to complete the fitting sequence for their prosthetic limb without allowing the individual to make any errors. Each individual was video taped following completion of the learning trials.

Randomisation of individuals to a particular group was done by placing a four digit number within an envelope. The four digit number corresponded to either treatment condition or control condition. The digit number was placed into an envelope by the field supervisor to
ensure that the researcher was unaware which digit numbers related to the treatment or control condition until after a number had been chosen for a participant. There was a number on the outside of the envelope ranging from one to thirty. The envelopes were in batches of ten; five treatment condition, five control condition. This was to ensure that for every ten individuals recruited into the study, fifty percent went into the treatment condition. The researcher used the first batch of ten envelopes (i.e. numbers 1 – 10) then the second batch of ten and so on. To ensure the researcher was blind to the cognitive abilities of the participants, cognitive measures were completed following completion of the learning trials.

Participants
All participants were transtibial amputees. That is, they have had below the knee surgery, and had not yet been fitted with a prosthetic limb. In addition, they were unilateral amputees so that they had no prior knowledge of how to put on a prosthetic limb. This was to ensure that prior knowledge would not interfere with the learning sequence. The average age for participants in the experimental group was 62 years (SD = 14.6) and the average age for participants in the control group was 66 years (SD = 6.8). The majority of participants had an amputation due to peripheral arterial disease (PAD) secondary to diabetes mellitus (n = 20, 66.7%).

Inclusion and Exclusion Criteria
Exclusion criteria for this study were:

- Neurological disorder with persisting cognitive disability.
- Current psychiatric disorder requiring treatment, for example, Major Depressive
Disorder, Psychosis.

- Non-transtibial amputees.
- Non-English speaking participants.

Procedure

Individuals first attend WestMARC to assess suitability for a prosthetic limb. Once this had been decided, they were sent for a casting of their limb. The potential participant was approached once it was deemed by the consultant physician that they were suitable for a limb fitting. Potential participants were given an information sheet and had a week to decide whether they wanted to take part in the study. If they decided that they did want to take part, they were asked to sign a consent form. One week later, participants had a fitting session with the prosthettist to ensure that their prosthetic limb was the correct size and fit. This was the first time the individual was able to fit their prosthetic limb; this is referred to as a fitting day. The individual was then requested to attend the clinic the following week to receive their prosthetic limb; this is referred to as a delivery day.

The treatment condition and control condition took place on the fitting day for their prosthetic limb within the WestMARC clinic. This was approximately five to six weeks post surgery. This was to ensure that the participants had no prior knowledge in relation to fitting their prosthetic limb. The five to six week period between surgery and prosthetic limb fitting also allowed for the residual effects of anaesthesia to be minimal. The time spent with the participant during the fitting session was between fifteen and thirty minutes.
With regard to the experimental condition (the errorless learning approach) the fitting sequence for the prosthetic limb involved a procedure whereby the participant was unable to make any errors. The researcher gave the participant the appropriate parts they needed to move to the next stage of the fitting sequence, as such, completing the fitting sequence the correct way. This was to ensure the participants in the errorless condition did not make any errors. The number of steps involved in the procedure depended on the individual requirements of the participant. Prior to commencing the intervention, the participants were first shown how to put on the prosthetic limb. For example, the first part of the sequence was the individual putting on a sock. As such, the researcher gave the participant the sock rather than allowing them to choose which sock they needed to put on first. The second part was the individual removing wrinkles from the sock. The third part involved the individual putting on a thin sock. This was then followed by the individual removing the wrinkles from this sock. A full list of the fitting procedure is in Appendix 2.4. This sequence was repeated five times within the session. Once this had been completed, the participant was asked to complete the fitting sequence without any additional support. This final part was video taped.

The control condition (errorful learning approach) involved the same fitting procedure. As previously mentioned the number of steps involved in the fitting procedure varied depending on the individual requirements of the participant. In this condition the participant was first shown how to put on the prosthetic limb and then asked to put on their prosthetic limb with the same instructions and encouragement from the researcher, however, they were allowed to make errors. That is, rather than the researcher giving the participant the correct part of the sequence, they were allowed to choose the part of the sequence they thought was appropriate
to complete the fitting sequence. As with the experimental condition, the participant repeated
the sequence five times. Upon completion of this sequence, they were asked to put on their
prosthetic limb without any support. The participant was not given any further guidance. This
final fitting sequence was video taped.

Follow-up of participants took place on average one week after the learning intervention for
both the experimental and control conditions. For varying reasons, the follow-up session was
delayed with some participants for up to two weeks. The researcher video recorded the
individual putting on their prosthetic limb without providing any additional guidance. Once
the follow-up trial had been completed, the researcher administered two cognitive measures;
the Addenbrookes Cognitive Examination – Revised (ACE-R, Mathuranath, Nestor, Berrios,
Rakowicz, & Hodges, 2000) and the list learning test of the Adult Memory and Information
Processing Battery (AMIPB, Coughlan & Hollows, 1985). This was to enable the researcher
to compare the neuropsychological characteristics of the two groups.

Neuropsychological Measures

The Addenbrookes Cognitive Examination - Revised (ACE-R), (Mathuranath et al., 2000)
was administered to assess the participants overall cognitive functioning. The ACE-R is a
bedside cognitive screening measure that gives a brief overview of orientation, attention,
memory, language, and visuo-spatial ability. Within the ACE-R, is the Mini-Mental State
Examination (MMSE; Folstein, Folstein, & McHugh, 1975). This is a commonly used
screening measure which has been incorporated into the ACE-R.
To determine participants’ memory functioning, it was deemed important to administer a measure of episodic memory. The word list learning subtest of the Adult Memory and Information Processing Battery (AMIPB; Coughlan & Hollows, 1985) was thought to be an appropriate test as it is a UK validated measure. The test consists of 15 words which are read to the listener at a rate of one word per second. The list of words is presented over five consecutive learning trials. Each trial is followed by a test trial. That is, the participant has to recall as many words from the list as possible. Only the immediate delay component of the test was administered.

It was deemed appropriate to obtain a measure of the participants’ level of premorbid functioning. This was estimated using an equation that took into account a person’s age, occupation, and years of education to provide an estimate of the individual’s level of premorbid functioning (Crawford & Allan, 1997).

**Outcome Measures**

Once all participants completed the five learning trials, they were video taped putting on their prosthetic limb for a sixth time (the test phase). There were five outcome measures used from the information gained from the video recordings:

- Total number of correct steps (percentage).
- Number of omissions (i.e. errors)
- Number of deviations (i.e. make an error but correct themselves)
- Number of hesitations (i.e. hesitate for more than 3 seconds)
Time taken to complete the fitting sequence (seconds)

Inter-rater reliability

An independent rater blind to the treatment and control conditions assessed fifty percent of the video recordings and rated them accordingly. This sample included video recordings of participants in both the treatment and control conditions (seven in the treatment condition and eight in the control condition). An inter-rater reliability analysis using the Kappa statistic was performed to determine consistency among raters. There was a good level of agreement between raters (Kappa = 0.70, p < 0.001).

Sample Size

This study was the first piece of research to look at the effects of using an errorless learning paradigm when learning a sequence with this patient population. The effect sizes observed in a previous study concerning errorless learning versus trial and error route learning with an acquired brain injury population (Lloyd, 2006) was used to estimate the sample size needed to detect a significant effect, if indeed, one exists. Calculations revealed an effect size of 1.2. With this effect size, setting the significance level at 0.05 and power at 0.8, then recruiting a total of 13 participants per group would allow detection of a significant difference, if one exists (Cohen, 1992). However, as the power calculations were based on a study that was using an acquired brain injury population, their level of impairment would be more severe that the current patient population. There was little research in this area so the researcher was cautious in terms of recruitment. Therefore, the researcher recruited a total of 30 people, 15 in each group.
Ethical Approval

An application for ethical approval was made to the South Glasgow and Clyde Local Research Ethics Committee in order to carry out this research. The study was approved by the committee on 30th August 2007.

Statistical Analysis

The Statistical Package for Social Sciences (SPSS Version 15) was used to store and analyse the data for this study. Non-parametric tests, Mann-Whitney U, were used to analyse the data as the data were ordinal and not normally distributed. Analysis comprised examination of the five outcome variables, i.e. total number of correct steps (percentage), number of omissions (i.e. errors), number of deviations, number of hesitations (more than 3 seconds) and time taken to complete the fitting sequence (seconds). The latter outcome variable was normally distributed so it was deemed appropriate to use an independent samples t-test to analyse the data. Independent samples t-tests were also used to analyse the neuropsychological measures data.

Results

Sample Characteristics (See Table 1)

Forty-nine patients were given information regarding the study. Of the 49, 30 patients (61%) agreed to take part. All 30 participants were followed up successfully and this comprised the final sample size. The average age of all participants was 64 years (SD = 11.4) with a range of 28 to 86 years. There was no significant difference in age between the control and errorless groups (Mann Whitney U = 98; p = 0.559 , 2-tailed). In total, there were 21 males
(70%) and 9 females (30%) with no significant association between group membership and gender ($\chi^2(1) = 0.159; \ p = 1.00$). The period between participants having their amputation and attending the WestMARC clinic for the fitting of their prosthetic limb was on average 9.3 weeks (SD = 7.2) with similar delays for both the control group and the errorless group (Mann Whitney U = 98; $p = 0.553$, 2-tailed). The most common reason for participants to have an amputation was peripheral arterial disease (PAD) with comorbid diabetes mellitus ($n = 20; 66.7\%$). PAD ($n = 7; 23.3\%$) without comorbidity was the next most common reason. There was no significant association between the group membership and reason for amputation ($\chi^2(1) = 3.143; \ p = 1.00$).

(Insert Table 1 here)

Table 2 highlights the neuropsychological characteristics of the study sample. Average estimated premorbid level of intelligence (IQ) was 101 (SD = 5.3) with no significant difference between the two groups ($t = 1.814$, df = 28, $p = 0.08$, 2-tailed). Not all participants completed the ACE-R ($n = 26, 87\%$). Participants who completed the measure had a mean total score of 83 (SD = 11.1) out of a possible 100 with no significant difference between the two groups ($t = 0.382$, df = 24, $p = 0.706$, 2-tailed). The clinical cut-off score of <82 gives 84% sensitivity and 100% specificity for dementia (Mioshi, Dawson, Mitchell, Arnold, & Hodges, 2006). Eleven participants (42%) in this study scored below this cut-off score and this was evenly distributed across groups (five participants in the control group and six participants in the errorless group). Scores on the ACE-R subtests did not differ significantly between groups for attention and orientation, ($t = 0.383$, df = 24, $p = 0.698$, 2-tailed),
memory (t = -1.107, df = 24, p = 0.279, 2-tailed), fluency (t = 0.788, df = 24, p = 0.439, 2-tailed), language (t = 0.750, df = 24, p = 0.461, 2-tailed), or visuo-spatial ability (t = 0.952, df = 24, p = 0.350, 2-tailed).

The ACE-R is an extension of the Mini-Mental State Examination (MMSE; Folstein et al., 1975) and this score can be derived from the full ACE-R. The average MMSE score was 26.4 (SD = 3.4). Differences between the control group and the errorless group were not significant (t = 0.713, df = 24, p = 0.483, 2-tailed). Age-related cut-off scores have been proposed to distinguish between impaired and normal subjects (Hodges, 1995). For a person aged between 50 to 70 years a cut-off score of 28 out of a possible 30 has been suggested. However, the MMSE is vulnerable to the effects of age and educational level. As such, adjustments are required (Hodges, 1995). Thirteen participants (50%) who completed the MMSE scored below this cut-off score and this was evenly distributed across groups (six in the control group and seven in the errorless group).

The list-learning subtest of the Adult Memory and Information Processing Battery (AMIPB; Coughlan & Hollows, 1985) was completed by 24 participants, (80%). In those completing this measure the mean number of words recalled by those in the control group (M = 32, S.D = 7.7) was lower than the errorless group (M = 40.1, S.D = 11.6) at a level of significance regarded as borderline (t = -2.029, df = 22, p = 0.055, 2-tailed).

(Insert Table 2 here)
Comparison of the Control and the Errorless groups

(See Table 3)

(Insert Table 3 here)

Total Number of Correct Steps (%)

Following the learning trials, the errorless learning group completed more correct steps (M = 90.9, S.D = 12.1) in the fitting sequence than the control group (M = 77.9, S.D = 8.4); (Mann-Whitney U = 28; p = 0.000, 2-tailed). This was found to be a large effect size, d = 1.25 (Cohen, 1992). Figure 1 highlights the significant difference between the two groups. This indicates that using an errorless learning strategy when individuals are learning to put on a prosthetic limb is more effective than a trial and error learning strategy.

(Insert Figure 1 here)

Total Number of Omissions (i.e. errors)

The errorless learning group made fewer omissions (i.e. errors) during the fitting sequence (M = 0.93, S.D = 1.3) than those in the control group (M = 2.1, S.D = 0.95); (Mann-Whitney U = 39; p = 0.002, 2-tailed). Once again, this was found to be a large effect size, d = 1 (Cohen, 1992). This suggests that errorless learning is effective in reducing the number of errors made when learning to put on a prosthetic limb. This is illustrated by Figure 2.

(Insert Figure 2 here)
Total Number of Deviations

There was no significant difference between the control group and the errorless group in terms of number of deviations made during the fitting sequence (Mann Whitney U = 98, p = 1.00, 2-tailed). This suggests that errorless learning does not impact or reduce the number of deviations made whilst learning a new procedure.

Total Number of Hesitations

Results showed that there was no significant difference between the control group and the errorless group in relation to the number of hesitations made during the fitting sequence (Mann Whitney U = 91, p = 0.483, 2-tailed). This suggests that the learning strategy used does not influence or impact on the number of hesitations made whilst completing their fitting sequence.

Time taken to complete fitting sequence

There was no significant difference between the control group and the errorless group with regards to the amount of time taken to complete the fitting sequence (t = -0.748, df = 26, p = 0.461, 2-tailed).

Predictors of Outcome

Outcome Variables associated with Immediate Memory

Due to there being a borderline significant difference between the control and the errorless groups in terms of immediate memory (AMIPB; Coughlan & Hollows, 1985) a Spearman’s Rho correlation was carried out to determine the association between the outcome variables
and the immediate memory score. When the group was analysed as a whole, there was no significant association between the immediate memory score and the outcome variables (see Table 4).

(Control Group)

The number of correct steps (%) made in the fitting sequence correlated significantly and negatively with the immediate memory score ($r = -0.616$, $n = 11$, $p = 0.044$). This was regarded as being a large effect size (Cohen, 1992). This was an unexpected finding due to the direction of the relationship; participants who scored high on the immediate memory test made fewer correct steps in the fitting sequence. No further significant correlations were found between the other four outcome variables (number of omissions, number of deviations, number of hesitations, time taken to complete fitting sequence) and the immediate memory scores (AMIPB; Coughlan & Hollows, 1985).

(Errorless Group)

There was no significant association found between the outcome variables (number of correct steps, number of omissions, number of deviations, number of hesitations, time taken to complete fitting sequence) and the immediate memory scores (AMIPB; Coughlan & Hollows, 1985).
Discussion

This study was the first of its kind to look at the effectiveness of errorless learning when applied to learning of a skill within a prosthetic rehabilitation population. The main aim of this study was to determine whether an errorless learning approach would be superior to trial and error learning when teaching individuals the complex sequence of putting on a prosthetic limb. This aim has been achieved. This study found that individuals learning to put on their prosthetic limb using an errorless learning strategy recall more correct steps in the fitting sequence than those using an errorful learning strategy. Additionally, in comparison to errorful learning, the use of an errorless learning approach decreases the number of errors made following the learning phase. The main findings from this study are clinically important as they demonstrate that errorless learning is effective to use when individuals are learning to put on their prosthetic limb and can be readily applied to a clinical setting.

Research has shown that cognition may be a predictor of outcome following lower-limb amputation (Hanspal & Fisher, 1997; O’Neill, 2008). Cognitive functioning in this study was assessed using the Addenbrookes Cognitive Examination – Revised (ACE-R, Mathuranath et al., 2000) and the list learning test of the AMIPB (Coughlan & Hollows, 1985). There were no significant differences between the two groups on all ACE-R subtests assessing attention and orientation, memory, fluency, language, and visuo-spatial ability. Surprisingly, a borderline significant difference was found between the errorless learning group and the control group on the AMIPB (Coughlan & Hollows, 1985). This was an unexpected finding as no difference between groups was found on the memory subtest of the ACE-R.
A strength of this study was that despite eleven (42%) participants scoring below the ACE-R (Mathuranath et al., 2000) cut-off score, participants in the errorless learning group still benefited from using an errorless learning approach. This demonstrates that individuals who may be in the early stages of a dementing type illness benefit from using an errorless learning approach when learning new information (i.e. fitting a prosthetic limb). The current findings are supported by several previous studies (Akhtar et al., 2006; Clare et al., 1999; 2000).

*Errorless versus Errorful Learning*

The current findings support the application of an errorless learning approach for individuals learning to put on a prosthetic limb. The benefits of errorless learning documented in this study are supported by several other studies in the literature (Akhtar et al., 2006; Baddeley & Wilson, 1994; Hunkin et al., 1998; Kessels & De Haan, 2003; Lloyd, 2006) which have shown that individuals benefit from an errorless learning approach when learning new information. However, others have found that errorless learning did not improve performance in procedural spatial tasks such as route learning (Evans et al., 2000; Kessels, van Loon, & Wester, 2007). Kessels et al. (2007) investigated the effectiveness of errorless learning for individuals with Korsakoff syndrome for a route learning task. They report that errorless learning was no more effective than trial and error learning of a procedural spatial task. Upon further inspection of this study’s findings, it was apparent that the study was under powered (Howell, 1997). As such, the conclusions of this study should be viewed cautiously as it would appear that the study did not have enough power to detect a significant finding, if indeed, one existed.
Cognitive Predictors of Outcome

Recent research suggests that poor outcome may be mediated by cognitive difficulties (Hanspal & Fisher, 1997; O’Neill, 2008; O’Neill & Evans, in press). O’Neill and Evans (in press) investigated mobility rehabilitation outcome following lower-limb amputation in relation to memory and executive functioning. A cohort of individuals under-going post-amputation rehabilitation were assessed prior to their prosthetic limb fitting and were followed up at 6 months. Results indicated that outcome was significantly predicted by a measure of visual memory while hours of prosthetic limb use was predicted by a verbal fluency test. It was concluded that neuropsychological and clinical variables predict outcome variance at six months. This suggests that there may be a role for cognitive rehabilitation in relation to improving the outcome of mobility rehabilitation. Further research is required to support these conclusions.

Clinical Applications

The results of this study have pertinent clinical applications within the field of prosthetic limb rehabilitation. Difficulties in the initial phase of learning how to put on a prosthetic limb can have major repercussions for the patient in terms of future rehabilitation and quality of life. In extreme circumstances, the risk of falls resulting from a failure to learn how to use the limb may mean that some individuals may not be able to keep their prosthetic limb. Results of this study suggest that by using errorless learning patients are likely to recall a greater number of correct steps which may have a positive effect on future rehabilitation programmes. Recommendations will be made to local clinicians working within prosthetic rehabilitation to use errorless learning when teaching individuals to put on their prosthetic
limb. It is a time efficient approach which may have long-term positive effects on rehabilitation outcome.

Prior to being referred for a prosthetic limb patients are clinically assessed to ensure they have the cognitive ability to use a prosthetic limb. Despite this, several participants included in this study scored below the cut-off score for individuals deemed to have dementia (Mioshi et al., 2006). The failure of the screening process in identifying these participants may leave some patients vulnerable to difficulties in learning the fitting procedure. The use of a more comprehensive screening process is advocated so that individuals who are experiencing cognitive difficulties are identified.

Additionally, while participants in both groups performed below expected on the ACE-R (Mathuranath et al., 2000), the errorless group still benefited from the errorless learning approach. This illustrates that the errorless learning approach is applicable to a large population as individuals with cognitive deficits have shown to benefit from such an approach. This study advocates the use of errorless learning with individuals who are experiencing cognitive difficulties.

**Study Limitations**

There are some methodological considerations that need to be taken into account when interpreting the present findings. The main limitation of this study was the screening process that took place prior to the participants’ entry into the study. This was out with the control of the researcher and was not as comprehensive as initially thought. As such, the participant
population was more impaired than anticipated.

The presence of cognitive deficits was not expected in this population sample and so these variables were not controlled. Differences were found between the errorless learning group and the control group in relation to participants’ immediate memory score. It is unclear what role this may have played in these unexpected findings. Future studies may benefit from controlling this variable.

**Future Research**

While this study has been able to demonstrate that errorless learning improves a patient’s ability to learn how to put on their prosthetic limb, it is as yet unclear if this translates into more frequent day to day use of their prosthesis. Future research would benefit from focusing on the impact of using an errorless learning approach on future prosthetic limb use. As mentioned previously, local clinicians have observed that difficulties may arise when individuals do not adequately learn how to put on their prosthetic limb, which then inhibits future use. It would be beneficial to carry out follow up studies to determine whether improved performance in the learning phase influences subsequent use of prostheses. Additionally, this study should be replicated with a larger participant population. This in turn will enable the findings to be generalised to a larger population.

More research is needed regarding the influence of the nature and type of learning task and the nature of the learned information. As the present findings do not support previous conclusions regarding procedural memory tasks, it may be that there is a fundamental
difference between learning a procedural spatial memory task compared to a procedural
motor memory task. Further research is required to identify the influence of the nature of the
learned information on the benefits of errorless learning.

Conclusions
This study has demonstrated the positive benefits of errorless learning of a procedural
memory task. Individuals learning to put on a prosthetic limb benefit from using an errorless
learning approach compared to those using trial and error learning. The results from this
study provide promising information regarding the potential benefits of an errorless learning
approach when applied to prosthetic rehabilitation. Further research within this area will
hopefully increase the clinical application of such an approach.
References


Publishing Company.


Table 1: Demographic Characteristics of Research Participants

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Errorless Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age:</strong></td>
<td>64 (11.4)</td>
<td>62 (14.6)</td>
<td>66 (6.8)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Gender:</strong> Frequency (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>21 (70)</td>
<td>10 (66)</td>
<td>11 (73)</td>
</tr>
<tr>
<td>Female</td>
<td>9 (30)</td>
<td>5 (34)</td>
<td>4 (27)</td>
</tr>
<tr>
<td><strong>Time Since Amputation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(weeks):</td>
<td>9.3 (7.2)</td>
<td>8.5 (3.5)</td>
<td>10 (9.6)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cause of Amputation:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes &amp; PAD</td>
<td>20 (66.7)</td>
<td>10 (66.7)</td>
<td>10 (66.7)</td>
</tr>
<tr>
<td>PAD</td>
<td>7 (23.3)</td>
<td>3 (20)</td>
<td>4 (26.7)</td>
</tr>
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<td>DVT</td>
<td>1 (3.3)</td>
<td>1 (6.7)</td>
<td>0 (0)</td>
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<td>Trauma</td>
<td>1 (3.3)</td>
<td>0 (0)</td>
<td>1 (6.7)</td>
</tr>
<tr>
<td>Infection</td>
<td>1 (3.3)</td>
<td>1 (6.7)</td>
<td>0 (0)</td>
</tr>
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</table>

PAD = Peripheral Arterial Disease; DVT = Deep Vein Thrombosis
Table 2: Neuropsychological Characteristics of Research Participants

<table>
<thead>
<tr>
<th></th>
<th>All Mean (S.D)</th>
<th>Errorless Group Mean (S.D)</th>
<th>Control Group Mean (S.D)</th>
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<tbody>
<tr>
<td>Predicted Level of Premorbid IQ</td>
<td>101 (5.3)</td>
<td>99.2 (4.6)</td>
<td>102.6 (5.6)</td>
</tr>
<tr>
<td>ACE-R – Total (100)</td>
<td>83 (11.1)</td>
<td>82.4 (13.5)</td>
<td>83.7 (8.6)</td>
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<tr>
<td>ACE-R – Attention &amp; Orientation (18)</td>
<td>16.2 (2.2)</td>
<td>16.1 (2.6)</td>
<td>16.4 (1.7)</td>
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<tr>
<td>ACE-R – Memory (26)</td>
<td>19.5 (4.1)</td>
<td>20.3 (4.1)</td>
<td>18.5 (4.1)</td>
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<tr>
<td>ACE-R – Fluency (14)</td>
<td>9.5 (3.2)</td>
<td>9 (3.9)</td>
<td>10 (2.3)</td>
</tr>
<tr>
<td>ACE-R – Language (26)</td>
<td>23.3 (2.2)</td>
<td>23 (2.4)</td>
<td>23.7 (2.1)</td>
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<td>ACE-R – Visuospatial (16)</td>
<td>14 (1.7)</td>
<td>13.7 (2.1)</td>
<td>14.3 (1.2)</td>
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<td>MMSE (30)</td>
<td>26.4 (3.5)</td>
<td>25.9 (4.3)</td>
<td>26.9 (2.4)</td>
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<td>AMIPB – Total (75)</td>
<td>36.1 (10.5)</td>
<td>40.1 (11.6)</td>
<td>32 (7.7)</td>
</tr>
</tbody>
</table>

ACE-R = Addenbrookes Cognitive Examination-Revised; MMSE = Mini-Mental State Examination; AMIPB = Adult Memory and Information Processing Battery
Table 3: Descriptive statistics of Outcome Variables for both groups

<table>
<thead>
<tr>
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<th>Errorless Group Mean (SD)</th>
<th>Control Group Mean (SD)</th>
<th>p-value</th>
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<tbody>
<tr>
<td>No. of Steps (%)</td>
<td>90.9 (12.1)</td>
<td>77.9 (8.4)</td>
<td>0.000*</td>
</tr>
<tr>
<td>No. of Omissions</td>
<td>0.93 (1.3)</td>
<td>2.1 (0.95)</td>
<td>0.002*</td>
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<tr>
<td>No. of Deviations</td>
<td>0.07 (0.26)</td>
<td>0 (0)</td>
<td>1.00</td>
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<tr>
<td>No. of Hesitations</td>
<td>0.2 (0.56)</td>
<td>0 (0)</td>
<td>0.483</td>
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<tr>
<td>Time Taken (secs)</td>
<td>90 (37.3)</td>
<td>78.7 (42.4)</td>
<td>0.461</td>
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</table>

*Mann Whitney U test – statistically significant
Figure 1: Mean Percentage of Correct Number of Steps made during the Fitting Procedure

Figure 2: Mean Number of Omissions made during the Fitting Procedure
Table 4: Correlations between Outcome Variables and Immediate Memory Score

<table>
<thead>
<tr>
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<tr>
<td><strong>No. of Steps (%)</strong></td>
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<tr>
<td>r</td>
<td>0.187</td>
<td>-0.112</td>
<td>-0.616*</td>
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<tr>
<td>Sig</td>
<td>0.394</td>
<td>0.729</td>
<td>0.044</td>
</tr>
<tr>
<td>N</td>
<td>23</td>
<td>12</td>
<td>11</td>
</tr>
<tr>
<td><strong>No. of Omissions</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td>-0.126</td>
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<tr>
<td>Sig</td>
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<tr>
<td>r</td>
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<tr>
<td>r</td>
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<td><strong>Time Taken (secs)</strong></td>
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<tr>
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<tr>
<td>Sig</td>
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<td>0.769</td>
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<td>11</td>
<td>11</td>
</tr>
</tbody>
</table>

*Correlation is significant at the 0.05 level (2-tailed)
Chapter 3: Advanced Clinical Practice I Reflective Account Abstract

A Reflective Account Based on Working Within a Community Mental Health Team (CMHT)

Address for correspondence:

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Glasgow  
G12 0XH

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology
Abstract

Reflective practice is a process used to enhance the learning experience. It is a very powerful form of learning as it enables the person to learn from their own actions and to become more insightful about their way of working. This is especially relevant for clinical psychologists as it is vital for enhancing their personal and professional development.

Several models have been developed which are used to aid the process of reflective writing. I am using Gibbs’ (1988) reflective cycle to foster my reflections concerning an incident. This incident took place over several days of my first week working within a community mental health team (CMHT). I chose this incident as it elicited several strong emotions. In addition, I feel that my management of this incident is applicable to the National Occupational Standards for Psychology (NOS) as I was able to communicate psychological knowledge and principles to the team.
A Reflective Account Based on the Implementation of a Group Within an Early-Onset Dementia Service

Address for correspondence:
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G12 0XH

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology
Abstract

This reflective account is based on an experience involving service development. The account describes my initial experiences of becoming involved in service development through to the planning and implementation of a Cognitive Stimulation Therapy group (CST; Spector, Orrell, Davies, & Woods, 2001; Spector et al., 2003). This was an important experience for me to reflect on as I feel that service development is a key role of a clinical psychologist. It also meets several of the National Occupational Standards for Psychology (NOS), in particular, generic key role 5 “Develop and train the application of psychological skills, knowledge, practices and procedures” and generic key role 6 “Manage the provision of psychological systems, services and resources”. I have once again used Gibbs’ (1988) reflective cycle as I feel that this is a model that allows a person to develop their reflections within appropriate reflective structures.
Appendix 1.1: Notes for contributors to: Ageing & Mental Health

Aging & Mental Health

2007 Impact Factor of 1.264
Now included in Essential Science Indicators. Increase in pages in 2008
Published By: Routledge
Volume Number: 12
Frequency: 6 issues per year
Print ISSN: 1360-7863
Online ISSN: 1364-6915

Instructions for Authors

Aging & Mental Health welcomes original contributions from all parts of the world on the understanding that their contents have not previously been published nor submitted elsewhere for publication. We encourage the submission of timely review articles that summarize emerging trends in an area of mental health and aging, or which address issues which have been overlooked in the field. Reviews should be conceptual and address theory and methodology as appropriate. All submissions will be sent anonymously to independent referees. It is a condition of acceptance that papers become the copyright of the publisher.

Manuscripts

All submissions should be made online at Aging & Mental Health's Manuscript Central site. New users should first create an account. Once a user is logged onto the site submissions should be made via the Author Centre.

Authors should prepare and upload two versions of their manuscript. One should be a complete text, while in the second all document information identifying the author should be removed from files to allow them to be sent anonymously to referees. When uploading files authors will then be able to define the non-anonymous version as "File not for review".

Books for review should be sent to Professor Murna Downs, Bradford Dementia Group, School of Health Studies, University of Bradford, Bradford BD5 0BB, UK.

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The first page should include the title of the paper, first name, middle initial(s) and last name of the author(s), and for each author a short institutional address, and an abbreviated title (for running headlines within the article). At the bottom of the page give the full name and address (including telephone and fax numbers and e-mail address if possible) of the author to whom all correspondence (including proofs) should be sent. The second page should repeat
the title and contain an abstract of not more than 250 words. The third page should repeat the title as a heading to the main body of the text.

Structured abstracts: The main text should be preceded by a short structured abstract, accompanied by a list of keywords. The abstract should be arranged as follows: Name of author(s); title of manuscript; name of journal; abstract text containing the following headings: Objectives, Method, Results, and Conclusion.

Key words: A list of 3-5 keywords should be provided. Words already used in the title should be avoided if possible

The text should normally be divided into sections with the headings Introduction, Methods, Results, and Discussion. Long articles may need subheadings within some sections to clarify their content. Within the text section headings and subheadings should be typed on a separate line without numbering, indentation or bold or italic typeface.

Style guidelines
Description of the Journal's articlestyle
Description of the Journal's reference style, Quick guide

A Word template is available for this journal (please save the Word template to your hard drive and open it for use by clicking on the icon in Windows Explorer). If you have any questions about references or formatting your article, please contact authorqueries@tandf.co.uk

Units of measurement
All measurements must be cited in SI units.

Illustrations
All illustrations (including photographs, graphs and diagrams) should be referred to as Figures and their position indicated in the text (e.g. Fig. 3). Each should be submitted numbered on the back with Figure number (Arabic numerals) and the title of the paper. The captions of all figures should be submitted on a separate page, should include keys to symbols, and should make interpretation possible without reference to the text.

Figures should ideally be professionally drawn and designed with the format of the journal (A4 portrait, 297 x 210 mm) in mind and should be capable of reduction.

Tables
Tables should be submitted on separate pages, numbered in Arabic numerals, and their position indicated in the text (e.g. Table 1). Each table should have a short, self-explanatory title. Vertical rules should not be used to separate columns. Units should appear in parentheses in the column heading but not in the body of the table. Any explanatory notes should be given as a footnote at the bottom of the table.
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Aging & Mental Health has a new editorial e-mail address: amh@ucl.ac.uk. General enquires can be sent to m.orrell@ucl.ac.uk.
### Appendix 1.2: SIGN Methodological Checklist: Case-control studies

#### Methodology Checklist 4: Case-control studies

<table>
<thead>
<tr>
<th>Study identification</th>
<th>Include author, title, year of publication, journal title, pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline topic:</td>
<td>Key Question No:</td>
</tr>
<tr>
<td>Checklist completed by:</td>
<td></td>
</tr>
</tbody>
</table>

#### SECTION 1: INTERNAL VALIDITY

**In an well conducted case control study:**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.2</td>
<td>The cases and controls are taken from comparable populations</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.3</td>
<td>The same exclusion criteria are used for both cases and controls</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.4</td>
<td>What percentage of each group (cases and controls) participated in the study?</td>
<td>Cases:</td>
</tr>
<tr>
<td>1.5</td>
<td>Comparison is made between participants and non-participants to establish their similarities or differences</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.6</td>
<td>Cases are clearly defined and differentiated from controls</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.7</td>
<td>It is clearly established that controls are non-cases</td>
<td>Well covered</td>
</tr>
</tbody>
</table>
### ASSESSMENT

<table>
<thead>
<tr>
<th>1.8</th>
<th>Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment</th>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>1.9</th>
<th>Exposure status is measured in a standard, valid and reliable way</th>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
</tr>
</thead>
</table>

### CONFOUNDING

<table>
<thead>
<tr>
<th>1.10</th>
<th>The main potential confounders are identified and taken into account in the design and analysis</th>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
</tr>
</thead>
</table>

### STATISTICAL ANALYSIS

<table>
<thead>
<tr>
<th>1.11</th>
<th>Confidence intervals are provided</th>
</tr>
</thead>
</table>

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th>2.1</th>
<th>How well was the study done to minimise the risk of bias or confounding?</th>
<th>Code ++, +, or −</th>
</tr>
</thead>
</table>

| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated? |
|-----|------------------------------------------------------------------------|----------------|

| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? |
|-----|--------------------------------------------------------------------------------------------------|----------------|
## Appendix 1.3: SIGN Methodological Checklist: Cohort studies

<table>
<thead>
<tr>
<th><strong>Methodology Checklist 3: Cohort studies</strong></th>
</tr>
</thead>
</table>

**Study identification**  
(*Include author, title, year of publication, journal title, pages*)

**Guideline topic:**  
Key Question No:

**Checklist completed by:**

### SECTION 1: INTERNAL VALIDITY

**In a well conducted cohort study:**  
**In this study the criterion is:**

<table>
<thead>
<tr>
<th><strong>1.1</strong></th>
<th>The study addresses an appropriate and clearly focused question.</th>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
<th>Not applicable</th>
</tr>
</thead>
</table>

**SELECTION OF SUBJECTS**

<table>
<thead>
<tr>
<th><strong>1.2</strong></th>
<th>The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.</th>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
<th>Not applicable</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>1.3</strong></th>
<th>The study indicates how many of the people asked to take part did so, in each of the groups being studied.</th>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
<th>Not applicable</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>1.4</strong></th>
<th>The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.</th>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
<th>Not applicable</th>
</tr>
</thead>
</table>

| **1.5** | What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed. | | | | |
|---------|-----------------------------------------------------------------|--------------|----------------------|------------------|--------------|--------------|---------------|

<table>
<thead>
<tr>
<th><strong>1.6</strong></th>
<th>Comparison is made between full participants and those lost to follow up, by exposure status.</th>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
<th>Not applicable</th>
</tr>
</thead>
</table>

### ASSESSMENT

<table>
<thead>
<tr>
<th><strong>1.7</strong></th>
<th>The outcomes are clearly defined.</th>
<th>Well covered</th>
<th>Adequately addressed</th>
<th>Poorly addressed</th>
<th>Not addressed</th>
<th>Not reported</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Description</td>
<td>Evaluation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>---</td>
<td>-----------------------------------------------------------------------------</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.8</td>
<td>The assessment of outcome is made blind to exposure status.</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
<td>Not reported</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.9</td>
<td>Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
<td>Not reported</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.10</td>
<td>The measure of assessment of exposure is reliable.</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
<td>Not reported</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.11</td>
<td>Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
<td>Not reported</td>
<td>Not applicable</td>
</tr>
<tr>
<td>1.12</td>
<td>Exposure level or prognostic factor is assessed more than once.</td>
<td>Well covered</td>
<td>Adequately addressed</td>
<td>Poorly addressed</td>
<td>Not addressed</td>
<td>Not reported</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**CONFOUNDING**

| 1.13 | The main potential confounders are identified and taken into account in the design and analysis. | Evaluation |
|      |                                                                                                                                 | Well covered | Adequately addressed | Poorly addressed | Not addressed | Not reported | Not applicable |

**STATISTICAL ANALYSIS**

| 1.14 | Have confidence intervals been provided?                                      | Evaluation |
|      |                                                                                                                                 | Well covered | Adequately addressed | Poorly addressed | Not addressed | Not reported | Not applicable |

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

| 2.1 | How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between exposure and effect? | Code ++, +, or – |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated? |
| 2.3 | Are the results of this study directly applicable to the patient group targeted in this guideline? |
### Appendix 1.4: Table of Excluded Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chandra, V, et al (1989)</td>
<td>The study did not use the NINCDS-ADRDA criteria or the DSM criteria to diagnose participants.</td>
</tr>
<tr>
<td>Luukinen, H, et al (1999)</td>
<td>The study does not specifically look at Alzheimer’s disease. They include participants who have been subject to cognitive decline but have not met any formal diagnosis.</td>
</tr>
<tr>
<td>Luukinen, H, et al (2005)</td>
<td>This study states ‘dementia’ but does not state which specific dementia type.</td>
</tr>
<tr>
<td>Mehta, K.M, et al (1999)</td>
<td>The study cohort included Alzheimer’s disease and other types of dementia. In addition, they did not use the NINCDS-ADRDA criteria or the DSM criteria to diagnose participants.</td>
</tr>
<tr>
<td>Nemetz, et al (1999)</td>
<td>The study did not use the NINCDS-ADRDA criteria or the DSM criteria to diagnose participants.</td>
</tr>
<tr>
<td>Williams, D.B., et al (1991)</td>
<td>The study did not use the NINCDS-ADRDA criteria or the DSM criteria to diagnose participants.</td>
</tr>
</tbody>
</table>
Appendix 2.1: Notes for contributors to: Neuropsychological Rehabilitation

Neuropsychological Rehabilitation

An International Journal
Impact Factor: 1.0 (Journal Citation Reports 2007, published by Thomson Scientific)
Published By: Psychology Press
Volume Number: 18
Frequency: 6 issues per year
Print ISSN: 0960-2011
Online ISSN: 1464-0694

Instructions for Authors
- Neuropsychological Rehabilitation

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Your covering email/letter must include full contact details (including email), the title of the journal to which you are submitting, and the title of your article.

All manuscripts must be accompanied by a statement confirming that it has not been previously published elsewhere and that it has not been submitted simultaneously for publication elsewhere.

All manuscripts should be submitted in American Psychological Association (APA) format following the latest edition of Publication Manual of the APA (currently 5th edition).

Authors will normally receive a decision on their papers within three months of receipt, and if accepted they will normally be published six to nine months later. The date of receipt of the manuscript will be printed. Where minor revision of a paper is requested the original date of receipt will appear, provided that a satisfactory revision is received within one month of the request. Otherwise it will bear the revised version date.

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Journal Production Editor: authorqueries@tandf.co.uk

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**Abstract.** An abstract of 50-200 words should follow the title page on a separate sheet.

**Headings.** Indicate headings and subheadings for different sections of the paper clearly. Do not number headings.

**Acknowledgements.** These should be as brief as possible and typed on a separate sheet at the beginning of the text.

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**Footnotes.** These should be avoided unless absolutely necessary. Essential footnotes should be indicated by superscript figures in the text and collected on a separate sheet at the end of the manuscript.

**Reference citations within the text.** Use authors' last names, with the year of publication in parentheses after the last author's name, e.g., "Jones and Smith (1987)"; alternatively, "(Brown, 1982; Jones & Smith, 1987; White, Johnson, & Thomas, 1990)". On first citation of references with three to six authors, give all names in full, thereafter use first author "et al.". If more than one article by the same author(s) in the same year is cited, the letters a, b, c etc. should follow the year.
Reference list. A full list of references quoted in the text should be given at the end of the paper in alphabetical order of authors' surnames (or chronologically for a group of references by the same authors), commencing as a new sheet, typed double spaced. Titles of journals and books should be given in full, e.g.:

Books:


Chapter in an edited book:


Journal article:


Tables. These should be kept to the minimum. Each table should be typed double spaced on a separate sheet, giving the heading, e.g., "Table 2", in Arabic numerals, followed by the legend, followed by the table. Make sure that appropriate units are given. Instructions for placing the table should be given in parentheses in the text, e.g., "(Table 2 about here)".

Figures. Figures should only be used when essential. The same data should not be presented both as a figure and in a table. Where possible, related diagrams should be grouped together to form a single figure. Figures should be drawn to professional standards and it is recommended that the linear dimensions of figures be approximately twice those intended for the final printed version. Each of these should be on a separate page, not integrated with the text. Figures will be reproduced directly from originals supplied by the author(s). These must be of good quality, clearly and completely lettered. Make sure that axes of graphs are properly labelled, and that appropriate units are given. Photocopies will reproduce poorly, as will pale or broken originals. Dense tones should be avoided, and never combined with lettering. Half-tone figures should be clear, highly-contrasted black and white glossy prints.

Black and white figures are included free of charge. Colour figures are not normally acceptable for publication in print -- however, it may be possible both to print in black and white and to publish online in colour. Colour figures will only be printed by prior arrangement between the editor(s), publisher and author(s); and authors may be asked to share the costs of inclusion of such figures.

The figure captions should be typed in a separate section, headed, e.g., "Figure 2", in Arabic numerals. Instructions for placing the figure should be given in parentheses in the text, e.g., "(Figure 2 about here)". More detailed Guidelines for the Preparation of Figure Artwork are
Statistics. Results of statistical tests should be given in the following form:

"... results showed an effect of group, $F(2, 21) = 13.74, MSE = 451.98, p < .001$, but there was no effect of repeated trials, $F(5, 105) = 1.44, MSE = 17.70$, and no interaction, $F(10, 105) = 1.34, MSE = 17.70$.

Other tests should be reported in a similar manner to the above example of an $F$-ratio. For a fuller explanation of statistical presentation, see pages 136-147 of the APA Publication Manual (5th ed.). For guidelines on presenting statistical significance, see pages 24-25.

Abbreviations. Abbreviations that are specific to a particular manuscript or to a very specific area of research should be avoided, and authors will be asked to spell out in full any such abbreviations throughout the text. Standard abbreviations such as RT for reaction time, SOA for stimulus onset asynchrony or other standard abbreviations that will be readily understood by readers of the journal are acceptable. Experimental conditions should be named in full, except in tables and figures.

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Appendix 2.2: Patient Information Sheet

Department of Psychological Medicine, University of Glasgow
WESTMARC, Southern General Hospital

Learning to fit a Prosthetic Limb: Which is an Effective Learning Strategy?

Information Sheet

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

Who is conducting the research?
The research is being carried out by Professor Tom McMillan and Miss Claire Donaghey from the Section of Psychological Medicine of the University of Glasgow and Dr Brian O’Neill from WESTMARC at the Southern General Hospital.

What is the purpose of the study?
Individuals who have undergone lower-limb amputation face many challenges following surgery. One of these challenges is learning how to fit their prosthetic limb. Studies have shown that efficient learning of new information can depend on the strategy being used. These studies have involved verbal tasks, and we do not know if these strategies affect learning of a new skill i.e., learning to fit a prosthetic limb. If this is found to be the case, this strategy will become part of the normal rehabilitation programme.

Why have I been invited?
You have been invited to take part in this study as you have recently undergone a lower-leg amputation operation and have been referred for a prosthetic limb. Furthermore, you have never had a prosthetic limb so you do not already know how to fit a prosthetic limb.
Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving reason. This would not affect the standard of care you receive or your future rehabilitation programme.

What does taking part involve?

If you decide to take part in the study, the researcher will meet with you to discuss the project further. Your consultant will also be notified of your participation in this study. Following this, you will meet with the researcher on two occasions. The first time will be when you attend the WESTMARC clinic at the Southern General Hospital to be fitted with the prosthetic limb. The researcher will be involved in helping you learn how to fit your prosthetic limb. You will be asked to repeat the fitting process five times. The final time you fit the prosthetic limb, the researcher will video tape you. This will last for approximately 30 minutes. The next time you meet with the researcher will be on the delivery day of your prosthetic limb. This time, the researcher will ask you to fit your prosthetic limb without any additional help. The researcher will video tape you fitting your prosthetic limb. Prior to completing the intervention, you will be asked to complete 3 pen and paper measures. One measure is a measure of memory, one measures several areas of your thinking and learning ability, for example, memory, language, and orientation. The final measure is a measure of previous thinking and learning ability.

This study is a randomised study. It is this kind of study as sometimes we do not know which way to treat patients is best. To find this out, we need to compare different treatments. In this study we need to compare two learning strategies in order to find out which is the more effective strategy. We will put people into two different groups and give each group a different learning strategy. To make sure the groups are the same to start with, each patient is put into a group by chance (randomly).

What happens to the information?

Your identity and personal information will be completely confidential and known only to the researcher Miss Claire Donaghey and clinical supervisor Dr Brian O’Neill. The information obtained from the video tapes will remain confidential and stored within a locked filing cabinet. The data are held in accordance with the Data Protection Act, which means that we keep it safely and cannot reveal it to other people, without your permission.
What are the possible benefits of taking part?
It is hoped that by taking part in this research, you will be providing valuable information regarding which learning strategies are effective when learning how to fit a prosthetic limb.

Who has reviewed the study?
This study has been reviewed by the NHS South Glasgow and Clyde Local Research Ethics Committee.

If you have any further questions?
We will give you a copy of the information sheet and signed consent form to keep. If you would like more information about the study and wish to speak to someone not closely linked to the study, please contact Dr Brian O’Neill.

Contacts:
Miss Claire Donaghey, Trainee Clinical Psychologist, Department of Psychological Medicine, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow, G12 0XH.
Telephone number: 0141 211 0607.

Professor Tom McMillan, Professor of Clinical Neuropsychology, Department of Psychological Medicine, Gartnavel Royal Hospital, 1055 Great Western Road, G12 0XH.
Telephone number: 0141 211 0694.

Dr Brian O’Neill, Clinical Psychologist, WestMARC, Southern General Hospital, Govan Road, Glasgow, G51 4TF.
Telephone number: 0141 201 2391.

If you have a complaint about any aspect of the study?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (Tel no: 0141 211 0607). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Southern General Hospital.

Thank-you for your time and co-operation
Appendix 2.3: Patient Consent Form

Learning to fit a Prosthetic Limb: Which is an Effective Learning Strategy?

Consent Form

Please initial box

I confirm that I have read and understand the information sheet dated 09/08/2007 (version 2) for the above study and have had the opportunity to ask questions

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

I understand that sections of my medical notes may be looked at by the research team where it is relevant to my taking part in the research. I give my permission for the research team to have access to my records.

I agree to take part in the Learning to fit a Prosthetic Limb: Which is an Effective Learning Strategy?

Name of Participant                     Date                     Signature

Name of Researcher                      Date                     Signature
### Appendix 2.4: Prosthetic Limb Sequencing Form

**SEQUENCE PERFORMANCE SCALE - LIMB DONNING**

Sequence:  
Date:  
Condition:

**DIRECTIONS**

1. Identify the steps relevant for the participant. Delete steps in the sequence if not indicated.

2. **Order:** Enter number to indicate order in which person first interacts with item key to step.

3. **Achieved:** Tick if step successfully achieved.

4. **Repeated:** Tick if participant returns to a completed step.

<table>
<thead>
<tr>
<th>STEP</th>
<th>ORDER OF OBJECTS USED</th>
<th>ACHIEVED</th>
<th>REPEATED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sock 1 (Thick)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove wrinkles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sock 2 (Thin)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remove wrinkles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ensure Nylon Sock attached to liner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roll back Nylon Sock from opening</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pull on Foam Liner</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check Fit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retrieve Prosthesis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roll back Silicone Sleeve</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Push Leg into Socket</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Check Security</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pull up Elastic Suspension Sleeve</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Time:  
Total correct: (1 point for each step achieved)  
Deviations: Count number of times participant deviated from ideal sequence  
Cessation: Number of times goal directed behaviour stops for 3 seconds+
Appendix 3: Major Research Proposal

Abstract

There is a dearth of research in this area concerning reasons for unsuccessful prosthetic use. Clinicians have suggested that difficulties in relation to individuals using their prosthetic limb may arise when individuals do not adequately learn how to use their prosthetic, which then inhibits future use. Cognitive rehabilitation may be a worthwhile technique to use in terms of focusing on possible cognitive difficulties in order to increase prosthetic use. A technique that has shown promising results within cognitive rehabilitation research is errorless learning. The aim of this study is to use a cognitive rehabilitation technique, i.e. an errorless learning paradigm, with individuals who are learning how to fit their prosthetic limb. This is to determine whether errorless learning is a useful strategy to incorporate into an individuals rehabilitation programme when they are learning how to fit their prosthetic limb.

Participants will be recruited from five hospitals within NHS Greater Glasgow and Clyde, and NHS Lanarkshire who make referrals to the WestMARC clinic. This study will utilize a between-subjects design. Participants will be randomly assigned to either a control group (treatment as usual), whereby the individual is able to make errors, or an experimental group (i.e. an errorless learning paradigm), whereby the individual is unable to make any errors.

Informal discussions with physiotherapists working within prosthetic rehabilitation have highlighted that difficulties that arise during the initial learning phase of appropriately fitting their prosthetic limb can have major repercussions in terms of their rehabilitation programme.
and progress. If it is possible to overcome some of these difficulties during the learning phase, then this will in turn have positive benefits in terms of future rehabilitation progress, quality of life and increased independence.

Introduction

Individuals who have undergone lower-limb amputation face many challenges post surgery. Individuals can spend up to two months in hospital. This time involves recovery from surgery and numerous fitting appointments with the prosthetic department. Once they have recovered from surgery and have been fitted with a prosthetic limb, they face a long rehabilitation programme. Rehabilitation takes a structured and supportive approach which gradually becomes less supportive until discharge. Physiotherapy is initially heavily involved in terms of physical and supervision support moving towards using less supportive devices and support such as walking frames and walking sticks to discharge. Individuals that go through this rehabilitation programme are not always successful in terms of their use of the prosthetic limb once they have been discharged.

There is a dearth of research in this area concerning reasons for unsuccessful prosthetic use. However, research has pointed towards a link between cognitive difficulties and prosthetic use. Hanspal and Fisher (1997) reported achieved prosthetic use was significantly correlated with cognitive ability. This correlation is supported by clinicians working in the field of prosthetic rehabilitation. Local clinicians have observed that difficulties may arise when individuals do not adequately learn how to use their prosthetic, which then inhibits future use. As there has been a noted link, albeit not well researched, between cognitive ability and
prosthetic use, cognitive rehabilitation may be a worthwhile technique to use in terms of focusing on possible cognitive difficulties in order to increase prosthetic use.

Cognitive rehabilitation is an approach which is used to help individuals with cognitive impairments work together with healthcare professionals to identify and devise strategies for addressing their difficulties (Wilson, 2002). Cognitive rehabilitation takes a functional approach as its main emphasis is to enhance functioning in everyday contexts and to maximise intact functioning. Compensatory techniques include enhanced learning such as vanishing cues and errorless learning, mnemonics, environmental modification, and external aids. Previous research has demonstrated that cognitive rehabilitation techniques, specifically, errorless learning is an effective strategy for increasing learning of new material, and useful in addressing everyday memory problems (Clare et al., 2000).

In terms of particular compensatory techniques that are used within cognitive rehabilitation, errorless learning and vanishing cue methods, are paradigms that have received much attention in recent years. The main premise behind the use of these techniques is derived from work on the distinction between implicit and explicit memory. Explicit memory refers to knowledge that is acquired, for example, memory for words, names, and places, i.e. conscious retrieval of information. Implicit memory refers to knowledge that is not consciously retrieved, for example, memory for skills, habits and subconscious processing (Kessels & de Haan, 2003; Schacter & Tulving, 1984). Research concerning amnesic patients has reported that individuals suffering from amnesia usually display impairments on tasks measuring explicit memory whilst implicit memory remains relatively intact (Kuzis et al.,
The errorless learning paradigm was developed from research in this area and works on the principle that errors that are made during a learning task interfere with the correct responses. As these individuals have difficulty correcting their errors through explicit memory, it is assumed that the errors that are made are consolidated and stored as a result of intact implicit memory (Kessels & de Haan, 2003). As such, it is assumed that learning methods which prevent errors will lead to greater learning than allowing the individual to make errors, i.e., trial and error.

The evidence base for both compensatory learning techniques, i.e. errorless learning and the vanishing cues method, has been gradually building over the past decade. However, the evidence for the use of vanishing cues is not as strong as using an errorless learning paradigm. Baddeley and Wilson (1994) compared three groups of 16 subjects (amnesic, healthy elderly controls, and healthy younger controls) on a word completion task. They compared two learning conditions, an errorless learning method and an errorful (trial and error) approach. Baddeley and Wilson (1994) used a stem completion task in which the subject is given the first two letters of a five letter word and asked to produce the target word. They generated two lists of five letter words. Amnesic subjects were given lists of five words and controls were given lists of ten words. One list was presented in an 'errorful learning' way and the other in an 'errorless learning' way with the order and condition counterbalanced across subjects. Results from this study illustrated that the errorless condition produced better performances than the errorful condition for all groups, with the greatest benefit for the amnesic group. Baddeley and Wilson (1994) concluded that errorless learning was effective because it capitalised on intact implicit memory skills.
A meta-analysis was carried out with the objective being to review the treatment effects of errorless learning and the vanishing cues method on people with amnesia. A total of eleven papers were reviewed (eight used an errorless learning strategy, three used a vanishing cues strategy). The results revealed that amnesic patients benefit most from an errorless learning paradigm. Moreover, it was concluded that material is better learned during an errorless condition, resulting in a higher number of recalled items. (Kessels & de Haan, 2003).

The majority of studies that have been compiled to date concerning errorless learning have used semantic information. That is, they have compared the effectiveness of errorless learning with trial and error learning (i.e. errorful learning) by using word lists or face-name association. There is a dearth of information and research concerning the effectiveness of errorless learning in terms of a procedural memory task. However, Maxwell, Masters, Kerr, and Weedon (2001) looked at the benefits of errorless learning when learning a motor skill, golf putting. They wanted to determine whether the number of errors made in learning a motor task, differentially influences the adoption of an explicit (selective) or an implicit (unselective) learning mode. The authors recruited a total of 29 undergraduate sport science students. The results from this study indicated that those in the errorless condition made fewer errors than individuals in the errorful condition. The number of errors made in the random group did not differ to the amount made in the errorful condition. As such, the authors assumed that participants in the errorless condition adopted an implicit learning mode.

In addition to the above study, an investigation was completed looking into the benefits of
errorless versus trial and error route learning for individuals with an acquired brain injury (Lloyd, 2006). The author recruited 20 participants with moderate to severe acquired brain injury. Participants acquired their brain injury via traumatic brain injury, vascular disorder, or other incident (brain tumor or removal of cortical cyst). This study revealed that there was a significant difference between the number of errors made under the errorless learning condition compared with the errorful learning condition.

**Rationale**

Following lower-limb amputation, individuals face many challenges post surgery. One challenge is in relation to future successful use of their prosthetic limb. It has been suggested that there is a correlation between prosthetic limb use and cognitive difficulties (Hanspal & Fisher, 1997). Local clinicians have highlighted that there are a number of individuals that experience great difficulty learning how to fit their prosthetic limb in the appropriate way. If individuals are unable to fit their prosthetic limb, then this inhibits future prosthetic limb use.

There is a gap in the literature concerning cognitive rehabilitation in relation to cognitive ability and prosthetic limb use. Although a tentative link has been made between cognitive ability and prosthetic limb use, it is not yet known whether addressing individuals cognitive difficulties will increase prosthetic limb use. However, rather than address the notion that cognitive rehabilitation may increase future prosthetic use, it would be worthwhile to first determine whether cognitive rehabilitation, in particular errorless learning, is an effective learning strategy for this patient population. As errorless learning has a relatively strong evidence base for effective learning of semantic information in amnesic patients (Baddeley &
Wilson, 1994), individuals with an acquired brain injury (Evans et al., 2000) and individuals in the early stages of dementia (Akhtar, Moulin, & Bowie, 2006; Clare et al., 2000), it appears plausible that this effectiveness can be transferred to learning of procedural information.

Aims and Hypotheses

The aim of this project is to use a cognitive rehabilitation technique, i.e. an errorless learning paradigm, with individuals who are learning how to fit their prosthetic limb. This is to determine whether errorless learning is a useful strategy to incorporate into an individual's rehabilitation programme when they are learning how to fit their prosthetic limb.

Main hypothesis:

- Errorless learning will increase the number of individuals who learn how to fit their prosthetic limb correctly.

Plan of Investigation

Participants

Dr Brian O'Neill has access to individuals who are under-going prosthetic rehabilitation based at WestMARC at the Southern General Hospital. All participants will be transtibial amputees and have not yet been fitted with their prosthetic limb. The average age for individuals referred to the WestMARC department is 69 years old. The demographics for each participant will be obtained from their medical records.
Inclusion and Exclusion Criteria

Exclusion criteria will include the following:

- Neurological disorder with persisting cognitive disability
- Current Psychiatric disorder requiring treatment, for example, Major Depressive Disorder, Psychosis
- Non-transtibial amputees
- Non-English speaking participants

Recruitment Procedures

Participants will be recruited from five hospitals within NHS Greater Glasgow and Clyde, and NHS Lanarkshire who make referrals to the WestMARC clinic. Those hospitals are The Western Infirmary Hospital, The Glasgow Royal Infirmary, The Gartnavel General Hospital, The Southern General Hospital, and Wishaw General Hospital. Contact with participants will be made whilst they are receiving physiotherapy following their surgery. This will be via their consultant or their physiotherapist. Consultants and physiotherapists will be briefed on the objectives and aims of the study. They will be provided with information regarding the study and asked to give participant information to patients provided by the researcher. Initial contact will be made approximately three weeks after their surgery. Once individuals have read the patient information regarding the study and wish to take part in the study, they will be asked to complete a form with their name and contact details. Participants will then be provided with a consent form and additional information concerning the nature of the study.
**Design**

This study will utilize a between-subjects design. Participants will be randomly assigned to either a control group (treatment as usual), whereby the individual is able to make errors or an experimental group (i.e. an errorless learning paradigm). The errorless learning paradigm will involve the researcher working with the individual to complete the fitting sequence for their prosthetic limb without allowing the individual to make any errors. Each individual will be video taped whilst they are fitting their prosthetic limb.

Randomization of individuals to a particular group will be done by placing three digit numbers within an envelope. The three digit number will correspond to either a treatment condition or a control condition. The digit number will be placed into an envelope by the field supervisor to ensure that the researcher is unaware which digit numbers relate to the treatment or control condition until after a number has been chosen for a participant. There will be a number on the outside of the envelope ranging from one to thirty. The envelopes will be in batches of ten; five treatment condition, five control condition. This is to ensure that for every ten individuals recruited into the study, fifty percent will go into the treatment condition. The researcher will use first batch of ten envelopes (i.e. numbers 1 – 10) then the second batch of ten and so on.

**Pilot Study**

A checklist will be used in this study to determine the amount of errors made within a fitting sequence. As this checklist has been developed primarily for this research project, it was deemed appropriate to complete a pilot study. The researcher will be able to determine the
inter-rater reliability of this checklist prior to commencing the research. This will be done by the researcher rating the number of errors made during a fitting procedure and having an individual independent from the study rate the same data using the checklist. An ethics application will be submitted prior to commencing the pilot study.

Research Procedure

The treatment condition and control condition will take place on the fitting day for their prosthetic limb within the WestMARC clinic. This is roughly five to six weeks post surgery. This is to ensure that the participants have no prior knowledge in relation to fitting their prosthetic limb. The time spent with the participant during this fitting session will be between fifteen and thirty minutes. Once this session has finished, the researcher will not have any further contact with the participants in relation to their prosthetic rehabilitation. However, as the researcher will be completing a follow-up session one week post intervention, they will be in contact with the participants. It must be noted that this will not influence the participants’ rehabilitation in any way.

With regard to the experimental condition, i.e. the errorless learning approach, the fitting sequence for the prosthetic limb will involve a thirteen part procedure whereby the participant is unable to make any errors. That is, the researcher will be either giving them the appropriate parts they need of the fitting sequence or telling them what they need to do to move to the next stage of the fitting sequence, as such, completing the fitting sequence the correct way. This is to ensure the participants in the errorless condition do not make any errors. Prior to commencing the intervention, the participants will first be shown how to fit
the prosthetic limb. A full list of the fitting procedure is enclosed in the appendix. This sequence will be repeated five times within the session. Once this has been completed, the participant will be asked to complete the fitting sequence without any additional support from the researcher. This will be video taped. A clinician independent from the study that is blind to the treatment conditions will rate and score the video tape recordings.

The control condition, i.e. treatment as usual, will involve the same thirteen part procedure. In this condition, the participant will be first shown how to fit the prosthetic limb and then asked to fit their prosthetic limb with the same instructions and encouragement from the researcher; however, they will be allowed to make errors. That is, rather than the researcher giving the participant the correct part of the sequence, they will be allowed to choose the part of the sequence they think is appropriate to complete the fitting sequence. As with the experimental condition, the participant will repeat the sequence five times. Upon completion of this sequence, they will be asked to fit their prosthetic limb without any support. This final fitting sequence will be video taped.

**Measures**

1. The screening tool that will be administered by a member of the research team is the Addenbrookes Cognitive Examination - Revised (ACE-R), (Mathuranath, Nestor, Berrios, Rakowicz, & Hodges, 2000). The ACE is a bedside cognitive screening measure that gives a brief overview of orientation, memory, language, and visuo-spatial ability.
2. It was deemed appropriate to obtain a measure of the participants’ level of premorbid functioning. The Speed and Capacity of Language-Processing Test (SCOLP) (Baddeley, Emslie, & Nimmo Smith, 1992) will be used. As non-psychological professionals will be administering this measure of premorbid functioning, it was thought to be more appropriate than other measures as there is not much training required for the use of this measure.

3. In order to determine the participants’ memory functioning, it was deemed important to administer a measure of episodic memory. The word list learning test of the Adult Memory and Information Processing Battery (AMIPB; Coughlan & Hollows, 1985) was thought to be an appropriate test as it is a UK validated measure. It involves a list of 15 words which are read to the listener at a rate of one word per second. Once all words have been read, the listener then has to recall as many words from the list as possible. This process is repeated for a further four times. The word list learning test is a measure that is easy to administer and does not require specific training. Therefore, it is suitable for a non-psychological professional to administer.

4. Once all participants have completed the five learning trials, they will be video taped fitting their prosthetic limb for a sixth time (the test phase). The participants will not be given any further guidance in terms of how to fit their prosthetic limb. There will be three outcome measures will be used from the information gained from the video recordings: (1) number of errors made whilst fitting their prosthetic limb, (2) length of time taken to fit their prosthetic limb, (3) whether they complete a successful
sequence, i.e. yes or no.

5. Previous research concerning naturalistic action and awareness of making errors considered a way of assessing error detection and correction (Hart, Giovannetti, Montgomery, & Schwartz, 1998; Schwartz, Segal, Veramonti, Ferraro, & Buxbaum, 2002). Hart et al. (1998) were interested in whether error detection and correction can be objectively and reliably measured during performance of routine tasks. From this research, the Naturalistic Action Test was developed. This test is intended for use by clinicians and researchers to screen for naturalistic action impairment and to provide an estimate of its severity (Schwartz et al., 2002). The Naturalistic Action Test provides a good framework to develop a checklist to assess error making for the current study. If necessary, adaptations to the checklist will be made following the pilot study to ensure that the checklist is appropriate for this patient population and is detecting common errors made during the fitting procedure.

A follow-up of participants will also take place one week after the errorless learning intervention. This would be a good opportunity to determine if they have had any difficulty using their prosthetic limb and to follow up any issues raised with the participant. The researcher will video tape the individual fitting their prosthetic limb.

*Justification of Sample Size*

This study is the first piece of research to look at the effects of using an errorless learning paradigm when learning a sequence within this patient population. As such, there was little
previous research that could be used to estimate the number of participants required for this study. The effect sizes observed in a previous study concerning errorless learning versus trial and error route learning with an acquired brain injury population (Lloyd, 2006) was used to estimate the sample size needed to detect a significant effect, if indeed, one exists. Calculations revealed an effect size of 1.2. With this effect size, setting the significance level at 0.05 and power at 0.8, then recruiting a total of 13 subjects would allow detection of a significant difference, if one exists. However, as the power calculations are based on a study that was using an acquired brain injury population, their level of impairment would be more severe that the current patient population. There is little research in this area so the researcher intends to be cautious in terms of recruitment. Therefore, the researcher will recruit a total of 15 people in each group.

**Settings and Equipment**

The proposed intervention will be carried out at WestMARC based within the Southern General Hospital. A room will be available for the researcher within the clinic to allow the intervention to be carried out. The Addenbrookes Cognitive Examination-Revised (ACE-R) is available from the clinicians working within WestMARC and will therefore not need to be purchased. The Speed and Capacity of Language-Processing Test (SCOLP) is readily available from the Department of Psychological Medicine, University of Glasgow. The sequencing errors checklist is being developed by the researcher and will not incur any financial costs. Each participant will be video taped whilst completing their fitting sequence. A video recorder is readily available from the WestMARC clinic.
Data Analysis

The Statistical Package for Social Sciences (SPSS Version 14) will be used to store and analyse the data for the current study. To ensure confidentiality, participants will be given a code number.

A non-parametric test, i.e. Chi Square, will be used to analyse the data. This is in relation to whether or not the individual succeeds or fails the fitting sequence. The second part of the analysis will also involve non-parametric testing as it is assumed that the data are not normally distributed and the fitting sequence is ordinal data. The data that will be analysed will be the number of errors the individual makes whilst fitting their prosthetic limb and the number of people that achieved the goal (i.e. complete the fitting sequence). The non-parametric test will be the Mann Whitney U test.

Health and Safety Issues

Researcher Safety Issues

There are no perceived health and safety issues for this research project. The study will be carried out at WestMARC, based at the Southern General Hospital. As such, the researcher will be following the hospitals health and safety protocol. The hospital has procedures in place for staff to follow to minimise risk. These procedures are adequate for the proposed study.

The study is based within hospital grounds. If any medical emergencies do occur, clinicians are within close proximity and will be able to respond appropriately. The procedures that will be carried out in this study are routinely carried out with this patient population and are not
associated with causing significant amounts of distress.

An application will be made to the research ethics committee at the Southern General Hospital in order to carry out this research. The Southern General Hospital has a policy that individuals who are deemed to be cognitively impaired will not be referred for a prosthesis. As such, those who are referred to the department are not classified as having a cognitive impairment. This then enables the individual to give informed consent to their participation in the study. The scores from the ACE-R will also give the researchers an indication of their cognitive ability.

Participants will also be made aware that if they choose not to partake in this study, their medical treatment will not be compromised in anyway. Furthermore, participants who do decide to take part will be able to withdraw from the study at any point during the intervention.

Financial Issues

Equipment costs will mainly entail the purchasing of video tapes. There will be no travel expenses as the intervention will be carried out at WestMARC. Participants are usually residing at one of the wards within the Southern General Hospital, so they will not need any travel expenses to get to the clinic. If participants are not residing within the hospital, they will be able to get to the hospital by way of ambulance transportation due to the intervention being carried out on the delivery day of their prosthetic limb.
**Timetable**

The timetable for this project will be to submit an ethics form for this study in June 2007. This process usually takes up to six weeks. Once ethics have approved this study, the study will be finalised in August 2007. The pilot study will commence in September 2007, which will take 2 – 3 weeks to complete. Recruitment of participants will commence in October 2007. The researcher will complete the recruitment and the intervention within a five to six month period. As such, all research data will be collected by April 2008. Analyses of data will take place at the end of April 2008. Following analyses of data, drafts will be submitted to supervisors involved in the study during May 2008 and June 2008. A finalised copy of the study will be bound and submitted in July 2008.

**Practical Applications**

A survey of the lower limb amputee population in Scotland (Condie, Scott, & Cargill, 2006) was completed looking at the aetiology and level of amputation, demographics of patients, referral rates for a prosthesis, rehabilitation and functional abilities. Condie et al. (2006) noted that in the year 2004, there were 831 amputees. Of the 831 amputees, only 302 transtibial amputees were fitted with a prosthesis. This is a relatively large number of individuals who may not be reaping the full benefits of having a prosthetic limb due them not being able to adequately fit their prosthetic limb. As such, by focusing on the initial learning phase when individuals first receive their prosthetic limb, this may in turn increase their usage of their prosthetic limb, leading to greater independence and an improved quality of life.
Ethical and Management Approval Submissions

An application for ethics approval will be made to South Glasgow and Clyde Local Research Ethics Committee, and to Research and Development at the Southern General Hospital.
References


<table>
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<tr>
<th>Authors / Year</th>
<th>Quality Rating</th>
<th>Settings and Subjects</th>
<th>Age range</th>
<th>Design</th>
<th>Follow-up</th>
<th>Prognostic factors / Outcomes</th>
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<tr>
<td></td>
<td></td>
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<td>or older</td>
<td>(retrospective)</td>
<td></td>
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<tr>
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<td></td>
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<td></td>
<td></td>
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<td>(retrospective)</td>
<td></td>
<td>Outcome: Late-onset Alzheimer’s disease</td>
<td></td>
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<tr>
<td>Ferini-Strambi et al., (1990)</td>
<td>2+</td>
<td>Cases: AD n = 63</td>
<td>40 years</td>
<td>Case-control</td>
<td>No follow up</td>
<td>Prognostic factors: Familial / Personal / Medical</td>
<td>Personal or medical history was not predictive for the development of presenile AD. They concluded that head injury is not a risk factor for AD.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC: n = 126</td>
<td>or older</td>
<td>(retrospective)</td>
<td></td>
<td>Outcome: Presenile Alzheimer’s disease</td>
<td></td>
</tr>
<tr>
<td>Forster et al., (1995)</td>
<td>2+</td>
<td>Cases: AD n = 109</td>
<td>Not stated</td>
<td>Case-control</td>
<td>No follow-up</td>
<td>Prognostic factors: Familial / Genetic / Environmental / Personal</td>
<td>Family history of dementia is a risk factor for AD. Head injury was not found to be a significant risk factor.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC: n = 109</td>
<td></td>
<td>(retrospective)</td>
<td></td>
<td>Outcome: Presenile Alzheimer’s disease</td>
<td></td>
</tr>
<tr>
<td>Fratiglioni et al., (1993)</td>
<td>2+</td>
<td>Cases: AD n = 98</td>
<td>75 years</td>
<td>Case-control</td>
<td>No follow-up</td>
<td>Prognostic factors: Genetic / Environmental</td>
<td>Head injury was not associated with AD.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC: n = 216</td>
<td>or older</td>
<td>(retrospective)</td>
<td></td>
<td>Outcome: Alzheimer’s disease</td>
<td></td>
</tr>
<tr>
<td>French et al., (1992)</td>
<td>2+</td>
<td>Cases: AD n = 78</td>
<td>40 – 90</td>
<td>Case-control</td>
<td>No follow-up</td>
<td>Prognostic factors: Viral / Genetic / Environmental</td>
<td>Significantly greater occurrence of</td>
</tr>
<tr>
<td>Year</td>
<td>Study</td>
<td>Type</td>
<td>Eligible Population</td>
<td>Methodology</td>
<td>Exposure</td>
<td>Outcome</td>
<td>Findings</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>1985</td>
<td>HC: n = 76&lt;br&gt;PC: n = 48</td>
<td>years (retrospective)</td>
<td>Environmental</td>
<td>Outcome: Alzheimer’s disease</td>
<td>antecedent head injury in patients with AD (odds ratio = 4.5).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gedye et al., 1989</td>
<td>2- Cases: AD n = 148&lt;br&gt;Non-AD dementia n = 33</td>
<td>Not stated (retrospective)</td>
<td>Prognostic factors: History of head injury of any severity</td>
<td>Outcome: Alzheimer’s disease</td>
<td>AD cases with severe head injury before the age of 65 showed onset of symptoms at an earlier age than AD cases without a head injury.</td>
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</tr>
<tr>
<td>Graves et al., 1990</td>
<td>2+ Cases: AD n = 130&lt;br&gt;CC: n = 130</td>
<td>50 years and older (retrospective)</td>
<td>Prognostic factors: History of prior head injury</td>
<td>Outcome: Alzheimer’s disease</td>
<td>The risk of AD increased as the time between the head injury and the onset of AD symptoms diminished.</td>
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</tr>
<tr>
<td>Guo et al., 2000</td>
<td>2- Cases: AD n = 2,233&lt;br&gt;Affected 1st degree family members: n = 1239&lt;br&gt;Unaffected family members: n = 13429</td>
<td>Not stated (population-based)</td>
<td>Prognostic factors: History of prior head injury</td>
<td>Outcome: Alzheimer’s disease</td>
<td>Head injury with loss of consciousness increased the risk of Alzheimer’s disease.</td>
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</tr>
<tr>
<td>Henderson et al., 1992</td>
<td>2+ Cases: AD n = 170&lt;br&gt;PC: n = 170</td>
<td>Not stated (case-control)</td>
<td>Prognostic factors: Familial / Genetic / Environmental / Personal</td>
<td>Outcome: Alzheimer’s disease</td>
<td>Head injury was associated with sporadic AD.</td>
<td></td>
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</tr>
<tr>
<td>Jellinger et al., 2001</td>
<td>2- Cases: AD n = 55&lt;br&gt;TBI: n = 53</td>
<td>60 years and older (case-control design)</td>
<td>Prognostic factors: Traumatic brain injury and genetic factors</td>
<td>Outcome: Alzheimer’s disease</td>
<td>This autopsy study confirms clinical studies suggesting severe TBI to be a risk factor for the development of AD.</td>
<td></td>
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<tr>
<td>Kondo et al., 1994</td>
<td>2+ Cases: AD n = 60&lt;br&gt;PC = 120</td>
<td>43 - 89 (case-control)</td>
<td>Prognostic factors: Life style factors</td>
<td>Outcome: Alzheimer’s disease</td>
<td>5 significant risk factors for AD: psychosocial inactivity, physical inactivity, head injury, loss of teeth, low education.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Launer et al., 2+</td>
<td>Cases: AD n = 528</td>
<td>Not stated (population-based)</td>
<td>Prognostic factors: Familial / Genetic / Environmental</td>
<td>Outcome: Alzheimer’s disease</td>
<td>Head injury was not a risk factor for AD.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year</td>
<td>Study Type</td>
<td>Subjects</td>
<td>Age</td>
<td>Design</td>
<td>Follow-up</td>
<td>Prognostic Factors</td>
<td>Outcome</td>
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<tr>
<td>1992</td>
<td>Li et al.</td>
<td>2+</td>
<td>AD 70 PC 140</td>
<td>Not stated</td>
<td>Case-control</td>
<td>6 month follow-up</td>
<td>Familial / Genetic / Environmental</td>
</tr>
<tr>
<td>1994</td>
<td>Lindsay et al.</td>
<td>2+</td>
<td>258 AD and 535 Controls</td>
<td>65 years and older</td>
<td>Case-control (retropective)</td>
<td>No follow-up</td>
<td>Environmental / Familial</td>
</tr>
<tr>
<td>1993</td>
<td>Mayeux et al.</td>
<td>2+</td>
<td>138 AD and 193 Controls</td>
<td>65 years or older</td>
<td>Case-control (retropective)</td>
<td>No follow-up</td>
<td>Genetic susceptibility and Head injury</td>
</tr>
<tr>
<td>1985</td>
<td>Mortimer et al.</td>
<td>2+</td>
<td>78 AD HC 76 PC 48</td>
<td>60 years or older</td>
<td>Case-control (retropective)</td>
<td>No follow-up</td>
<td>Head injury</td>
</tr>
<tr>
<td>1997</td>
<td>O’Meara et al.</td>
<td>2++</td>
<td>357 AD and 345 PC</td>
<td>60 years or older</td>
<td>Case-control (retropective)</td>
<td>No follow-up</td>
<td>Head injury with LOC and ApoE-e4 genotype</td>
</tr>
<tr>
<td>2000</td>
<td>Plassman et al.</td>
<td>2++</td>
<td>'Exposed' AD 548 and 'Unexposed' AD 1228</td>
<td>70 years or older</td>
<td>Population based Cohort</td>
<td>53 years</td>
<td>Head injury of any severity and ApoE-e4</td>
</tr>
<tr>
<td>1995</td>
<td>Rasmussen et al.</td>
<td>2+</td>
<td>68 AD and 34 Controls</td>
<td>62 years or older</td>
<td>Case-control (retropective)</td>
<td>No follow-up</td>
<td>Head injury of any severity</td>
</tr>
<tr>
<td>Study</td>
<td>Type</td>
<td>Design</td>
<td>Age</td>
<td>Study Design</td>
<td>Follow-up</td>
<td>Prognostic factors</td>
<td>Outcome</td>
</tr>
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<tr>
<td>Salib &amp; Hillier (1997)</td>
<td>2+</td>
<td>Case-control</td>
<td>65 years or older</td>
<td>Case-control (retrospective)</td>
<td>No follow up</td>
<td>Prognostic factors: Familial / Environmental</td>
<td>Alzheimer’s disease / non AD dementia</td>
</tr>
<tr>
<td>Schofield et al., (1997)</td>
<td>2+</td>
<td>Population based</td>
<td>60 years or older</td>
<td>Population based Cohort (prospective)</td>
<td>Up to 5 years (annual evaluations)</td>
<td>Prognostic factors: History of head injury</td>
<td>Alzheimer’s disease</td>
</tr>
<tr>
<td>Shalat et al., (1987)</td>
<td>2+</td>
<td>Cases: AD n = 98</td>
<td>Not stated</td>
<td>Case-control (retrospective)</td>
<td>No follow up</td>
<td>Prognostic factors: Familial / Medical / Environmental</td>
<td>Alzheimer’s disease</td>
</tr>
<tr>
<td>Suhanov et al., (2006)</td>
<td>2+</td>
<td>Cases: AD n = 260</td>
<td>40 years or older</td>
<td>Case control (retrospective)</td>
<td>No follow up</td>
<td>Prognostic factors: Environmental / Familial / Genetic</td>
<td>Alzheimer’s disease</td>
</tr>
<tr>
<td>Tsolaki et al., (1997)</td>
<td>2+</td>
<td>Cases: AD n = 65</td>
<td>70 years or older</td>
<td>Case control (retrospective)</td>
<td>No follow-up</td>
<td>Prognostic factors: Environmental / Familial / Genetic</td>
<td>Alzheimer’s disease</td>
</tr>
<tr>
<td>van Duijn et al., (1992)</td>
<td>2+</td>
<td>Cases: AD n = 198</td>
<td>Not stated</td>
<td>Case control (retrospective)</td>
<td>No follow up</td>
<td>Prognostic factors: History of head injury with LOC</td>
<td>Alzheimer’s disease</td>
</tr>
</tbody>
</table>

TBI = Traumatic Brain Injury; AD = Alzheimer’s Disease; HC = Hospital Controls; PC = Population Controls; CC = Case Controls; LOC = Loss of Consciousness